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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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KEYWORDS
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/

items (committee 1, part 1); individual scoring (by email) of the relevance and appropriateness of the tools/items in three rounds (committee 1, part 2) [13]; (b) reporting to the steering committee (SC) the results from the scoring committee (committee 1); (c) assessment of the face validity of the G-CODE (i.e. the extent to which the G-CODE is subjectively viewed as covering the concept it purports to measure) by two panels of national experts (n = 55, committee 2) and international experts (n = 42, committee 3) including oncologists, geriatricians, clinical research associates and nurses.

No ethical approval was required to conduct this research.

The SC supervised the research (Delphi consensus method, national and international survey), identified and appointed experts to the committees and analysed the results. The SC included four oncologists (P.S., C.T., E.B., L.M.), one public health specialist (SMP) and three geriatricians (E.P., P.C., T.C.).

2.2. Development of the initial geriatric core data set (committee 1, part 1)

All 14 members of committee 1 agreed to include tools/items exploring the following seven domains of GA: social environment, functional status, mobility, nutritional status, cognitive status, mood and comorbidities. Working in pairs, they selected one domain to investigate. From recommendations on GA developed by the International Society of Geriatric Oncology (SIOG) [3], EORTC [4] and National Comprehensive Cancer Network [14], the geriatrician pairs had to list the available tools/items by domain, determine the most commonly used, search studies assessing the sensitivity and specificity of each and assess tools/items from a practical standpoint. Tools/items could be validated for use in older patients with or without cancer. They had to be brief and practical for widespread use. Then committee 1 members attended an in-person meeting at the annual SoFOG conference (October 7–9, 2015; Toulouse, France). Each geriatrician pair presented its recommendations of tools/items and the reasons for supporting their choices to include in the assessment. These initial sets were then shared and discussed with the SC in a plenary meeting (October 29, 2015, Paris), while the Delphi consensus methodology was explained.

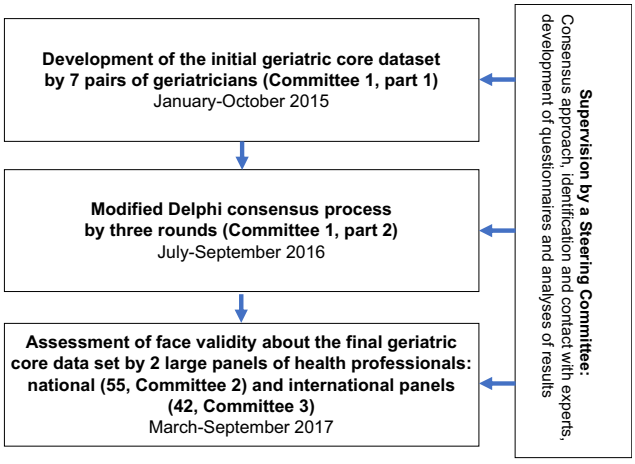

Fig. 1. Main steps of development of the geriatric core data set in cancer clinical research for older patients.

2.3. Modified Delphi consensus (committee 1, part 2)

Committee 1 members agreed on tools/items to be selected in a three-round Delphi method. Rules for scoring and analysis of the scores were defined *a priori*. The first set of tools/items was sent by email to each member of the committee for individual rating. For each tool/item, experts were asked to indicate, on a scale ranging from 1 (totally disagree) to 9 (totally agree), the degree to which the specific tool was relevant to assess the investigated domain.

After each round, only tools/items with strong consensus (rating score range 7–9) were included for consideration in the G-CODE, with all others being tested in a new questionnaire. Therefore, questionnaires were drafted for further rounds with only tools/items lacking strong consensus before being sent to each member of committee 1 with the results of previous round(s) and a copy of their previous scores. Scales and rating methodology were identical across the successive rounds.

To reach a final proposition for the G-CODE, the SC held an in-person meeting to discuss the results after each round.

2.4. Face validity of the G-CODE assessed by national and international panels (committees 2 and 3)

The SC developed a questionnaire adapted from the Appraisal of Guidelines for Research and Evaluation II Instrument [15] with eight questions in five sections (Supplementary Data S2: scope and purpose, stakeholder involvement, accuracy of development, clarity of presentation and applicability). Experts completed an online survey [16] and rated each of the eight questions from 1 (totally disagree) to 7 (totally agree); they could provide additional comments (open text).

2.5. Pilot study of the G-CODE administration

The time to complete the G-CODE final version was measured in three university hospitals with 50 consecutive cancer older patients. The full questionnaire was administrated by a geriatrician, an oncologist or a nurse.

2.6. Data analyses

The 14-member committee 1 is described by the practice location and experience (senior $\geq$ 10 years). National and international panels are described by country and

specialty. Each round of the Delphi method with consensus level is reported. We report results from the national and international panels for each question, including the median and minimum and maximum scores as well as the proportion of disagreement, defined as the proportion of scores ranging from 1 to 3. Finally, from the pilot study, we report the median, range and interquartile range for the administration of the G-CODE by health professionals.

3. Results

3.1. Development of the initial geriatric core data set

Expert geriatricians represented 11 different French geriatrician teams involved in oncology, and 12 (85%) had a senior clinical practice in geriatrics (Supplementary Data S1). The initial data set was derived for seven domains (Table 1): social environment, functional status, mobility, nutritional status, cognitive status, mood and comorbidities. The list of available tools/items by geriatric domain was discussed in a plenary meeting (October 29, 2015) and is presented in Supplementary Table S1. For each domain, one pair of geriatricians selected a tool/item based on its brevity and ability to be administered in the cooperative group setting. However, for a given geriatric domain, we could not compare the diagnostic accuracy of the available tools/items given the lack of data in the literature.

3.2. Delphi process

After sharing results of the selection of the initial geriatric core data set, all 14 geriatricians from committee 1 went through the Delphi process. In the first round, the questionnaire included 15 tools/items. Results showed strong consensus for two tools: Activities of Daily Living (ADL) and short-IADL (4-IADL). Other tools/items were included in the second round, which led to strong consensus for 10 tools (Table 2). After the third round, 12 tools/items were selected for presentation to the SC. To keep the instrument short and user-friendly, all SC members agreed to limit the selection to one tool/item per domain, ruling out 'gait speed' and the Mini Nutritional Assessment-Short Form. For the cognitive status, the Mini-Cog was selected.

Table 1
Tools/items identified as relevant by the geriatrician experts.

Geriatric domains	Selected tools/items for scoring
Social status	- Do you live alone? - Do you live in nursing home? - Do you have a person or caregiver to help you?
Functional status	- Katz Activity of Daily Living (ADL) index (6 items) - Lawton Instrumental ADL score (4 items)
Mobility	- Timed Up and Go test - Gait speed
Nutritional status	- Weight loss during the last 6 months > 10% - Body mass index - Mini Nutritional Assessment
Depression	- Mini-Geriatric Depression Scale (4 items)
Cognition	- The 5-word test - Clock drawing test - Mini-Cog (3 items)
Comorbidity	- Updated Charlson Comorbidity Index (12 items)

Finally, seven domains and ten tools/items were retained in the G-CODE final version: (1) 'Do you live alone?' AND 'do you have a person or caregiver able to provide care and support?'; (2) ADL [17] and 4-IADL [18]; (3) Timed Up and Go test (TUG) [19]; (4) weight loss during the past 6 months and body mass index (BMI); (5) Mini-Cog [20]; (6) mini-Geriatric Depression Scale (mini-GDS) [21] and (7) Charlson Comorbidity Index [22].

Face validity of the geriatric core data was assessed by the national and international panels (Supplementary Data 1 and 2).

Of 55 members in the national panel, 42 (76%) completed the survey. Members lived in 20 cities within France. Among the 42 members of the international panel, 31 (74%) completed the survey. Members were from 13 countries.

None of the panel members suggested including additional items. All questions (Table 3) were scored 4–7 by 95% of the national panellists; only the question of the composition of the validation group (16.7%) was scored 1–3 by 16.7% of the members. Most members of the international panel (90%) rated all questions with 4–7 scores. In free comments (Supplementary Table S2), the participants asked for additional clarification and/or more information on the research context, the definition of 'old age' (≥70 year) and the composition of panels and disciplines represented.

The final G-CODE with the user guide is presented in Supplementary Data S3. We administered the G-CODE to a sample of 50 older patients (median age 81 years, range 70–97), with stage I to IV breast (36%), GI (18%), gynaecologic (14%), genitourinary (12%), lung (10%), head and neck (4%) or other (6%) cancer. The median completion time was 8.05 min (interquartile range 6.22–9.07).

4. Discussion

The goal of the G-CODE project was to define a minimum set of geriatric data to be collected in cancer clinical trials that would allow for both a minimal geriatric description of the older patients with cancer and standardisation of geriatric data. An essential

Table 2
Tool/item assessment and selection by round in the Delphi consensus and final Geriatric Core Dataset (G-CODE).

Delphi rounds	Appropriate with strong consensus[a]	Appropriate with relative consensus	Uncertain
Round 1			
	ADL, 4-IADL	Other items	The 5-word test 'Do you live in nursing home?' Y/N
Round 2			
	Mini-Cog Mini-GDS UpCCI MNA-SF, BMI, weight loss TUG, GS 'Do you live alone?' 'Do you have a person or caregiver to help you?'	The 5-word test Clock drawing test	'Do you live in nursing home?'
Round 3			
			'Do you live in nursing home?' The 5-word test Clock drawing test
Final G-CODE with 10 tools[b]	ADL and 4-IADL Mini-Cog Mini-GDS UpCCI BMI and weight loss TUG 'Do you live alone?' Y/N 'Do you have a person or caregiver to help you?' Y/N		

ADL, Activities of Daily Living; IADL, Instrumental Activities of Daily Living; Mini-GDS, mini-Geriatric Depressive Scale; UpCCI, updated Charlson Comorbidity Index; MNA-SF, Mini Nutritional Assessment-Short Form; BMI, body mass index; TUG, Timed Up and Go; GS, gait speed.

[a] Each tool was defined as appropriate, (i.e. relevant and to be included in the core data set) if the median of all scores was $\geq$7 with strong (rating score range 7–9) or relative (5–9) consensus among all members; inappropriate (i.e. not to be included in the G-CODE) if the median of all scores was <3.5, with strong (rating score range 1–3) or relative (1–5) consensus and uncertain if the median of all scores was 4–6.5 or with absence of consensus.

[b] Exclusion by the steering group of redundant tools in the same domain after round 3: GS for mobility and MNA-SF for the nutritional status.

prerequisite was to develop a tool that would be user-friendly for any professional involved in cancer care for older patients, so as to be easily implemented in any clinical trial for any tumour type at study entry and at follow-up. The G-CODE was developed after a multi-stage modified Delphi consensus method with individual ratings of appropriateness. Consensus resulted in the selection of two social questions, two autonomy scales (ADL and 4-IADL), one mobility scale (TUG), two nutrition items (weight loss and BMI), one cognitive scale (Mini-Cog), one scale assessing the mood (mini-GDS) and one comorbidity overview (updated Charlson Comorbidity Index). The face validity of this selection was checked with one national and one international multidisciplinary panel, which besides cancer specialists also included clinical research associates and nurses.

The inclusion of the G-CODE in clinical trials will provide a clearer description of the characteristics of older patients enrolled in clinical trials, with a better chance to interpret the application of results to standard practice. Moreover, it will allow for comparing and merging data from different studies.

Several researchers have developed brief GA instruments or comprehensive GA to help oncologists select patients for cancer strategies, including self-administered tools [23–26] and frailty screening tools [10,27,28]. Except for the two tools [9,25], none was devised for research purposes to provide comprehensive information on the overall health status of older patients at baseline when enrolled in a clinical trial. The tool developed by Hurria *et al.* [25] (CALGB) has 75 items and a median completion time of 22 min. It is primarily self-administered by the patient, and only a small part requires a healthcare provider. Although CALGB has been found feasible in the US trials [26], European cooperative groups are often reluctant to propose it widely in trials of older patients. Although cognitive and mood domains have predictive and prognostic value for mortality, toxicity and functional decline in older patients with cancer [29–31], these are not accounted for in the EORTC minDS [9].

Recently, the published ASCO Guidelines for GA established a minimum GA for clinical practice in older patients undergoing chemotherapy [32], including IADL to assess function, a thorough history or validated tool to assess comorbidity, a single question for falls, the GDS to screen for depression, the Mini-Cog or the Blessed Orientation-Memory-Concentration test to screen for cognitive impairment and an assessment of unintentional weight loss to evaluate nutrition. Except

Table 3
Results of scores by questions (face validity survey of the G-CODE) from the national and international panel survey (score 1 [totally disagree] to 7 [totally agree]).

	1. Objectives are clearly explained	2. The patient population addressed is clearly defined	3. Validation group represents all professionals concerned with its use	4. The target users	5. The approach and the scientific method used	6. The items are precise and unambiguous	7. Advice is provided for the use	8. All the questions can be easily completed
National panel (n = 42)								
Min	1	1	1	1	4	4	1	1
Max	7	7	7	7	7	7	7	7
Median	6	7	5	6	6	7	6	6
% score 1–3	2%	5%	16.7%	5%	0%	0%	5%	5%
International panel (n = 31)								
Min	2	3	3	2	4	2	2	3
Max	7	7	7	7	7	7	7	7
Median	6	6	6	6	6	6	6	6
% score 1–3	6.5%	6.5%	6.5%	6.5%	0%	3.2%	9.7%	3.2%

G-CODE, Geriatric Core Dataset.

for the single question for falls and the longer version of GDS, the proposed tools are identical to those of the G-CODE.

To the best of our knowledge, no such set of geriatric data to be collected has been proposed based on a rigorous development method (e.g. Delphi consensus process) and a formalised international validation process.

Various specific points were discussed in the face validity step. First, the 70-year age cut-off was debated. Indeed, 65 years is often used as a threshold age for performing a GA in international studies. We preferred to recommend the G-CODE for patients $\geq$70 years because this is the age threshold chosen by the EORTC [4] and SIOG [33] and is being used more often in recent clinical trials. Second, some tools/items selected for the final version (mini-GDS, TUG, BMI) have thresholds. Given the descriptive essence of the G-CODE, we decided to remove these thresholds. Third, some tools/items were debated: social questions (Are they precise and unambiguous?), 4-GDS (Is it efficient to detect depression?) and 4-IADL (Is it validated in oncology?). For social questions, all participants eventually agreed on the essential information for available social support not covered by any short tool [3], and we provided instructions on how to complete these two questions (Supplemental S3). Depression is commonly found in patients with cancer, as a preexisting condition or as a result of illness and treatment [34]. Short screening tools or self-reported questionnaires have shown limited accuracy to diagnose depression [35]. The main purpose of the G-CODE was to provide descriptive and quantitative information about enrolled patients, and hence, the GDS-4 achieved consensus as a fast yet effective screening test. The 4-IADL questionnaire evaluates advanced self-care activities (ability to use a telephone, take medications, manage finances and use transportation). We decided to keep the 4-IADL questionnaire because of its brevity and its association with poor survival in haematological malignancies [36]. Finally, one expert questioned the inclusion of performance tests (i.e. TUG and Mini-Cog) because they cannot be administered in all circumstances. However, because the G-CODE aimed at describing all geriatric domains, mobility and cognition had to be included and quantified.

Limitations to this study include the lack of international geriatricians in the first committee (development of the initial core data set), which may limit the wide dissemination and international use of the G-CODE. However, the face validity, assessed by the two large panels of national and international health professionals, highlights its good acceptability. Moreover, neither of the two panels suggested additional items.

5. Conclusion

This is the first report of a Delphi method to establish a minimum geriatric data set for cancer research purposes. Here, we propose a simple instrument based on validated tools for older patients, allowing for a standardised description of these patients with cancer when enrolled in specific or non-specific clinical trials.

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Conflict of interest statement

The authors have declared no conflict of interest.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.ejca.2018.07.137.

Appendix B

Collaborators of G-CODE project:

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