

DIALOG task force for definition of a geriatric minimum data set for clinical oncology research

Paillaud E, Caillet P, Cudennec T, Pamoukdjian F, Fossey-Diaz V, Liuu E, Albrand G, Boulahssass R, Couderc AL, Retornaz F, Mertens C, Balardy L, Rollod-Trad F, De Decker L, Aparicio T, Mourey L, Brain E, Terret C, Bellera C, Mathoulin Pelissier S, Soubeyran P



CONFLICT OF INTEREST DISCLOSURE

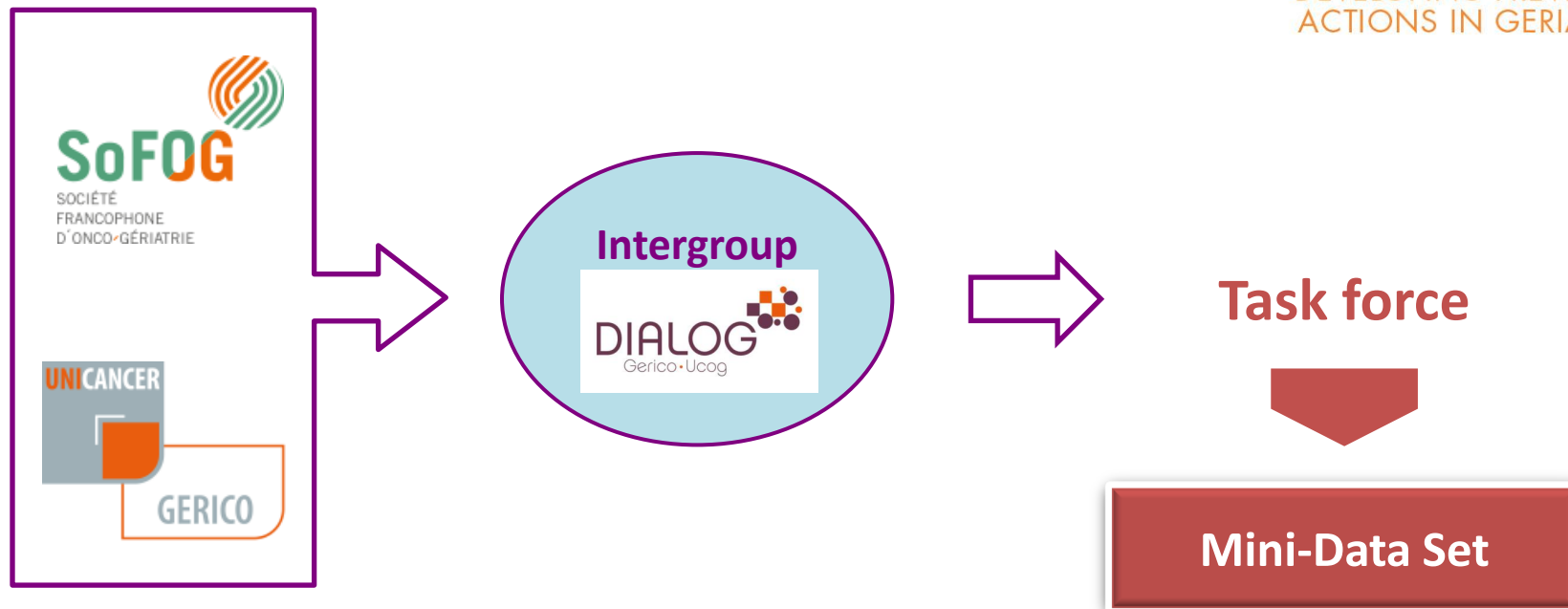
I have the following potential conflicts of interest to report

- Sanofi
- Nutricia
- Amgen
- Roche

Background

- The evidence-based added value of Comprehensive Geriatric Assessment in clinical oncology remains limited, partly due to few specific clinical research and lack of data homogenization.
- A minimum set of geriatric data at baseline would allow to standardize the collection of geriatric data in clinical trials and to compare results across studies.

INTERGROUP



- Both, French Society of Geriatric Oncology (SoFOG), and the Unicancer GERICO cooperative group (dedicated to clinical research in geriatric oncology) joined their efforts into an intergroup called DIALOG.
- **DIALOG launched a task force in order to develop a consensual geriatric minimum data set for research purposes in geriatric oncology setting.**

Objective

- To reach a consensus on a minimum set of geriatric data to be incorporated in clinical trials to describe the elderly cancer population.
- This **Core Data Set (CDS)** should be simple, short and efficient, based on assessment by validated tools to assess the 7 following geriatric domains:
 - **social environment**
 - **functional status**
 - **mobility**
 - **nutritional status**
 - **cognitive status**
 - **mood**
 - **comorbidities**

Experts' committees

Four committees were involved in this consensus process

- **A steering committee (SC)**
 - composed of 4 oncologists, 3 geriatricians, 1 biostatistician, 1 epidemiologist
 - involved in the design and in all steps of the process
- **A rating committee (RC)**
 - composed of 14 geriatricians experts
 - **RC had to elaborate a first version of the CDS which has been debated** at a plenary meeting with the SC
- **A validation national multidisciplinary panel (n=54)**
 - composed of medical oncologists, surgeons, radiation oncologists, disease-oriented oncologists, geriatricians, clinical research associates and nurses
- **A validation international multidisciplinary panel (n= 41)**
 - composed of medical oncologists, surgeons, radiation oncologists, disease-oriented oncologists, geriatricians, clinical research associates and nurses

Methods

Formal consensus process was developed following a **modified DELPHI consensus** with the rating based on the RAND/UCLA scoring methodology

The consensus process proceeded in 3 steps:

- 1. Initial literature search of available tools** by seven pairs of geriatrician experts and elaboration of the questionnaire – **first version of Core Data Set (CDS)**
- 2. Individual scoring (by e-mail) of the relevance of the selected tools** by the 14 geriatrician experts using a graduated (1 to 9) visual scale in 3 rounds
- 3. Presentation of the final version of CDS** to multidisciplinary national and international panels **for appropriation**

January 2015 to January 2016

Elaboration of the first version of the Core Data Set (CDS)

Presentation of domains and instruments by 7 pairs of geriatricians in a person-meeting and discussion of the 1st CDS proposal with the steering committee (4 oncologists, 3 geriatricians and 1 public health specialist)

July to October 2016

Final reporting

Delphi consensus with three rounds by the national panel of experts
(rating group : 14 geriatricians)

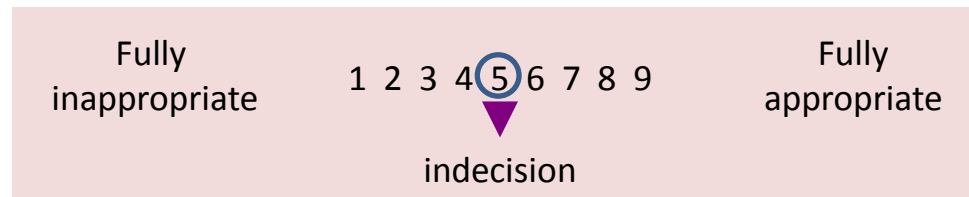
March to September 2017

Opinion about the final geriatric Core Data Set among

- 1) a national multidisciplinary panel (54)**
- 2) a international multidisciplinary panel (41)**

Method of individual scoring

For each tool, geriatrician experts have to indicate using a visual analogue scale **ranging from one (totally inappropriate) to nine (totally appropriate)** how the tool is relevant for the Core Data Set.



Analysis:

Considered item	Degree of agreement	Conditions for obtaining	
		Median	Range
Appropriate	Strong agreement	≥ 7	[7-9]
	Partial agreement	≥ 7	[5-9]
Inappropriate	Strong agreement	≤ 3	[1-3]
	Partial agreement	≤ 3.5	[1-5]
Unclear	Indecision	$4 \leq \text{median} \leq 6.5$	[1-9]
	No consensus	All other situations	

Results

SOCIAL ENVIRONMENT

- | | |
|---|---|
| <ul style="list-style-type: none"> ▪ Selected tools ✓ “Do you live alone?” ✓ “Do you have a caregiver or person able to help you?” ✓ “Living in nursing home” | <p>and scoring:</p> <p>9 [6-9] ; strong agreement (2ndRound)</p> <p>9 [7-9] ; strong agreement (2nd Round)</p> <p>5 [1-9] ; no consensus (3rd Round)</p> |
|---|---|

FUNCTIONAL STATUS

- | | |
|---|---|
| <ul style="list-style-type: none"> ▪ Selected tools ✓ ADL (abnormal if $\leq 5/6$) ✓ IADL 4 items (abnormal if $\leq 3/4$) | <p>and scoring:</p> <p>9 [8-9] ; strong agreement (1rd R)</p> <p>9 [8-9] ; strong agreement (1rd R)</p> |
|---|---|

MOBILITY

- | | |
|---|---|
| <ul style="list-style-type: none"> ▪ Selected tools ✓ Gait speed (abnormal if $\leq 0.8\text{m/s}$) ✓ TGUG test (abnormal if $>20\text{s}$) | <p>and scoring:</p> <p>8 [7-9] ; strong agreement (2nd R)</p> <p>9 [7-9] ; strong agreement (2nd R)</p> |
|---|---|

Results

NUTRITIONAL STATUS

- Selected tools
- ✓ **MNA-SF** (abnormal if <12/14)
- ✓ **Weight loss in the past 6 months** (abnormal >10%)
and **BMI** (abnormal if <21kg/m²)

and scoring :

9 [7-9] ; strong agreement (2nd Round)

9 [6-9] ; strong agreement (2nd R)

COGNITIVE STATUS

- Selected tools
- ✓ **Dubois' 5-words**
- ✓ **Clock drawing test**
- ✓ **Mini-Cog** (abnormal if <3/5)

and scoring :

7 [1-9] ; no consensus (3rd R)

7 [3-9] ; no consensus (3rd R)

9 [6-9] ; strong agreement (2nd R)

MOOD

- Selected tools
- ✓ **Mini-GDS** (4 items) (abnormal if ≥1/4)

and scoring:

9 [7-9] ; strong agreement (2nd R)

COMORBIDITIES

- ✓ **Updated Charlson**

9 [5-9] ; strong agreement (2nd R)

Final Report – 10 items

1. **Are you living alone?**
2. **Would you have a person or caregiver able to help you?**
3. **Activities of Daily Living (ADL)** (abnormal if $\leq 5/6$)
4. **4-IADL** (abnormal if $\leq 3/4$)
5. **Timed get up and go test** (abnormal if > 20 sec)
6. **Unintentional weight loss in last 6 months** (abnormal if $> 10\%$)
7. **Body Mass Index** (abnormal if < 21 kg/m²)
8. **Mini-Cog**
9. **Mini-Geriatric Depression Scale** (abnormal if $\geq 1/4$)
10. **Updated Charlson Comorbidity Index**

The final step of this consensus process is to assess Geriatric Core Data Set acceptability through a questionnaire completed by one national panel and one international panel of experts including cancer specialists, clinical research associates and nurses. It 's ongoing.

Questionnaire

Question 1. The objectives of the MINI DATA-SET are clearly explained.

Question 2. The patient population addressed by the MINI DATA-SET is clearly defined.

Question 3. The MINI DATA-SET validation group represents all professionals concerned with its use.

Question 4. The target users of the MINI DATA-SET are clearly defined.

Question 5. The approach and the scientific method used to define the MINI DATA-SET are clearly explained

Question 6. The items of the MINI DATA-SET are precise and unambiguous.

Question 7. Advice is provided for the use of the MINI DATASET.

Question 8. All the questions of the MINI DATA-SET can be easily completed during selection of a patient aged 70 and older for a research program or a clinical trial

(if in disagreement, please specify in the comments section the items of which completion might be compromised)

For each question, experts have to indicate **on a scale ranging from one (totally inappropriate) to seven (totally appropriate)** how the GCDS is relevant.

Conclusion

- DIALOG intergroup reached an agreement for a Geriatric Core Data Set to be incorporated in future clinical trials for the older cancer patients.
- This initiative has been evaluated for appropriation by a French, and an international panels of oncologists and geriatricians.



*Thank you for your
attention*