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Knowledge, attitude and barriers of the Italian National Guidelines System for the development of clinical practice guidelines: a cross-sectional survey of registered scientific-technical societies

Greta Castellini[1], Silvia Bargeri[1], Daniela Coclite[2], Daniela D'Angelo[2], Alice Josephine Fauci[2], Ornella Punzo[2], Antonello Napoletano[2], Primiano Iannone[2] and Silvia Gianola[1]

[1]Unità di Epidemiologia Clinica, IRCCS Istituto Ortopedico Galeazzi, Milan, Italy
[2]Centro Nazionale per l'Eccellenza Clinica, la Qualità e la Sicurezza delle Cure, Istituto Superiore di Sanità, Rome, Italy

Abstract

Background. To explore knowledge, attitude, and barriers of the Italian National Guidelines System (SNLG) for the development of clinical practice guidelines (CPG) among scientific-technical societies (STS) of health care professional.

Methods. A cross-sectional survey was distributed to the STS registered in the Italian Ministry of Health (n = 336). The questionnaire consisted of three sections: Respondent characteristics; Perception, knowledge, attitude, and use of CPGs; Knowledge of the SNLG.

Results. The survey sample was 194 (57.7%) STS: 69% STS members stated they "often consulted CPGs". Two out of three STS perceived scientific activities as extremely important. Additionally, 20.6% STS had submitted at least one CPG to the SNLG platform after the Gelli-Bianco Law went into effect (median 1 CPG; interquartile range, IQR, 1-4). The most often cited barrier (62.7%) to CPG submission was limited economic resources.

Conclusions. STS members hold a positive attitude towards CPGs despite barriers to CPG development.

Key words

- evidence-based practice
- cross-sectional studies
- clinical practice guidelines
- surveys and questionnaires

INTRODUCTION

Clinical practice guidelines (CPGs) provide support for evidence-based clinical decisions. The World Health Organization (WHO) defines evidence-informed CPGs as "a set of recommendations to support informed decision-making on the desirability of carrying out specific interventions at clinical or public health level, since these guidelines provide a basis for selecting and prioritizing, among a set of possible interventions, the most appropriate" [1]. The purpose of CPGs is to support practitioners in their evidence-based clinical decision making and to maximize the effectiveness of treatment allocation for specific outcomes [2]. CPGs thus encourage standardised health care practices across a country, reducing inconsistency and disparities, increase accessibility to the best evidence, and create a shared understanding of a topic for researchers and for clinicians in particular [3].

Criticism has been raised that CPGs are an oversimplified "cook book" approach to complex clinical questions [4]: CPGs may restrict clinician autonomy in personalizing interventions to individual patients, local resources, or cultural values [5]. Nonetheless, CPGs have gained increasing acceptance for reducing "postcode" variations in clinical practice: CPGs are defined as "a reasonable body of opinion" in cases of litigation in some countries [6, 7].

Address for correspondence: Greta Castellini, Unità di Epidemiologia Clinica, IRCCS Istituto Ortopedico Galeazzi, Via Riccardo Galeazzi 4, 20162 Milan, Italy. E-mail: greta.castellini@grupposandonato.it.

In Italy, the quality and number of national CPGs has been unsatisfactory so far, indeed only a small number of guidelines were made by Italian scientific-technical societies (STS).

The Gelli-Bianco Law (no. 24/2017) concerning professional responsibility has assigned a pivotal role to CPGs in clinical decision making and liability [8]. By law, CPGs are to be developed by public or private institutions or STS of health care professionals registered within the List of STS of the Italian Ministry of Health, in implementation of article 5 of Law no. 24/2017 and Ministerial Decree of 2 August 2017 [8, 9].

The Italian National Institute of Health (Istituto Superiore di Sanità, ISS), through the National Centre for Clinical Excellence, Quality and Safety of Care (Centro Nazionale per l'Eccellenza Clinica, la Qualità e la Sicurezza delle Cure, CNEC), drives CPGs governance by its methodological authority and provides access to CPG development through the National Guidelines System (Sistema Nazionale Linee Guida, SNLG) [10, 11]. The CNEC applies national and international quality standards [12] outlined in its methodological manual [13] to screen and assess the quality of CPGs submitted by public and private institutions or a STS. Submitted CPGs that meet the high quality criteria are then posted on the SNLG website [11].

With the present study we wanted to explore the perception, knowledge, attitude, use, and barriers of CPGs development in clinical practice. We also wanted to determine how well STS members were acquainted with the Italian SNLG. The overarching aim was to gain insight into how to improve national governance of the CPG process.

METHODS

Design

For this cross-sectional study involving a structured online survey to ensure high quality standards for reporting, we followed the Checklist for Reporting Results of Internet E-Surveys (CHERRIES) [14]. Details are given in the protocol, shared publicly via the Open Science Framework, at https://osf.io/4m6kf/. No major protocol amendments were made.

Survey questionnaire

There existed no questionnaires to appropriately address the aim of this study, which was to investigate a specific local system (i.e., SNLG). Drawing on similar questionnaires published in the literature [15-20], we built our theoretical framework *(Supplementary material A available online)* and piloted the survey with CNEC members to assess content validity of survey development. Ten STS members provided additional comments to refine the face validity of the final questionnaire version. The final questionnaire version consisted of 32 items divided into three sections: 1) Respondent characteristics (items 1 to 9); 2) Perception, knowledge, attitude, and use of CPGs (items 10-18); 3) Knowledge of the Italian National Guidelines System (SNLG) (items 19-32). Response to all items was mandatory. Questionnaire details are provided in the *Supplementary material B available online*.

Survey invitation and sample

A web-based closed questionnaire posted on the SurveyMonkey platform [21] was launched on 23 June 2021 by email sent to STS registered within the List of the Italian Ministry of Health updated to 18 December 2019, and therefore authorized to generate CPGs [9] *(Supplementary material C available online)*. The survey invitation identified the target respondents (i.e., representative STS member involved in CGP development) and explained the aim, the contents, and the time needed to complete it. Data collection terminated on 30 September 2021. Informed consent was obtained from survey respondents before they completed and submitted their survey responses.

Sample size calculation

We used the SurveyMonkey sample size calculator [22] to calculate the number of responders with completed responses that we expected to receive as sample size. Based on a population size of 336, which is the total number of STS registered within the List of the Italian Ministry of Health, a margin of error of 5% (how many survey results reflect the views of the overall population), and a sampling confidence level of 95% (how confident we can be that the population would select an answer within a certain range), the calculated sample size of completed responses was 180 completed answers.

Statistical analyses

Descriptive statistics are presented as median and interquartile range (IQR) or absolute frequency and related percentage, when appropriate. The questionnaire responses are presented in tabular and graphic formats (Microsoft Excel or Power Point 2016). An automated count of the response rate was acquired for each of the four sections in order to account for the sample size and to determine whether the questionnaires were terminated early (i.e., users did not go through all four questionnaire sections). Questionnaires which were terminated early (where users did not go through all four sections) were not included in the analyses. We used intention-to-treat analysis in cases of dropouts (failure to complete later questionnaire sections, e.g., Section 3). Data were exported from SurveyMonkey and analysed with STATA software [23].

RESULTS

Response rate

Overall, 194/336 STS responded to the survey, yielding a response/participation rate of 57.7%. The sample for each section is presented in the flow diagram *(Figure 1)*. Two respondents dropped out before completing Section 3, question 27.

Section 1. Respondent characteristics

Table 1 presents the general characteristics of the overall cohort of respondents. The median year of STS foundation was 1989 (1970-1999 IQR, min 1879, max 2017) and the majority of STS (41.2%) had from 51 to 500 registered members. More than half (56.7%) had registered members from different health care catego-

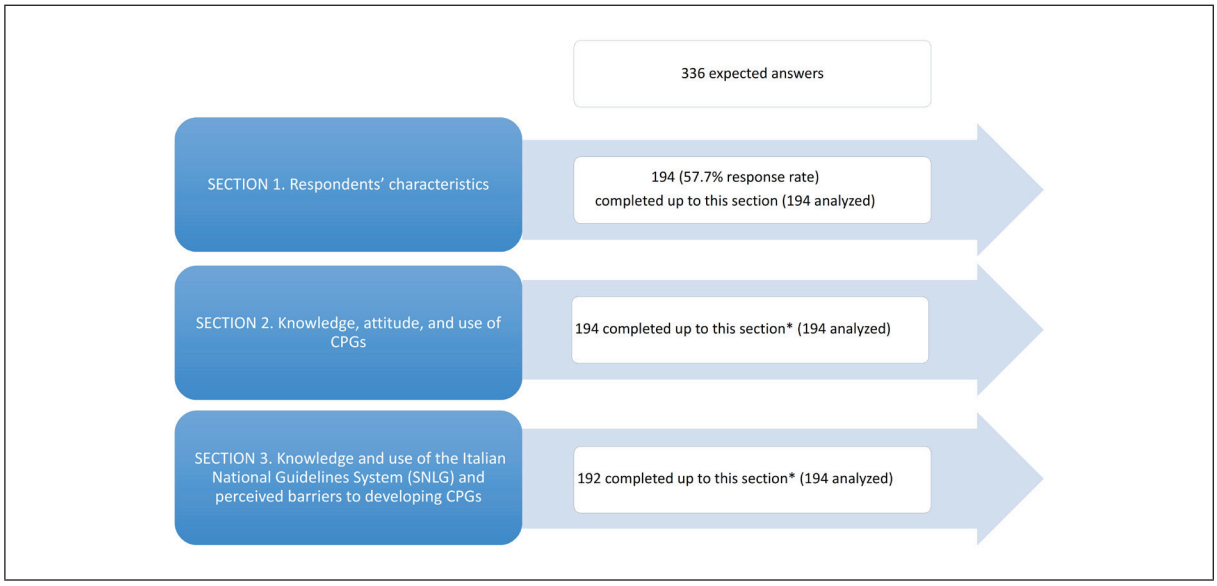

Figure 1
Flow diagram of respondents.
*Indicates the presence of conditional items.

Table 1
General characteristics of the scientific-technical societies

Number of registered members	Frequency (percentage of 194)
0-50	1 (0.52)
51-500	80 (41.24)
501-1000	47 (24.23)
1001-5000	55 (28.35)
>5000	11 (5.67)
Members from different health care worker categories	**Frequency (percentage of 194)**
No	84 (43.30)
Yes	110 (56.70)
Registration date*	**Frequency (percentage of 194)**
18/03/19	21 (10.82)
18/12/19	13 (6.70)
19/12/18	21 (10.82)
07/11/18	139 (71.65)

*Registration date in the Italian Ministry of Health List of scientific-technical societies (in implementation of article 5 of Law no. 24/2017 and Ministerial Decree of 2 August 2017).

ries (e.g., physicians, nurses, physiotherapists). November 7, 2018 was the most frequent registration date with the Italian Ministry of Health (71.7%). Before the Gelli-Bianco Law went into effect, a median of 1 (0-5 IQR, min 0, max 45) CPG was produced by the STS (*Supplementary material D available online*, *Figure 1*).

Section 2. Use and perceived effectiveness of clinical practice guidelines

Training courses (73.1%), scientific production and development of CPGs (67%), and communication, information, and dissemination (76.3%) were perceived as extremely important scientific activities by the majority of the STS. The STS seemed well (42.3%) or very well acquainted (54.1%) with the purposes of CPGs but less (39.7%) and much less (51.5%) about CPGs development. STS members reported that they often used and referred to CPGs (68.6%), which were stored in a repository in 52% of the STS. Nearly half of the respondents (48.4%) stated that their STS had never had a stakeholder role *(Table 2)*.

Section 3. Knowledge of the Italian National Guidelines System

Overall, 92.3% (n = 179) of STS members stated they were acquainted with the SNLG and 91.1% stated they had consulted its website at least once in the past. Overall, 73.2% consulted the methodological manual for CPGs development and the operative manual (54.6%) at least once in the past. Among those who responded "never consulted" (26.8%), the most frequent reason given was "no need" (48.1%). Overall, 20.6% had submitted at least one CPG to the SNLG platform (median 1 CPG; IQR 1-4), while 39.7% responded that they are working on or planning CPGs. Among those who had never submitted a CPG (38.7%), the most frequent reason was difficulty in management and development (42.7%) *(Table 3)*.

Perceived barriers to implementing CPGs in clinical practice are presented in *Figure 2*. The most often cited barrier was limited economic resources (62.7%) followed by overly complex CPG development (50.8%), and inadequate internal methodological competence (33.9%). Around 5% of the respondents (n = 11) added comments about barriers to CPG development, such as unclear role of funding source, not enough time, unclear operative procedures, and some topics were not applicable.

Table 2
Use and perceived effectiveness of CPGs

How important do you rate the following scientific activities of your STS (scale 1-9)?			
	Training in the clinical field of interest	**Scientific production, CPG development**	**Comunication/information/ dissemination**
	Frequency (%)	**Frequency (%)**	**Frequency (%)**
1 (not important)	0 (0)	1 (0.52)	0 (0)
2	1 (0.52)	0 (0)	0 (0)
3	0 (0)	3 (1.55)	0 (0)
4	0 (0)	1 (0.52)	0 (0)
5	3 (1.55)	4 (2.06)	2 (1.03)
6	5 (2.58)	4 (2.06)	1 (0.52)
7	12 (6.19)	14 (7.22)	8 (4.12)
8	30 (15.46)	37 (19.07)	35 (18.04)
9 (extremely important)	143 (73.71)	130 (67.01)	148 (76.29)
How well do you think that your registered STS members (scale 1-5)			
	Knows about the purpose of CPGs	**Knows about how CPGs are developed**	**Uses/consults CPGs?**
	Frequency (%)	**Frequency (%)**	**Frequency (%)**
Not at all	0 (0)	3 (1.55)	0 (0)
Little	7 (3.61)	77 (39.69)	29 (14.95)
Much	82 (42.27)	100 (51.55)	133 (68.56)
Very much	105 (54.12)	12 (6.19)	28 (14.43)
Don't know	0 (0)	2 (1.03)	4 (2.06)

CPG: Clinical Practice Guideline; STS: Scientific-technical society.

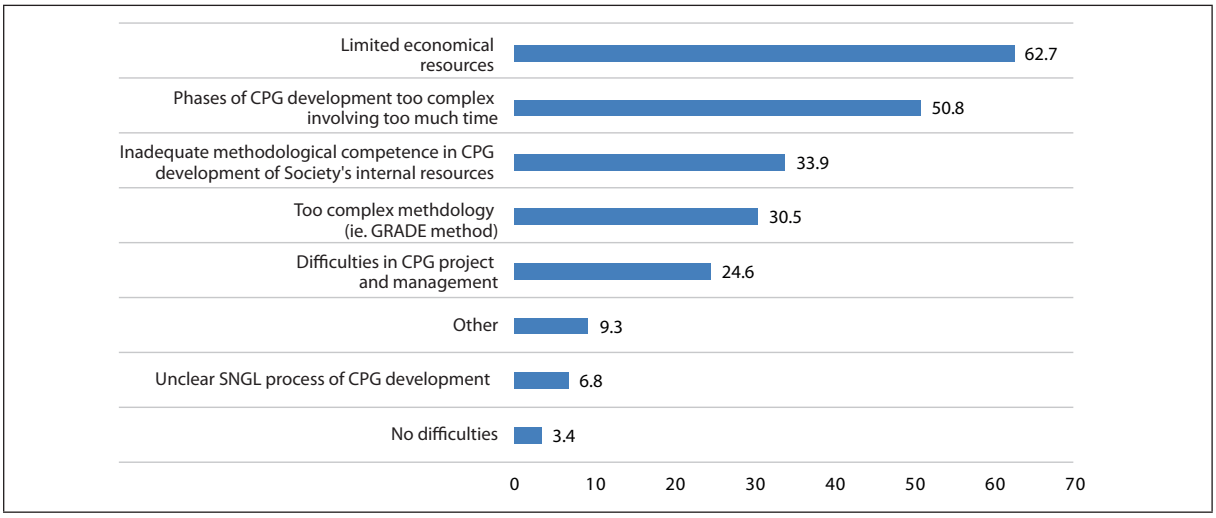

Figure 2
Barriers to implementing CPGs in clinical practice.
CPG: Clinical Practice Guideline; SNLG: Italian National Guidelines System (Sistema Nazionale Linee Guida); GRADE: Grading of Recommendations Assessment, Development and Evaluation.

DISCUSSION

Main findings

Our findings are based on a moderate response rate (about 60%) of Italian STS authorized to generate CPGs. Overall, 41.2% of the STS contacted have more than 500 registered members, half of which belonging to different health care categories. Three out of four STS held a very positive opinion of perception, knowledge, attitude, and use of CPG in clinical practice (e.g., CPG education, development, dissemination). STS members often use and refer to CPGs in their clinical work, but only one out of two STS provide CPGs access through a repository or have played a stakeholder role.

Nearly all respondents stated they knew the SNLG

Table 3
Knowledge of the Italian National Guidelines System (SNLG)

Are you acquainted with the Italian SNLG? (n = 194)	**Frequency (% out of 194)**
Yes	179 (92.27)
No	15 (7.73)
If yes, have you ever consulted the SNLG website?§ (n = 179)	**Frequency (% out of 179)**
Yes	163 (91.06)
No	16 (8.94)
Which sections of the website do you consult often? (more than one answer possible)§ (n = 179)	**Frequency (% out of 179)**
News	61 (34.08)
Communication CNEC	24 (13.41)
CPG SNLG - consultation	108 (60.34)
CPG SNLG - assessments and publications	63 (35.2)
CPG SNLG - production	63 (35.2)
Good practice	90 (50.28)
International guidelines	87 (48.6)
FAQ	20 (11.17)
Have you ever had difficulty consulting the Italian SNLG website? (more than one answer possible)§	**Frequency (% out of 179)**
Not difficult	90 (50.28)
Not user-friendly for browsing	32 (17.88)
Unattractive graphic interface	31 (17.32)
Unclear information	12 (6.7)
Redundant information	3 (1.68)
Incomprehensible information (e.g., technical terms)	8 (4.47)
Difficulty in searching for guidelines of interest (e.g., "search" tab faulty)	39 (21.79)
Other (specify)*	6 (3.35)
Has your STS ever submitted a proposal for an ongoing CPG or a complete CPG to the SNLG?	**Frequency (% out of 194^)**
Yes	40 (20.62)
No	75 (38.66)
Not yet (ongoing/planned)	77 (39.69)
If you have submitted CPGs, has your STS had difficulty submitting a CPG proposal or a complete CPG to the Italian SNLG? (more than one answer possible)§	**Frequency (% out of 40)**
No difficulties	15 (37.5)
Yes, unclear submission procedure	15 (37.5)
Yes, long and complex Document A	7 (17.5)
Yes, difficulty uploading the final document	8 (20)
Other (specify)**	5 (12.5)

CPG: Clinical Practice Guideline; SNLG: Italian National Guidelines System (Sistema Nazionale Linee Guida); STS: scientific-technical society.
^192/194 respondents (intention-to-treat analysis); *most STS reported other difficulties to find their field of interest in the website; **mainly difficulties with saving data in the system; §conditional questions.

and had accessed its website at least once in the past. More than half had consulted the operative and methodological manual for CPG development. This positive attitude is dampened by the gap between theory and practice, however [24]. Despite legislative efforts toward promoting civil responsibility and care safety [25], CPGs production is still limited: a median of only one CPG submitted (or ongoing) after the Gelli-Bianco Law went into effect in 2017 and subsequent legislation in 2018 [8].

While investment in the "CPG industry" seems socially and economically viable for improving quality of care and patient outcomes and reducing costs [26], social and organizational factors remain critical in CPG development, implementation, and use. The three barriers most often cited were limited economic resources, overly complex CPG development, and inadequate methodological competence of STS members.

Comparison to previous studies

Previous surveys investigating CPG knowledge, perception, use, and barriers to development [17-20] includ-

ed health care workers from a specific health care field or STS. Differently, our survey addressed the perspective of many STS (represented by one member of an STS mainly involved in CPG development) in various health care fields. Our response rate is similar to that of previous surveys. In addition, similar studies [17-20] investigated barriers to the implementation of CPGs, whereas none investigated obstacles to CPGs development.

Strengths and limitations

This is the first web-based survey to investigate the perception of knowledge, attitude, use, and perceived barriers to developing CPGs among STS in Italy after the Gelli-Bianco Law went into effect in 2017. The present study has several limitations. We were able to reach a sample size sufficient to achieve high statistical precision at a 95% confidence level with a type I error of 5%; nonetheless, this does not mean that selection bias was absent. For example, non responders may hold views that differ from responders: less compliance with the SNLG, less motivation or lack of interest in endorsing CPGs development and implementation. In addition, we cannot be certain that the survey was delivered as intended due to missing certified email addresses.

We did not collect STS characteristics (i.e., Section 1) of non responders since most characteristics were unavailable or irrelevant (e.g., number of registered members or year of foundation).

Finally, the data accuracy for perceived knowledge and importance is uncertain as the data were collected via a self-reported survey from representative members of the STS involved in CPG development. While we cannot be sure that the perceptions and the beliefs of the representative STS member are shared by its other members, we can use it as a proxy for feasibility purposes. A future area of focus is to identify knowledge, attitudes, and barriers to CPGs from the perspective of STS members.

Implications for practice

Developing CPGs is challenging: it involves making changes within the STS and the Italian health care system [27]. A closer relationship between the STS and the ISS is necessary to achieve this. To overcome operative and methodological barriers (i.e., overly complex CPGs development and inadequate methodological competence among STS members), we identified key interventions at all levels. For instance, there is a need for greater involvement of STS at all stages of CPG development (production, dissemination, implementation, auditing) as promoters of CPG submission or as stakeholders. Taking a more active role could boost their engagement in CPG development by identifying barriers to development, linking interventions to barriers, and planning and implementing the change process [28].

Our findings reflect scarce collaboration among STS, as highlighted in a retrospective Italian study (published prior to enactment of the Gelli-Bianco Law) where a lack of cooperation "to bring about necessary changes in the healthcare process and to define the benefits expected from adopting the guidelines" emerged [29]. STS should promote change and foster the formation of multidisciplinary work teams with other STS to optimize resources. Indeed, a criterion for publication in the SNLG is that CPGs are developed in a multidisciplinary and multi-professional approach.

Poor participation in CPG development and lack of collaboration between STS may be explained by the differences in health care education programs. EBM is not widely taught, though a better understanding of the knowledge, skills, and expertise in guideline development is urgently needed [27, 30]. STS should invest in education and training in EBM (e.g., training courses) for their health care providers to gain an understanding of the advantages of evidence-based CPGs [27]. As mentioned by David Sackett in 1996, any external guideline must be integrated with individual clinical expertise in deciding whether and how it matches the patient's clinical state, predicament, and preferences, and thus whether it should be applied [31]. Greater awareness could fill the void created by the perceived inadequate methodological competence within STS. Gaining more methodological competence could promote collaboration with recognized methodological centers in the synthesis of evidence, such as the Lazio Region-ASL Rome GRADE Center [32] and clinical epidemiology departments in Italy.

The ISS, through the CNEC, can increase its efforts to encourage and boost CPGs production by enhancing participation in CPG guideline development groups, which is key to guideline success. The goal is to orient and train STS member who have no experience with CPGs. An operative manual [33] guiding CPG submission, assessment, and publication is available, however, contribution and participation by STS have become more demanding. As in other international CPG organizations (e.g., World Health Organization, European Commission), STS need to be oriented to the tasks and the processes for developing tools, such as the Guideline Participant Tool (GPT) so that the STS can be informed about their role (e.g., conducting guideline group meetings) [34]. For instance, supporting checklist, frequently asked questions (FAQs) via videos or websites could be effective strategies to support STS and communicate with them. In this context, we advocate the ongoing efforts by the Guidelines International Network (GIN) and McMaster University to overcome methodological issues and to create a guideline development certification and credentialing program (INGUIDE.org). The GIN prepares methodologist courses for promoting standardization of skills. The ISS, through the CNEC, should establish an expert referral system that meets certified criteria (e.g., recognized methodological centers for the synthesis of evidence), as reported in other experience [35].

The main barrier of limited economic resources refers to the substantial cost of full CPG production, which depends on "the availability of monetary and non-monetary resources, credibility, maximization of uptake, the benefits of sharing information widely, and the avoidance of duplication of efforts". Professional societies cannot support such costs independently; they need to decide on the best approach to optimize their resources and define strategies and capabilities [36].

Trade-offs in internal financial sources must be settled: an STS needs to define where to invest its mon-

etary and non-monetary resources, while sacrificing something to obtain something else ("opportunity cost"). For instance, an STS that wants to invest more in residential clinical courses will have fewer or no resources to invest in CPGs production. Economical alternatives in the organisational CPG budget can be devised. For example, virtual meetings may allow expert panels to meet at lower cost, thus releasing resources toward methodological support, such as recognized centers for the synthesis the evidence [37]. This is the need for trade-offs as "guns versus butter" expressed in introductory economic courses [38].

STS might look for external financial sources (e.g., biomedical companies) as demonstrated in 63% of published CPGs on the National Guideline Clearinghouse website in Campsall *et al*., in 2016 [39], however, effective policies for transparently managing direct and indirect conflicts of interest need to be put into practice [39, 40]. The GIN has published principles for the management of financial conflicts of interest of CPG committee members [41].

CONCLUSION

CPGs development is a resource-intensive undertaking. STS hold a positive attitude towards CPGs principles. Barriers (i.e., financial, managerial, knowledge-based) might be more appropriately assessed as a stimulus than as an obstacle. Clinical guidelines risk remaining limited to a juridical role, with a weak impact on professional practice. Coordinated efforts between STS and the SNLG System are necessary to develop national CPGs of high quality that can be beneficial for all health care providers working in the public or the private sector, health care payers, health sector regulators, patients, and all other stakeholders.

Availability of data and materials

The dataset supporting the conclusions of this article is available in the OSF repository at https://osf.io/4m6kf/.

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Authors' contributions

GC and SG conceived the original idea for the study, designed the study, and planned the methods. GC and SG developed the first version of the questionnaire. DD, AN, DC, AF, OP, PI revised, piloted, and approved the questionnaire final version and provided input for the study protocol. GC, SG, and SB collected the data. GC, SG, and SB wrote the first draft of the manuscript. All Authors provided important intellectual content of the manuscript, its revision, and approved the final version. All Authors approved submission of the manuscript, the accuracy/integrity of the work.

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Conflict of interest statement

The Authors declare no competing interests.

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