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International consensus on the requirements for definitions of complete remission and recurrence of differentiated thyroid cancer: a Delphi Study (ICON-DTC)

Berg, D.J. van de; Santen, H.M. van; Clement, S.C.; Vriens, M.R.; Trotsenburg, A.S.P. van; Bruinstroop, E.; ... ; Differentiated Thyroid Canc Recurrence Collaborat Grp

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Original Research

International Consensus on the Requirements for Definitions of Complete Remission and Recurrence of Differentiated Thyroid Cancer: a Delphi Study (ICON-DTC)

Daniël J. van de Berg,[1,2,*] Hanneke M. van Santen,[3,4] Sarah C. Clement,[3] Menno R. Vriens,[5] A.S. Paul van Trotsenburg,[2,6] Eveline Bruinstroop,[2,7] Schelto Kruijff,[8,9] Robin P. Peeters,[10] Frederik A. Verburg,[11] Romana Netea-Maier,[12,13] Els J.M. Nieveen van Dijkum,[2,14,15] Laura Fugazzola,[16,17] Marek Dedecjus,[18] W. Edward Visser,[10,19] Kenneth K. Baidoo,[20] Joep P.M. Derikx,[1,2] and Anton F. Engelsman,[2,14,15]; Differentiated Thyroid Cancer Recurrence Collaboration Group

[1]Emma Childrens's Hospital, Amsterdam UMC, University of Amsterdam, Department of Pediatric Surgery, Meibergdreef 9, 1105 AZ, Amsterdam, The Netherlands
[2]Amsterdam Gastroenterology Endocrinology Metabolism Research Institute, Amsterdam, Meibergdreef 9, 1105 AZ, Amsterdam, The Netherlands
[3]Wilhelmina Children's Hospital,University Medical Center Utrecht, Department of Pediatric Endocrinology, Lundlaan 6, 3584 EA, Utrecht, The Netherlands
[4]Princess Máxima Center, Department of Pediatric Oncology, Heidelberglaan 25, 3584 CS, Utrecht, The Netherlands
[5]University Medical Center Utrecht, University of Utrecht, Department of Surgery, Heidelberglaan 100, 3584 CX, Utrecht, The Netherlands
[6]Emma Children's Hospital, Amsterdam UMC, location University of Amsterdam, Department of Pediatric Endocrinology, Meibergdreef 9, 1105 AZ, Amsterdam, The Netherlands
[7]Amsterdam UMC, location University of Amsterdam, Department of Endocrinology, Meibergdreef 9, 1105 AZ, Amsterdam, The Netherlands
[8]University Medical Center Groningen, University of Groningen, Department of Surgery, Hanzeplein 1, 9713 GZ, Groningen, The Netherlands
[9]Karolinksa Institutet,Department of Molecular Medicine and Surgery, Karolinska universitetssjukhuset, 171 76, Stockholm, Sweden
[10]Erasmus Medical Center, Erasmus University Rotterdam, Department of Internal Medicine, Dr. Molewaterplein 40, 3015 GD, Rotterdam, The Netherlands
[11]Erasmus Medical Center, Erasmus University Rotterdam, Department of Radiology & Nuclear Medicine, Dr. Molewaterplein 40, 3015 GD, Rotterdam, The Netherlands
[12]Radboud University Medical Center, Radboud University, Department of Internal Medicine, Division of Endocrinology, Geert Grootplein Zuid 10, 6525 GA, Nijmegen, The Netherlands
[13]Research Center for Functional Genomics, Biomedicine and Translational Medicine, Iuliu Hatieganu University of Medicine and Pharmacy, Victor Babes Street 8, 400012 Cluj-Napoca, Romania
[14]Amsterdam UMC, location Vrije Universiteit Amsterdam, Department of Surgery, De Boelelaan 1117, 1081 HV, Amsterdam, The Netherlands
[15]Cancer Center Amsterdam, De Boelelaan 1117, 1081 HV, Amsterdam, The Netherlands
[16]IRCCS Istituto Auxologico Italiano, Department of Endocrine and Metabolic Diseases and Laboratory of Endocrine and Metabolic Research, Via L. Ariosto 13, 20145 Milan, Italy
[17]University of Milan, Department of Pathophysiology and Transplantation, Via Franscesco Sforza 35, 20122, Milan, Italy
[18]Maria Sklodowska-Curie National Research Institute of Oncology, Department of Oncological Endocrinology and Nuclear Medicine, Wawelska 15/B, 00-001 Warsaw, Poland
[19]Erasmus Medical Center, Academic Center for Thyroid Diseases, Dr. Molewaterplein 40, 3015 GD, Rotterdam, The Netherlands
[20]Korle-Bu Teaching Hospital, Ear, Nose and Throat Department, Guggisberg Avenue, Accra, Ghana

*Corresponding author: Emma Children's Hospital, Amsterdam UMC, location University of Amsterdam, Department of Pediatric Surgery, Meibergdreef 9, 1105 AZ, Amsterdam, The Netherlands. Email: d.j.vandeberg@amsterdamumc.nl

Abstract

Objective: Recurrence is a key outcome measure of treatment for differentiated thyroid carcinoma (DTC). In international guidelines and current literature, a consistent definition is lacking, which hinders comparison of treatment-related oncological outcomes. Therefore, the aim of this study was to reach international consensus among experts from all medical specialties involved in the care of patients with DTC on the essential elements minimally required for a universal definition of recurrence—serving as a first step toward developing a new, universally accepted definition of DTC recurrence.

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Design: We conducted an international Delphi study.

Methods: A steering committee provided advice on the study protocol and Delphi rounds. Experts were identified through various scientific associations, international guidelines, ClinicalTrials.gov, our systematic review on definitions of DTC recurrence, and suggestions from the steering committee. A 3-round Delphi process was conducted to reach consensus on the minimally essential components of the definition of DTC recurrence. The initial list of components was derived from our systematic review.

Results: In total, 127 experts from all medical specialties involved in the diagnosis and treatment of DTC, representing 35 countries across 4 continents, completed 3 Delphi rounds. Thirteen key components critical for defining complete remission and recurrence of DTC were identified, following treatment with total thyroidectomy and postoperative radioiodine therapy (RIT), total thyroidectomy without RIT, and less-than-total thyroidectomy.

Conclusions: The components identified through this international Delphi consensus can serve as the foundation for the further development of universal definitions of DTC recurrence.

Keywords: definitions, complete remission, recurrence, differentiated thyroid cancer

Significance

Recurrence is a key outcome in differentiated thyroid carcinoma (DTC), yet definitions vary widely across studies and guidelines. This international Delphi study is the first to reach expert consensus across all medical specialties involved in DTC care on the minimally essential components for defining recurrence. By involving 127 experts from 35 countries, this study provides a globally informed foundation for a universal definition. These findings are an important step toward harmonizing oncological outcome reporting, improving comparability of studies, and guiding future research and clinical decision-making in the management of DTC.

Introduction

Cancer recurrence is a key oncological outcome for differentiated thyroid carcinoma (DTC), given that the 10-year survival exceeds 95%.[1-4] Reported recurrence rates of DTC vary widely across cohorts, ranging from 4% to 42%.[5-8] This variation can partly be attributed to the lack of a consistent definition of recurrence in both international guidelines and current literature.[3,4,9–11] Moreover, most international guidelines and nearly half of the studies on recurrence do not provide any definition of recurrence at all, despite its use as an outcome measure.[3,4,11] Additionally, differences in recurrence rates may be attributed to varying inclusion criteria, follow-up duration, histological subtypes, and other clinicopathological criteria.[5-8] The lack of a universal definition of DTC recurrence hampers the ability to compare recurrence rates and assess treatment effects across studies, which in turn poses a major obstacle to advancing care for patients with DTC. Standardization of the definition is crucial for facilitating global discussion, improving research comparability, enhancing the assessment of treatment outcomes related to recurrence, and ultimately improving patient outcomes. Naturally, definitions should be grounded in evidence-based medicine and original data. However, synthesizing these data into clear definitions ultimately requires expert consensus. Therefore, we presented the findings from our previously conducted systematic review—focusing on the components that currently define recurrence in the literature—to an international panel of specialists from all medical disciplines involved in the care of patients with DTC, with the aim of reaching consensus on the essential elements minimally required for a universal definition of recurrence. This consensus could serve as the foundation for developing a new, universally accepted definition of DTC recurrence.

Methods

This study was an international, prospective Delphi process to seek expert consensus on the minimal required elements of a universal definition of DTC recurrence. The Delphi consensus methodology was chosen due to its advantages over other structured forecasting approaches.[12,13] The Delphi methodology is distinct in relying solely on the structured input of a predefined expert panel; neither authors nor external stakeholders may retrospectively add or remove components once the process has begun. The list of components included in this study originated from our systematic review,[11] with additional suggestions only accepted by the experts during the first round, as per standard Delphi procedure. Components were then refined and scored iteratively by the same panel over multiple rounds. The primary outcome was to evaluate the critical components required in a universal definition of recurrence of DTC. Consent to participate in the survey was declared by answering and returning the survey. The study protocol was published on the Open Science Framework.[14] The Delphi study was conducted and managed by the online Welphi software (Decision Eyes, Lisbon, Portugal). The study was conducted in accordance with the Declaration of Helsinki of ethical principles for scientific research.

Steering committee

A steering committee was established, comprising 8 medical experts on DTC from various medical (sub-)specialties, including endocrinology, pediatric endocrinology, endocrine surgery, pediatric surgery, and radiology and nuclear medicine, affiliated with University Medical Centers (UMCs) in The Netherlands. The committee agreed on the final study protocol and provided input on the results of each round and on subsequent rounds. The steering committee members were not involved as participants in the Delphi study. Within the steering committee, a smaller study management group (DB, JD, END, AE) met regularly to discuss the study progress.

Participants

There is no rationale for determining the number of respondents for a Delphi Survey.[15] However, it is generally accepted that at least 12-18 participants should be included per group, in this case, per medical field related to DTC.[16] The primary users of a universal definition would be clinicians and

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researchers from various medical fields throughout the world, in both adult and pediatric care. Therefore, we aimed to invite a diverse subset of clinicians and researchers from different disciplines across the world who are involved in the management of DTC in both adult and pediatric populations. First, the European Thyroid Association (ETA), the EU reference Network Rare Endocrine Conditions (Endo-ERN), the European Organisation for Research and Treatment of Cancer—Endocrine Tumor Group (EORTC-EnTG), the European Reference Network on Rare Adult Solid Cancers (ERN-EURACAN), and the African Head and Neck Society (AfHNS) distributed the invitation to participate in our Delphi study among their members. Second, experts and research groups involved in the development of international thyroid guidelines, such as those from the European Society for Medical Oncology (ESMO), American Thyroid Association (ATA), and the European Thyroid Association (ETA) (pediatric) clinical practice guidelines were invited.[3,4,9,17] Third, experts were identified via www.clinicaltrials.gov. Fourth, last authors of more than 2 studies included in our systematic review regarding the definition of recurrence of DTC were invited.[11] Last, members of the steering committee provided suggestions on additional international experts in their field.

Initial list of potential components

To develop a list of potential components of the definition of recurrence to present to the participants, we performed a systematic review to identify the reported definitions of recurrence of DTC.[11] The initial list of identified components included: clinical symptoms, cytology/pathology, varying imaging studies, thyroglobulin (Tg) with or without Tg-antibodies, and a predetermined minimum tumor-free time span following initial therapy.

Study design

The list of components was formatted into questions, which were initially kept as broad as possible (see Supplement 1 for full rounds). Participants rated each question on a 1-9 Likert scale based on how important they judged the component to be for inclusion in a universal recurrence definition, as recommended by the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) working group.[18] A score of 7-9 indicated that this component is considered critically important for defining recurrence of DTC, 4-6 is considered important but not critical, and 1-3 indicated that the component has low importance for the definition of recurrence. In addition, participants could select "not my area of expertise" per question, if they did not feel equipped to score certain questions. Each round had to be completed within 4 weeks. In that time, 2 reminder emails were sent to participants that had not yet completed the round. Only participants who completed the round were invited to participate in the subsequent one, and only those who completed all rounds became part of the collaboration group for the final publication. In round 1, participants could propose additional components that were not included in the initial list. The steering committee decided whether suggested components were to be considered as new components and should be added to the new round. Components that did not reach consensus were presented again in rounds 2 and 3. Additionally, components that reached consensus-in were further specified in these rounds (Supplement 1). In consecutive rounds, participants could see the scoring distribution of the other participants' answers and a reminder of their individual answer from the previous round, in accordance with the Delphi principle. Participants were then asked to re-score the remaining outcomes in the same manner as the previous round.

In the absence of a formal guideline but in accordance with common practice,[15] consensus was defined as follows:

Consensus-in: 70% of the participants or more (excluding "Not my area of expertise") rating the component as 7-9, and less than 15% rating the variable as 1-3;

Consensus-out: 70% of the participants or more (excluding "Not my area of expertise") rating the component as 1-3, and less than 15% of participants rating it 7-9.

Results

On January, 10, 2024, invitations were sent by email for the first round. There were 208 respondents, with 182 complete responses and 26 incomplete responses. On April 2, the second round was sent by email. There were 130 respondents, with 128 complete responses and 2 incomplete responses. On May 23, the third round was sent by email. There were 127 respondents, all of whom completed the round, representing 35 countries across 4 continents (Figure 1). The respondents included endocrinologists, oncologists, surgeons, pathologists, radiologists and nuclear medicine physicians, pediatricians, and researchers (see collaboration group and Supplement 2 for the specialty distribution). In the first round, the initial list of 5 components identified by our systematic review was presented, with 3 components reaching consensus-in and none reaching consensus-out.[11] The components that reached consensus-in were further refined with new questions. Based on suggestions from experts and after discussions with the steering group, 5 new components were added. Among the suggestions were proposals that it is critical to define complete remission, persistent disease, and recurrence of DTC separately, rather than a single universal definition of recurrence, and to stratify these definitions according to treatment type: total thyroidectomy with postoperative radioiodine therapy (RIT), total thyroidectomy without RIT, and less-than-total thyroidectomy. In round 2, 5 components reached consensus-in, and none reached consensus-out. In the third and final round, no new components were added, in accordance with the Delphi principle. In this round, 5 components reached consensus-in, and one component reached consensus-out. After 3 rounds, 13 components reached consensus-in and one component reached consensus-out (Table 1). The median and IQR for each component across rounds are presented in Supplement 3. No substantial changes in the median or IQR were observed from round 1 to round 3, supporting the stability of the final consensus (Supplement 3).[19]

Minimally required components for the definitions

The following elements were deemed essential in developing a universal definition of DTC recurrence: there should be separate definitions for *complete remission*, *persistent disease*, and *recurrence* of DTC following treatment with total thyroidectomy and RIT, total thyroidectomy without RIT, and less-than-total thyroidectomy. Per category, there are different components essential for the definitions.

Total thyroidectomy with RIT

Complete remission* of DTC following total thyroidectomy and RIT should minimally be defined with:

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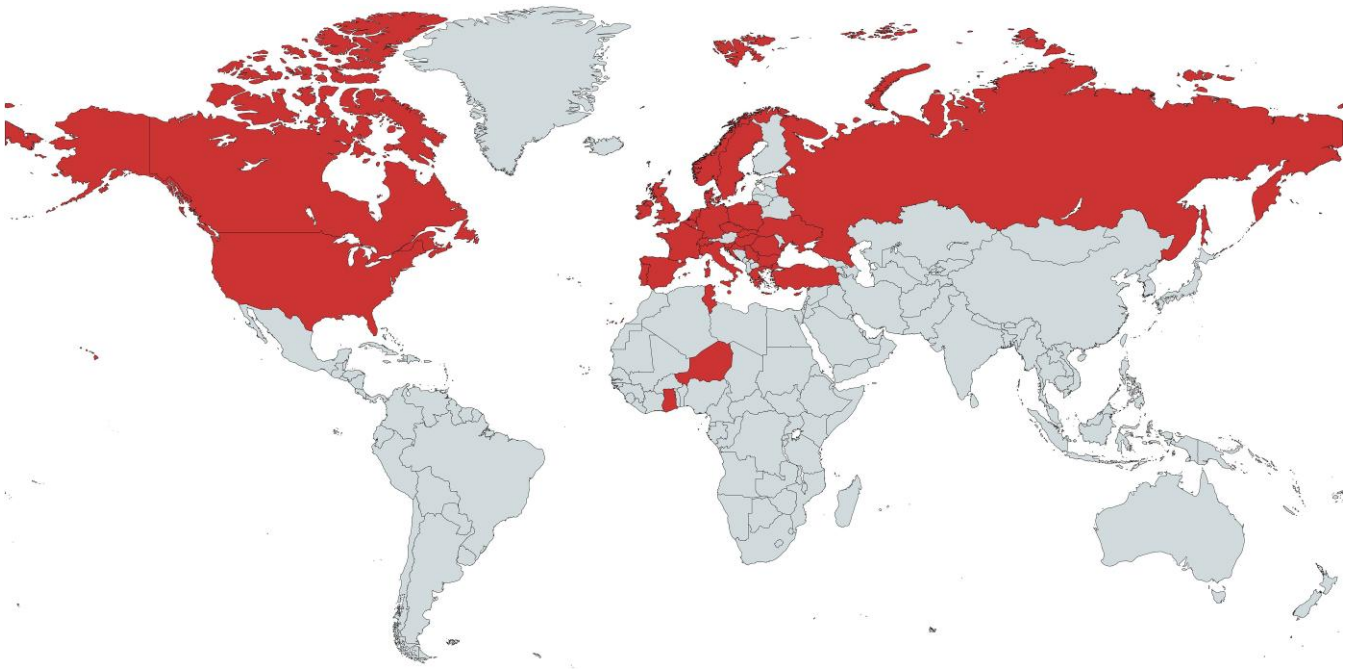

Figure 1. Distribution of the Delphi participants worldwide (red).

Table 1. Consensus-in after 3 Delphi rounds for the definition of recurrence of DTC.

Component	Consensus-in
Thyroglobulin/ thyroglobulin-antibodies	It is critical to include **thyroglobulin and/or thyroglobulin-antibodies** (**1**) in the definition of recurrence
	Thyroglobulin and/or thyroglobulin-antibodies (**2**) are critical in the definition of recurrence, after treatment with total thyroidectomy and radioiodine ablation
	Rising thyroglobulin levels after initial stable levels (**2**) are critically important for the definition of recurrence
	The presence of **positive thyroglobulin-antibody levels after initial negative levels** (**3**) is critically important for the definition of recurrence
Imaging studies	It is critical to include **imaging studies** (**1**) in the definition of recurrence
	It is critical to include **neck ultrasonography** (**2**) in the definition of recurrence
Cytology/pathology	It is critical to include **cytology/pathology-confirmation** (**1**) in the definition of recurrence
Predetermined tumor-free time span	It is critical to include a **predetermined tumor-free time span** (**3**) in the definition of recurrence
After suggestions of experts	It is critical to formulate a definition of **complete remission** (**2**), in order to subsequently define recurrence
	It is critical to the definition of recurrence to formulate a separate definition for **recurrent disease** (**2**) and for **persistent disease** (**2**)
	It is critical to formulate separate definitions for **complete remission** (**3**) following treatment with **total thyroidectomy with radioiodine ablation, total thyroidectomy without radioiodine ablation, and less-than-total thyroidectomy** (**3**)
	It is critical to formulate separate definitions for **recurrence** (**3**) following treatment with **total thyroidectomy with radioiodine ablation, total thyroidectomy without radioiodine ablation, and less-than-total thyroidectomy** (**3**)
	It is critical to formulate separate definitions for **persistent disease** (**3**) following treatment with **total thyroidectomy with radioiodine ablation, total thyroidectomy without radioiodine ablation, and less-than-total thyroidectomy** (**3**)

Consensus achieved in round 1. Consensus achieved in round 2. Consensus achieved in round 3. Abbreviation: DTC, differentiated thyroid carcinoma.

- Undetectable Tg and Tg-antibody levels[†]
- Combined with negative[‡] neck ultrasonography
- For patients with synchronous distant metastases, negative results[‡] on other imaging studies are also required.

Recurrence of DTC following total thyroidectomy and RIT should minimally be defined as

- Initial achievement of complete remission

and

- Rising Tg levels *or* Tg-antibody levels
- In combination with anomalies found by neck ultrasonography (performed for suspicion on locoregional recurrence) *or* by other imaging studies (performed for suspicion on distant recurrence)
- and confirmed with pathology, if possible.

*These definitions should be considered in the context of a *predetermined tumor-free time span* after which complete remission can be determined.

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[†]For Tg levels: below either the functional sensitivity of the Tg-assay used or below a specific institutional cutoff of undetectable Tg levels; for Tg antibody levels: below the cutoff for positivity stated by the manufacturer or a specific institutional cutoff.

[‡]No lymph nodes or other structures suspicious for presence of disease.

Total thyroidectomy without RIT or less-than-total thyroidectomy

The definitions of *complete remission* and *recurrence* of DTC following either total thyroidectomy without RIT or less-than-total thyroidectomy were identical and are thus reported together.

Complete remission* of DTC following total thyroidectomy without RIT or less-than-total thyroidectomy should minimally be defined with

- Negative[†] neck ultrasonography.

Recurrence of DTC following total thyroidectomy without RIT or less-than-total thyroidectomy should minimally be defined as

- Initial achievement of complete remission

and

- Anomalies found by neck ultrasonography (performed for suspicion on locoregional recurrence) *or* by other imaging studies (performed for suspicion on distant recurrence)
- And confirmed with pathology, if possible.

*These definitions should be considered in the context of a *predetermined tumor-free time span* after which complete remission can be determined.

[†]No lymph nodes or other structures suspicious for presence of disease.

Definitions

Using the minimally required components selected by the expert panel, we developed preliminary definitions for complete remission and recurrence of DTC following treatment with total thyroidectomy and RIT, total thyroidectomy without RIT, and less-than-total thyroidectomy (see below). These definitions represent the minimal necessary criteria and are not yet intended for clinical use. They should first be discussed and refined within the DTC community. However, they may serve as a foundation for the future development of universal definitions for DTC recurrence.

Definitions following total thyroidectomy and RIT

Complete remission of DTC following total thyroidectomy and RIT is defined as undetectable Tg and Tg-antibody levels combined with neck ultrasonography showing no lymph nodes or other structures suspicious for presence of disease. For patients with synchronous distant metastases, other imaging studies showing no lymph nodes or other structures suspicious for presence of disease are also required.

Recurrence of DTC following total thyroidectomy and RIT is defined as initial achievement of complete remission and subsequent rising Tg levels or Tg-antibody levels in combination with anomalies found by neck ultrasonography (performed for suspicion on locoregional recurrence), or by other imaging studies (performed for suspicion on distant recurrence), and confirmed with pathology, if possible.

These definitions should be considered in the context of a predetermined tumor-free time span after which complete remission can be determined.

Definitions following total thyroidectomy without RIT and less-than-total thyroidectomy

Complete remission of DTC following total thyroidectomy without RIT and less-than-total thyroidectomy is defined as neck ultrasonography showing no lymph nodes or other structures suspicious for presence of disease.

Recurrence of DTC following total thyroidectomy without RIT and less-than-total thyroidectomy is defined as initial achievement of complete remission and subsequent anomalies detected by neck ultrasonography (performed for suspicion on locoregional recurrence), or by other imaging studies (performed for suspicion on distant recurrence), and confirmed with pathology, if possible.

These definitions should be considered in the context of a predetermined tumor-free time span after which complete remission can be determined.

Discussion

Through an international 3-round Delphi process, involving 127 DTC experts from 35 countries, we identified 13 key components critical for defining complete remission and recurrence of DTC following the initial treatment strategy.

These minimally required components were elected using a rigorous, protocol-driven Delphi consensus methodology, involving a diverse group of medical experts and researchers from all over the world in the field of DTC. These components can be the foundation for universal definitions that are intended to be applied in healthcare settings and the research community to facilitate the management of, research on, and communication about complete remission and recurrence of DTC in a more standardized way. To our knowledge, these are the first internationally agreed-upon components for defining complete remission and recurrence of DTC.

Based on the experts' suggestions from round 1, a consensus was reached to establish and categorize definitions for complete remission and recurrence according to the 3 treatment regimens, rather than adopting a single universal definition of recurrence. Given the ongoing trend toward de-escalation of treatment for patients with low-risk DTC, and the fact that diagnostic modalities for identifying recurrence, or achieving complete remission vary depending on treatment protocol, this is a logical approach. This is primarily because serum Tg concentrations are not reliable for confirming complete remission or diagnosing recurrence after less-than-total thyroidectomy, and likely not even after total thyroidectomy without RIT.[20]

The definitions have to be interpreted in light of the following nuances. Firstly, consensus on the tumor-free time span was reached in the final round. Consequently, no specific duration could be determined by the experts. The tumor-free time period is probably crucial for determining when complete remission can be confirmed. This is primarily because, after

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RIT, a period of 10-12 months is typically needed to assess its effect. Therefore, we propose that after treatment with total thyroidectomy and RIT, the tumor-free time span for establishing complete remission be set at 12 months after RIT. Also, after total thyroidectomy without RIT or less-than-total thyroidectomy, we also propose a period of 12 months, as delayed risk stratification is generally recommended after a minimum of 12 months.[9,21-24] However, we strongly support open discussion, as individual clinical cases or varying hospital treatment protocols may require a different tumor-free time span.

Secondly, the introduction of highly sensitive Tg (hsTg) assays has improved the ability to detect very low Tg concentrations, with substantial implications for how these results are interpreted in current clinical practice.[25-27] These hsTg assays are recommended over conventional Tg assays for monitoring patients with DTC after total thyroidectomy and RIT ablation, as they are highly precise and reliable and can detect an increasing Tg trend earlier and with greater accuracy; however, they are not yet used ubiquitously.[20] It is important to note that minimally detectable basal Tg concentrations (below 1 µg/L) with hsTg assays are not associated with a significant risk of disease recurrence or cancer-specific mortality.[20,28] Therefore, the definitions proposed in this study should be considered in the light of these advanced techniques. We have based the suggested definitions on conventional Tg assays because most existing literature and international guidelines rely on these methods, and because hsTg assays are not widely available in low-income countries.[3,9,29] The assessment of Tg and Tg-antibodies proposed in the current definitions should be used as the minimum standard for defining recurrence. However, we acknowledge that hsTg assays and newer methods, such as liquid chromatography-tandem mass spectrometry (LC-MS/MS) Tg assays, will affect the interpretation of "undetectable" Tg and Tg-antibody levels, as well as the use of neck ultrasonography. Therefore, we suggest that neck ultrasonography may be omitted to confirm complete remission if a highly sensitive Tg assay is used, and that "undetectable" Tg and Tg-antibody levels should be interpreted less strictly, as truly undetectable levels are rarely achieved with highly sensitive assays.

Our study has several limitations. First, we were unable to develop definitive universal definitions, as the components identified represent only the minimally required elements. However, establishing such universal definitions was not the aim of this study. This process will require further discussion, consensus, and refinement within the broader DTC community. Operationalizing these definitions in practice may be challenging due to diverse clinical cases and treatment protocols. Additionally, as new evidence emerges and diagnostic techniques continue to advance, the required components and definitions are likely to change. Nonetheless, the elected components in this study and the preliminary definitions proposed here can serve as a foundation for future efforts to develop universal definitions. Second, we did not define other entities such as persistent disease, biochemical incomplete or indeterminate responses, which may lead to an underestimation of the true complete remission rate in clinical studies using these definitions. Future studies should aim to define such other entities, perhaps employing a similar international Delphi study. Third, the English language was used for practical reasons, which might have discouraged participants with limited English proficiency from participating in this Delphi study. However, we anticipated that most international experts would have a proficient level of English to participate in the study. Fourth, responses were mostly from the European and North American continent. We attempted to include as many experts as possible from Africa, Asia, Australia, and Latin America to achieve a broad global consensus. We distributed our invitation through AfHNS and invited the last authors of more than 2 studies included in our systematic review, most of which were conducted in Asia. However, experts from these continents were underrepresented in our Delphi.

Recurrence remains one of the most important oncological outcomes in DTC. Many challenges persist in the diagnosis, follow-up, and treatment of recurrence, as each clinical case is unique. The components identified through this international Delphi consensus can serve as the foundation for the further development of universal definitions of DTC recurrence. Standardized definitions, if widely adopted, would benefit both clinical management and research in the field of DTC.

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Supplementary material

Supplementary material is available at *European Journal of Endocrinology* online.

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Authors' contributions

Daniël van de Berg (Conceptualization [lead], Formal analysis [lead], Funding acquisition [equal], Investigation [equal], Methodology [lead], Software [equal], Validation [equal], Writing—original draft [lead], Writing—review & editing [lead]), H van Santen (Conceptualization [equal], Data curation [equal], Formal analysis [equal], Methodology [equal], Resources [equal], Supervision [equal], Writing—review & editing [equal]), SC Clement (Methodology [equal], Supervision [equal], Validation [equal], Visualization [equal], Writing—review & editing [equal]), Menno Vriens (Conceptualization [equal], Formal analysis [equal], Funding acquisition [equal], Investigation [equal], Methodology [equal], Supervision [equal], Writing—review & editing [equal]), A S van Trotsenburg (Conceptualization [equal], Funding acquisition [equal], Methodology [equal], Resources [equal], Supervision [equal], Validation [equal], Writing—review & editing [equal]), Eveline Bruinstroop (Supervision [equal], Visualization [equal], Writing—review & editing [equal]), S Kruijff (Conceptualization [equal], Formal analysis [equal], Funding acquisition [equal],

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Methodology [equal], Resources [equal], Supervision [equal], Validation [equal], Writing—review & editing [equal]), Robin Peeters (Conceptualization [equal], Methodology [equal], Resources [equal], Supervision [equal], Writing—review & editing [equal]), Frederik Verburg (Conceptualization [equal], Investigation [equal], Methodology [equal], Resources [equal], Supervision [equal], Visualization [equal], Writing—review & editing [equal]), Romana T Netea-Maier (Conceptualization [equal], Methodology [equal], Supervision [equal], Validation [equal], Writing—review & editing [equal]), Els Nieveen van Dijkum (Conceptualization [equal], Methodology [equal], Supervision [equal], Validation [equal], Visualization [equal], Writing—review & editing [equal]), Laura Fugazzola (Validation [equal], Visualization [equal], Writing—review & editing [equal]), Marek Dedecjus (Supervision [equal], Validation [equal], Visualization [equal]), W. Edward Visser (Methodology [equal], Resources [equal], Supervision [equal], Validation [equal], Writing—review & editing [equal]), Kenneth K. Baidoo (Supervision [equal], Validation [equal], Visualization [equal]), Joep Derikx (Conceptualization [equal], Data curation [equal], Formal analysis [equal], Funding acquisition [equal], Methodology [equal], Resources [equal], Software [equal], Supervision [equal], Visualization [equal], Writing—review & editing [equal]), and Anton Engelsman (Conceptualization [lead], Data curation [equal], Formal analysis [equal], Funding acquisition [equal], Methodology [equal], Project administration [equal], Supervision [lead], Validation [equal], Visualization [equal], Writing—review & editing [equal])

D.B. coordinated the Delphi procedure under the supervision of A.E., J.D., E.D., and P.T. D.B. performed the analysis under the supervision of A.E., J.D., E.D., and P.T. Together with D.B., A.E., J.D., E.D., and P.T. also had access to the data and verified the results of each round. H.S., S.C., M.V., E.B., S.K., R.P., F.V., and R.M. all critically reviewed and approved the study protocol, assessed the data of each Delphi round, and approved each Delphi round. DB took the lead in writing the final manuscript under the supervision of A.E., J.D., E.D., and P.T. H.S., S.C., M.V., P.T., E.B., S.K., R.P., F.V., R.M., E.D., L.F., M.D., E.V., K.B., J.D., and A.E. all critically reviewed and improved the final manuscript. All authors agreed to the publication of the manuscript in its current form. The authors in the Differentiated Thyroid Cancer Recurrence Collaboration Group participated as experts in this Delphi study and completed all rounds.

Conflict of interest: F.V. declares to have received consultancy fees from GE Healthcare, Immedica (all money paid to employer), and speaker fees from Bayer, AstraZeneca, and GE Healthcare (all money paid to employer). M.D. declares to have received speaker and attending fees from Ipsen, Sanofi, and Novartis, and to be on the Advisory Board of Novartis, Ipsen, and Sanofi. M.D. declares to be a member of the Board of: EORTC EnTG Group, Polish Society of Endocrinology, Polish Society of Thyroidology, Polish Society of Endocrine Oncology, and Polish Society of Organ Biopsy. All other authors declare no competing interests.

Data sharing statement

The data that support the findings of this study are available on request from the corresponding author, Daniël J. van de Berg, after approval of a proposal, with a signed data access agreement. The data are not publicly available as they contain information that could compromise the privacy of the participating experts. The study protocol is available on the Open Science Framework.[14]

Collaborator

Names and affiliations Differentiated Thyroid Cancer Recurrence Collaboration Group – ICON-DTC study

Adekunle Daniel[1], Agnieszka Czarniecka[2], Alessandra Cassio[3], Alexis Vrachimis[4], Anca Sirbu[5], andrea frasoldati[6], Andrea Contarino[7], Andrej Belančić[8], Andrew J Bauer[9], Anna Crescenzi[10], Anna Konney[11], Anna M Sawka[12], Annamária Erdei[13], Antje Redlich[14], Marialuisa Appetecchia[15], Arseny Semenov[16], Ashok R Shaha[17], Berna O Evranos[18], MC Burlacu[19], Pietro G Calò[20], Camille Buffet[21], Carmine De Bartolomeis[22], Catherine A Dinauer[23], Corina E Andreescu[24], Dario Tumino[25], Doina Piciu[26], Domenico Albano[27], Elena Chobankova[28], Elin H Naderi[29], Ellen Kapiteijn[30], Esther Willemse[31], Ferenc Gyory[32], Flavia Magri[33], [34], Florence van Ryckeghem[35], Francesco Ferraù[36], Franco Grimaldi[37], Françoise Borson-Chazot[38], furio pacini[39], Gabriella Pellegriti[40], Gerasimos P Sykiotis[41], Gerdi Tuli[42], Gerlof D Valk[43], Gesthimani Mintziori[44], Gianni Bocca[45], Giulia Brigante[46], Giuseppe Costante[47], Giuseppe Fanetti[48], Gloria Marquina[49], Gordana Horvatić-Herceg[50], François Gorostidi[51], Greg Randolph[52], Ohanyan Haykanush[53], Iryna O Kostitska[54], james suliburk[55], Jan Krátký[56], Jan Podoba[57], Jan Zedenius[58], Jolanta Krajewska[59], Jon Wadsley[60], Jonathan D Wasserman[61], Juan C Galofré[62], Julie Hallanger- Johnson[63], Katerina Kopeckova[64], Katerina Saltiki[65], Kenneth Kojo Baidoo[66], Koen M A Dreijerink[67], Laszlo Hegedüs[68], Laura Fugazzola[69], Laura D Locati[70], Livia Lamartina[71], Luca Giovanella[72], Luca Persani[73], Luisa de Sanctis[74], Malek Mnejja[75], Malgorzata Trofimiuk- Müldner[76], Marcin Barczynski[77], Marco Raffaelli[78], Maria C Vigone[79], Maria G Castagna[80], Maria Grazia Maratta[81], Maria João Bugalho[82], Maria Sandström[83], Marie-Louise Healy[84], Mario Salvi[85], Mark Gruppetta[86], Martin Almquist[87], MT Stegenga[88], Michele N Minuto[89], Miklós Tóth[90], Miloš Žarković[91], Monica L Gheorghiu[92], Montserrat Negre Busó[93], Brooke Puttergill[94], Nicholas Reed[95], Nicole D Bouvy[96], Nikola Besic[97], Oleksandr Nechai[98], Özer Makay[99], Pablo Valderrabano[100], Paul A Onakoya[101], Peter Angelos[102], Petra Petranović Ovčariček[103], Petros Perros[104], Kristien Boelaert[105], Thomas J Musholt[106], Radu Mihai[107], Ramon R J P van Eekeren[108], Renuka P Dias[109], Roman Chernikov[110], Ronald R de Krijger[111], Patrick O Rosselet[112], Roussanka Kovatcheva[113], Salvatore Cannavò[114], Sam Van Slycke[115], Silvia A Eskes[116], Steven I Sherman[117], Steven G Waguespack[118], Thera P Links[119], Tessa Malaika van Ginhoven[120], Tiago nunes da silva[121], Tijana Ičin[122], Timm Denecke[123], Tobias Zingg[124], Ulla Feldt- Rasmussen[125], Valeriano Leite[126]

[1]Department of Otorhinolaryngology, College of Medicine, University of Ibadan, Ibadan, Nigeria.

[2]3rd Department of Oncological Surgery, M. Sklodowska-Curie National Research Institute of Oncology, Gliwice Branch, 44-101 Gliwice, Poland.

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[3]Department of Medical and Surgical Sciences, University of Bologna, Bologna, Italy
[4]Department of Nuclear Medicine, German Oncology Center, European University Cyprus, Limassol, Cyprus.
[5]Endocrinology Department, Carol Davila University of Medicine and Pharmacy, 020021 Bucharest, Romania.
[6]Endocrinology Unit, Azienda USL-IRCCS di Reggio Emilia, Reggio Emilia, Italy.
[7]Endocrinology Unit, Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milan. & Department of Clinical Sciences and Community Health, University of Milan, Milan, Italy
[8]Department of Clinical Pharmacssology, Clinical Hospital Centre Rijeka, Krešimirova 42, 51000 Rijeka, Croatia; a.belancic93@gmail.com; Department of Basic and Clinical Pharmacology with Toxicology, University of Rijeka, Faculty of Medicine, Braće Branchetta 20, 51000 Rijeka, Croatia; andrej.belancic@uniri.hr
[9]Director, The Thyroid Center Division of Endocrinology and Diabetes The Children's Hospital of Philadelphia, Philadelphia, PA, United States.; Professor of Pediatrics Perelman School of Medicine The University of Pennsylvania, Philadelphia, PA, United States.
[10]Department of Radiological, Oncological and Pathological Sciences, Sapienza University of Rome, Rome, Italy.
[11]Eye, Ear, Nose and Throat Department, Komfo Anokye Teaching Hospital, Kumasi, Ghana.
[12]Division of Endocrinology, Department of Medicine, University Health Network and University of Toronto, Toronto, Canada.
[13]Division of Endocrinology, Department of Internal Medicine, Faculty of Medicine, University of Debrecen, Debrecen, Hungary.
[14]Paediatric Oncology Department, Otto von Guericke University Children's Hospital, Magdeburg, Germany.
[15]Oncological Endocrinology Unit, IRCCS Regina Elena National Cancer Institute, Via Elio Chianesi 53, 00144 Rome, Italy.
[16]Department of Endocrine surgery, St. Petersburg State University Hospital
[17]Head and Neck Service, Department of Surgery, Memorial Sloan Kettering Cancer Center, New York, NY, USA.
[18]Ankara Yildirim Beyazit University, Bilkent City Hospital, Endocrinology and Metabolism Department, Ankara, Turkey.
[19]Department of Endocrinology Diabetology and Nutrition, Cliniques Universitaires St-Luc, Université Catholique de Louvain, Brussels, Belgium.
[20]Affiliation Department of Surgical Sciences University of Cagliari, Policlinico D. Casula, 09042 Monserrato (Cagliari) Italy
[21]Thyroid and Endocrine Tumors Department, Pitié-Salpêtrière Hospital, Thyroid Tumors Clinical Research Group n°16, Sorbonne University, Cancer Institute, Inserm U1146, CNRS UMR 7371, Paris, France
[22]Barbantini Hospital - Endocrine Surgery Unit - Lucca (Italy)
[23]Department of Pediatrics, Division of Endocrinology & Diabetes, Yale School of Medicine, New Haven, CT, USA.
[24]Department of Endocrinology, UZ Brussel, Vrije Universiteit Brussel, Brussels, Belgium
[25]Endocrinology Unit, Department of Clinical and Experimental Medicine, Garibaldi Nesima Hospital, University of Catania, Catania, Italy.
[26]Faculty of Medicine, "Iuliu Hatieganu" University of Medicine and Pharmacy, 400012 Cluj-Napoca, Romania.
[27]Nuclear Medicine Department, Università degli Studi di Brescia and ASST Spedali Civili of Brescia, Italy
[28]Department of Endocrinology, University Hospital Kaspela, Plovdiv, Bulgaria
[29]Section of Head and Neck Oncology, Department of Oncology, Oslo University Hospital, Oslo, Norway.
[30]Department of Medical Oncology, Leiden University Medical Center, Leiden, the Netherlands
[31]Department of Head and Neck Surgery, Jules Bordet Institute-HUB, Université Libre de Bruxelles, 93 rue Meylemeersch, Brussels, 1070, Belgium
[32]Department of Surgery, Faculty of Medicine, University of Debrecen, Debrecen, Hungary.
[33]Department of Internal Medicine and Therapeutics, University of Pavia, 27100, Italy; Istituti Clinici Scientifici Maugeri IRCCS, Unit of Internal
[34]Medicine and Endocrinology, Laboratory for Endocrine Disruptors, Pavia 27100, Italy.
[35]Department of Medical Oncology, AZ Groeninge Kortrijk, Belgium and AZ Glorieux Ronse, Belgium
[36]Department of Human Pathology of Adulthood and Childhood "G. Barresi", University of Messina, Messina, Italy; 3 Endocrine Unit, "G. Martino" University Hospital, Messina, Italy
[37]Endocrinology Unit, Former Director of the Endocrinology, Disease of Metabolism and Clinical Nutrition Unit, University Hospital S.M. Misericordia - Udine Italy Former Part-time Lecturer (Professor) at the University of Udine Italy
[38]Department of Endocrinology, Diabetes and Metabolic Diseases, Hospices Civils de Lyon and Claude Bernard University, 69394 Lyon, France.
[39]Section of Endocrinology, University of Siena, Siena, Italy. Electronic address: pacini8@unisi.it.
[40]Endocrinology Division, Garibaldi Nesima Hospital, Catania Italy.; Medical Oncology, Department of Internal and Experimental Medicine, University of Catania, Italy
[41]Service of Endocrinology, Diabetology and Metabolism, Lausanne University Hospital and University of Lausanne, 1011 Lausanne, Switzerland.
[42]Department of Pediatric Endocrinology, Regina Margherita Children's Hospital, Turin, Italy Department of Pediatrics, University of Turin, Turin, Italy
[43]Department of Endocrine Oncology, University Medical Center, Utrecht University, Utrecht, Netherlands.
[44]Unit of Reproductive Endocrinology, 1st Department of Obstetrics and Gynecology, Aristotle University of Thessaloniki Medical School, Thessaloniki, Greece.
[45]Division of Paediatric Endocrinology, Department of Paediatrics, Beatrix Children's Hospital, University Medical Centre Groningen, University of Groningen, Groningen, The Netherlands.
[46]1Unit of Endocrinology, Department of Biomedical, Metabolic and Neural Sciences, University of Modena and Reggio Emilia, Modena, Italy; 2Unit of Endocrinology, Department of Medical Specialties, Azienda Ospedaliero-Universitaria of Modena, Modena, Italy
[47]Departments of Endocrinology and Medical Oncology, Institut Jules Bordet Comprehensive Cancer Center - Hôpital Universitaire de Bruxelles, Université Libre de Bruxelles (ULB), Brussels, Belgium.

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[48]Division of Radiation Oncology, Centro di Riferimento Oncologico di Aviano (CRO) IRCCS, Aviano, Italy.
[49]Department of Medical Oncology, Hospital Clínico San Carlos, School of Medicine, Complutense University (UCM), IdISSC, 28040 Madrid, Spain. Electronic address: gloria.marquina@salud.madrid.org.
[50]Department of Nuclear Medicine and Radiation Protection, University Hospital Center Zagreb, Zagreb, Croatia.
[51]Service d'oto-rhino-laryngologie et chirurgie cervico-faciale Lausanne University Hospital, Lausanne Switzerland
[52]Division of Thyroid and Parathyroid Endocrine Surgery, Department of Otolaryngology-Head and Neck Surgery, Harvard Medical School, Boston, Massachusetts.
[53]Clinical Nutrition unit, Paul Brousse University Hospital (AP-HP), Villejuif, France.
[54]Ivano-Frankivsk National Medical University, endocrinology department, Ivano-Frankivsk, Ukraine
[55]Michael E. DeBakey Department of Surgery, Baylor College of Medicine, Houston, Texas.
[56]Clinic of Endocrinology and Metabolism, First Faculty of Medicine, Charles University and General University Hospital in Prague, Czech Republic
[57]Department of Endocrinology, Slovak Medical University and St. Elisabeth Cancer Institute, 812 50 Bratislava, Slovak Republic.
[58]Department of Molecular Medicine and Surgery, Karolinska Institutet, Stockholm, Sweden. & Department of Breast, Endocrine Tumors and Sarcoma, Karolinska University Hospital, Stockholm, Sweden.
[59]Nuclear Medicine and Endocrine Oncology Department, M. Sklodowska-Curie National Research Institute of Oncology, Gliwice Branch, 44-101 Gliwice, Poland.
[60]Weston Park Hospital, Sheffield, United Kingdom.
[61]Division of Endocrinology, The Hospital for Sick Children, Toronto, Canada
[62]Department of Endocrinology, Clínica Universidad de Navarra, Pamplona, Spain & Instituto de Investigación Sanitaria de Navarra, Pamplona, Spain.
[63]Division of Endocrinology, Diabetes, Metabolism, and Nutrition, Department of Medicine, Mayo Clinic, Rochester, MN
[64]Department of Oncology, Second Faculty of Medicine, Charles University and Motol University Hospital, V Uvalu 84, 150 06, Prague, Czech Republic.
[65]Endocrine Unit and Diabetes Center, Department of Clinical Therapeutics, Alexandra Hospital, School of Medicine, National and Kapodistrian University of Athens, Athens, Greece.
[66]EAR, NOSE AND THROAT DEPARTMENT, KORLE-BU TEACHING HOSPITAL, ACCRA, GHANA
[67]Department of Endocrinology and Metabolism, Amsterdam UMC Location VU University, De Boelelaan 1117, Amsterdam, The Netherlands; Amsterdam Center for Endocrine and Neuroendocrine Tumours (ACcENT), Cancer Center Amsterdam, The Netherlands.
[68]Department of Endocrinology, Odense University Hospital, Odense, Denmark.
[69]Department of Endocrine and Metabolic Diseases and Laboratory of Endocrine and Metabolic Research, Istituto Auxologico Italiano, Istituto Di Ricovero e Cura a Carattere Scientifico (IRCCS); Department of Pathophysiology and Transplantation, University of Milan, Milan, Italy.
[70]Department of Internal Medicine and Therapeutics, University of Pavia (Italy); Medical Oncology Unit, Istituti Clinici Scientifici Maugeri IRCCS, Pavia (Italy)
[71]Department of Imaging, Endocrine Oncology Unit, Gustave Roussy, University Paris Saclay, Villejuif, France.
[72]Department of Nuclear Medicine, Gruppo Ospedaliero Moncucco, Lugano, Switzerland. & Clinic for Nuclear Medicine, University Hospital of Zürich, Zürich, Switzerland.
[73]department of medical biotechnology and translational medicine, university of Milano; epartment of endocrine and metabolic diseases, IRCCS istituto Auxologico Italiano, milano, Italy
[74]Department of Pediatric Endocrinology, Regina Margherita Children's Hospital, Turin, Italy; Department of Pediatrics, university of Turin, Turin, Italy
[75]Department of otorhinolaryngology head and neck surgery, Habib Bourguiba University Hospital, Sfax, Tunisia. & Sfax Medical School, University of Sfax, Sfax, LR23ES01 Tunisia.
[76]Chair and Department of Endocrinology, Jagiellonian University Medical College, Kraków, Poland.
[77]Department of Endocrine Surgery, Jagiellonian University Medical College, Krakow, Poland.
[78]UOC Chirurgia Endocrina e Metabolica, Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Rome Italy; Centro di Ricerche in Chirurgia delle Ghiandole Endocrine e dell'Obesità (C.R.E.O.), Università Cattolica del Sacro Cuore, Rome, Italy; Department of Pediatric Endocrinology and Rheumatology, Institute of Pediatrics, Karol Jonscher Clinical Hospital, Poznan University of Medical Sciences, Poland, Marek Niedziela
[79]Department of Pediatrics, IRCCS San Raffaele Scientific Institute, Milan, Italy.
[80]Unit of Endocrinology, Department of Medical, Surgical and Neurological Sciences, University of Siena, Siena, Italy
[81]Comprehensive Cancer Center, Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Largo A.Gemelli, 8, Rome, Italy. ; Università Cattolica del Sacro Cuore, Largo F.Vito, 1, Rome, Italy.
[82]Endocrinology Department, Northern Lisbon University Center, Lisbon, Portugal; Endocrinology University Clinic, Lisbon Medical School, Lisbon, Portugal.
[83]Department of Diagnostics and Interventions, Oncology, Umeå University, Umeå, Sweden
[84]St James's Hospital, (Department of Endocrinology), Dublin, Ireland.
[85]Endocrinology Unit, Graves' Orbitopathy Center, Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milan, Italy.
[86]Department of Diabetes and Endocrinology, Mater Dei Hospital, Msida, Malta.
[87]Dept. of Surgery, Lund University Hospital, Lund, Sweden.
[88]Academic Center for Thyroid Diseases, Department of Internal Medicine, Erasmus Medical Center, Rotterdam, the Netherlands
[89]Unit of Surgery 2 (Endocrine Surgery), San Martino University Hospital, Genoa, Italy & Department of Surgical Sciences and Integrated Diagnostics (DISC), University of Genoa, Genoa, Italy
[90]Department of Internal Medicine and Oncology, Semmelweis University, Faculty of Medicine, Budapest, Hungary.

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[91]a. University of Belgrade Faculty of Medicine, Belgrade, Serbia b. Clinic of Endocrinology, Diabetes and Diseases of Metabolism UKCS, Belgrade, Serbia
[92]Carol Davila University of Medicine and Pharmacy and C.I. Parhon National Institute of Endocrinology, Bucharest, Romania
[93]Department of Nuclear Medicine, Dr Josep Trueta University Hospital, Girona, Spain.
[94]Department of Surgery, Buckinghamshire Healthcare Trust, Stoke Mandeville, United Kingdom
[95]Consultant Clinical Oncologist, Beatson Oncology Centre, Gartnavel General Hospital, 1089 Great Western Road, GLASGOW, G12 0YN, Scotland, UK
[96]Department of Surgery, Maastricht University Medical Center, 6229 HX Maastricht, The Netherlands & NUTRIM School for Nutrition and Translational Research in Metabolism, Maastricht University, 6211 LK Maastricht, The Netherlands.
[97]Department of Surgical Oncology, Institute of Oncology, Ljubljana, Slovenia; Faculty of Medicine, University of Ljubljana, Ljubljana, Slovenia.
[98]UKRAINIAN SCIENTIFIC and PRACTICAL CENTER of ENDOCRINE SURGERY, TRANSPLANTATION of ENDOCRINE ORGANS and TISSUES of MOH of UKRAINE Klovsky descent, 13A, Kyiv, 01021, Ukraine
[99]Özel Sağlık Hospital, Centre for Endocrine Surgery, Izmir, Türkiye
[100]Department of Endocrinology and Nutrition, Hospital Universitario Ramón y Cajal, IRYCIS, Carretera Colmenar Km 9,100, 28034 Madrid, Spain. ORCID: 0000-0001-8379-2709
[101]Department of Otorhinolaryngology, University College Hospital, University of Ibadan, Ibadan, Nigeria.
[102]Department of Surgery, University of Chicago. & MacLean Center for Clinical Medical Ethics, University of Chicago.
[103]Department of Oncology and Nuclear Medicine, University Hospital Center Sestre Milosrdnice, Zagreb, Croatia. & School of Medicine, University of Zagreb, Zagreb, Croatia.
[104]Institute of Translational and Clinical Research, Newcastle University, Newcastle upon Tyne, United Kingdom.
[105]Department of Applied Health, School of Health Sciences, College of Medicine and Health, University of Birmingham, Birmingham, UK
[106]Section of Endocrine Surgery, Department of General, Visceral and Transplantation Surgery, University Medical Centre, Johannes Gutenberg University Mainz, Mainz, Germany.
[107]Endocrine Surgery Unit, Churchill Cancer Centre, Oxford University Hospitals NHS Foundation Trust, Oxford, UK. Electronic address: radumihai@doctors.org.uk.
[108]Department of Surgical Oncology, Rijnstate Hospital, Arnhem, The Netherlands.
[109]Institute of Applied Health Research, University of Birmingham, UK; Department of Paediatric Endocrinology and Diabetes, Birmingham Children's Hospital, UK
[110]Department of Endocrine Surgery, Medical Institute, St Petersburg University, St Petersburg, Russia
[111]Princess Maxima Center for pediatric oncology, Heidelberglaan 25, 3584 CS Utrecht, The Netherlands & Department of Pathology, University Medical Center Utrecht, Heidelberglaan 100, 3584 CX Utrecht, The Netherlands
[112]Cabinet Médical 2, rue Bellefontaine, Lausanne, Switzerland.
[113]Department of Endocrinology, Medical University Sofia, University Hospital of Endocrinology "Acad. Ivan Penchev", Sofia, Bulgaria.
[114]Department of Human Pathology of Adulthood and Childhood "G. Barresi", University of Messina, Messina, Italy. & Endocrine Unit, "G. Martino" University Hospital, Messina, Italy.
[115]Department of General and Endocrine Surgery, Onze-Lieve-Vrouw (OLV) Hospital Aalst, Aalst, Belgium. & Department of Head and Skin, University Hospital Ghent, Ghent, Belgium. & Department of General Surgery, AZ Damiaan, Ostend, Belgium.; Laboratory of Experimental Radiotherapy, Department of Oncology, KU Leuven, 3000 Leuven, Belgium Department of Radiation Oncology, Leuven Cancer Institute, University Hospitals Leuven, 3000 Leuven, Belgium
[116]Department of Internal Medicine, Franciscus Gasthuis and Vlietland, Rotterdam, The Netherlands.
[117]Department of Endocrine Neoplasia and Hormonal Disorders, The University of Texas MD Anderson Cancer Center, Houston, TX 77030, USA.
[118]Department of Endocrine Neoplasia and Hormonal Disorders, University of Texas MD Anderson Cancer Center, Houston, TX, USA.
[119]Department of Internal Medicine, division Endocrinology, University of Groningen, University Medical Center Groningen, Hanzeplein 1, 9700. RB Groningen, The Netherlands.
[120]Academic center for Thyroid disease, Erasmus MC, department of surgical oncology, Rotterdam, The Netherlands
[121]Department of Endocrinology and Molecular Pathobiology Research Unit, Instituto Português de Oncologia de Lisboa Francisco Gentil, Lisbon, Portugal.
[122]University of Novi Sad, Faculty of Medicine in Novi Sad, Novi Sad, Serbia; Diabetes and Metabolic Disorders, Clinic for Endocrinology, Clinical Center of Vojvodina, Novi Sad, Serbia.
[123]Department of Diagnostic and Interventional Radiology, University Hospital Leipzig, Leipzig, Germany.
[124]Department of Visceral Surgery, Lausanne University Hospital and Lausanne University, Lausanne, Switzerland.
[125]Department of Nephrology and Endocrinology, Copenhagen University Hospital Rigshospitalet, Copenhagen, Denmark
[126]Serviço de Endocrinologia, Instituto Português de Oncologia de Lisboa Francisco Gentil, Lisbon, Portugal.

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