Noninvasive Follicular Thyroid Neoplasm with Papillary-Like Nuclear Features (NIFTP): Are We All on the Same Page?

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Abstract: Background: Noninvasive follicular thyroid neoplasm with papillary-like features (NIFTP) is a new histology of the thyroid that became reportable to the cancer surveillance community in the United States on January 1, 2017. The significance of the new histology NIFTP and its impact on reportability, histology, staging, and treatment is described. Secondly, some of the current challenges encountered by cancer registrars to process NIFTP cases, include contrasting responses on standard setters' resources, is presented. Third, central registries nationwide were queried to show the reported incidence of NIFTP in 2017. Purpose: The goals of this paper are to provide a certified tumor registrar's (CTR's) insight in trying to understand the domino effect of a new histology on reportability guidelines and the challenges determining the most accurate code for these reportable data items. Findings: Review of 24 inquiries on the Commission on Cancer CAnswer Forum from 2016 to 2019 showed that there were questions regarding histology, staging, and reportability for NIFTP. Analysis of these queries and follow-up queries by the author shows that each standard setter has a different time frame for updating their guidelines. Due to these different time frames, it can be challenging for CTRs to understand when and how to apply these changes as they process NIFTP cases. In addition, the NIFTP incidence count in 2017 is provided and compared to predicted estimates of NIFTP for the United States. Forty-seven of 52 central cancer registries nationwide participated in a survey demonstrating that 89% of reporting central registries (42 of 47) had a NIFTP case count in the range of 0–19, while 11% (5 of 47) were in other ranges, including the highest range of 100–119 cases. The total estimated incident count of NIFTP in 2017 is 475. Conclusion: In sharing lessons learned, the primary hope for this paper is to provide a helpful guide in maneuvering within the many standard setters' resources, and in the case of NIFTP, to highlight why changes may not always be consistent across standard setters. Perhaps the solution is to have 1 location, agreed upon by all standard setters, which would provide announcements and coding information for specific histologies and primary sites.

Key words: *encapsulated follicular variant of papillary thyroid carcinoma, noninvasive encapsulated follicular variant of papillary thyroid cancer, thyroid cancer*

Introduction

Certified tumor registrars (CTRs) are professionals who identify and track cancer data at hospitals, state registries, and federal agencies. Providing accurate and timely data is essential for the fight against cancer, and CTRs are indispensable in this fight. The amount of resources available to cancer registrars over the last 15 years—from hard copy manuals to online resources—has increased tremendously. Moreover, the data fields being captured and the number of standard setters requiring various data fields has expanded. The impetus for this paper was the discovery of a *New York Times* article regarding a new histology for thyroid cancer called noninvasive follicular thyroid neoplasm with papillary-like nuclear features (NIFTP).[5] The significance of the article and the corresponding study raises questions about capturing this new histology in the cancer surveillance community. By providing a fuller analysis of the study findings and reporting requirements from different standard setters, the goal is to present some of the challenges that arose for CTRs with accurately processing NIFTP cases.

Per the National Cancer Institute's (NCI's) Surveillance, Epidemiology, and End Results (SEER) Program's Cancer Statistics Facts, thyroid cancer is the 12th most common cancer, with new cases in 2020 estimated at 52,890 in the United States.[1] Women are diagnosed at a rate approximately 3 times higher than men, with a median age of 51 years at the time of diagnosis.[1] With the incidence of thyroid cancer in 2013 being 3 times higher than 30 years ago in the United States, many health experts point to overdiagnosis of indolent tumors as the reason for the rising incidence of thyroid cases.[2,3] *Overdiagnosis* may be defined as identifying tumors or nodules that would not cause medical issues and may lead to unnecessary aggressive treatment that affects patients' overall health, finances, and well-being.[3] Due to the increasing incidence of thyroid cancer, the American Thyroid Association updated screening guidelines in 2009 and 2015 that recommended observation over biopsy of lower risk nodules.[2] In addition, in 2017, the US Preventive Services Task Force recommended against screening for thyroid cancer for asymptomatic adults.[24] The updated guidelines may have resulted in "less intensive workup of thyroid nodules."[3] Furthermore, a 2016 study that addressed overdiagnosis of indolent types of thyroid cancer was reported by Nikiforov.[5] The creation of the new NIFTP

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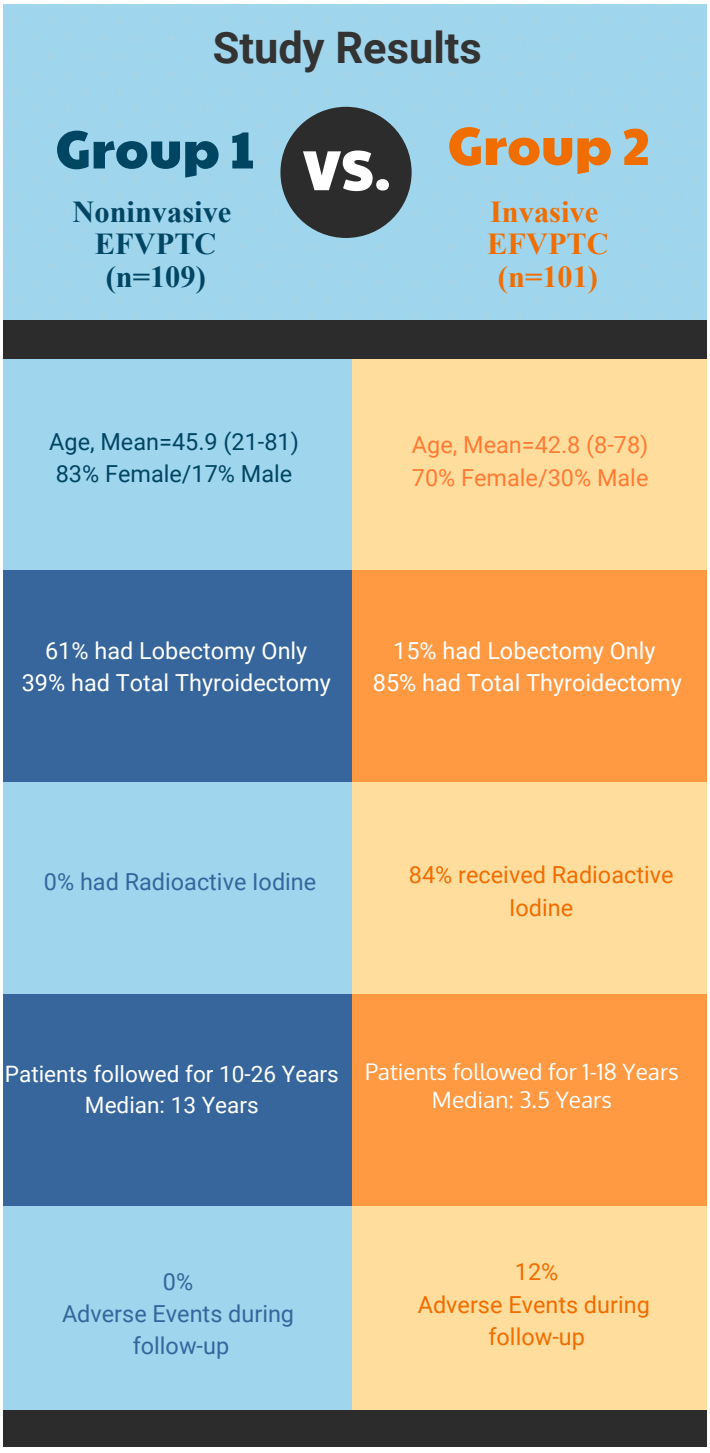
nomenclature was based on this study to rename an indolent type of noninvasive encapsulated follicular variant of papillary thyroid carcinoma (EFVPTC) and became reportable in 2017 by the cancer surveillance community. Although rates of invasive thyroid cancer steadily increased between 1974 and 2013 (4.5 to 14.4 per 100,000), the most recent time trend analysis from 2015–2017 showed the annual percent change in thyroid cancer falling. The observed incidence rate decreased from 14.7 per 100,000 in 2015 to 13.2 per 100,000 in 2017.[2,4] With reporting of NIFTP diagnosis starting January 1, 2017, the rate of invasive thyroid cancer is predicted to decrease annual thyroid cancer rates.[12] The objectives of this article are to present the importance and implications of the study and how it affects reporting guidelines, discuss challenges encountered by cancer registrars to process NIFTP cases, and, finally, to show incidence counts for NIFTP in 2017 from central cancer registries nationwide to determine nationwide alignment in reporting of NIFTP.

Figure 1. Key Findings of Reclassification Study Coining Term *NIFTP* (Noninvasive Follicular Thyroid Neoplasm with Papillary-like Features)



Methods

To better understand the new NIFTP guidelines and the impact of the study, "Nomenclature Revision for Encapsulated Follicular Variant of Papillary Thyroid Carcinoma: A Paradigm Shift to Reduce Overtreatment of Indolent Tumors" in *Journal of the American Medical Association Oncology*, the study and standard setter websites were reviewed.[5] The standard setter websites include those provided by North American Association of Central Cancer Registries (NAACCR)[11-12]; NCI-SEER,[8] and American College of Surgeons Commission on Cancer (CoC) CAnswer Forum[7]. Questions and answers on the CoC CAnswer Forum and NCI/SEER websites were reviewed.[7,8] The author submitted additional questions to the NCI/SEER inquiry system and CoC CAnswer Forum, as well as sending emails to NCCN.[7-9] In addition, a presentation at the 2017 Annual National Cancer Registrars Association (NCRA) Conference and documents entitled "What You Need to Know for 2017, Version 1.1, Revised March 2017" and "Addressing Overdiagnosis in Thyroid Cancer" by NAACCR were reviewed.[10-12] Based on these reviews, potential challenges for CTRs with processing cases for reportability, staging, and histology coding were identified and analyzed further.

The author queried central registries funded by the NCI/SEER and/or the Centers for Disease Control and Prevention National Program of Cancer Registries (CDC/NPCR) for all 50 states, 1 territory, and 1 federal district. The query requested incidence count for all NIFTP cases with the *International Classification of Diseases, 3rd Edition for Oncology (ICD-O-3)* with 2018 NAACCR updates histology of 8343 histology and ICD-O-3 behavior code 2 (in situ) diagnosed from January 1, 2017, to December 31, 2017.[20,21] The incidence data is provided as aggregate counts, using de-identified registry data.

Findings

Significance of Study: From Noninvasive Encapsulated Follicular Variant of Papillary Thyroid Carcinoma (Noninvasive EFVPTC) to a New Nomenclature NIFTP

In April 2016, an international, multidisciplinary, retrospective study published in *JAMA*, of 210 patients with thyroid nodules diagnosed with EFVPTC was published.[5] Participants were separated into 2 groups by disease invasiveness: 109 patients had noninvasive EFVPTC and 101 patients had invasive EFVPTC. Findings of the study are shown in Figure 1.

All 109 patients with noninvasive EFVPTC underwent surgery only (without radioactive iodine ablation) and were observed for 10 to 26 years, with no evidence of disease at

final follow-up. In addition to showing the indolent nature of noninvasive EFVPTC, the study created a new nomenclature for NIFTP to clearly distinguish between noninvasive and invasive EFVPTC. The significance of the NIFTP diagnosis represents a tumor with specific histology features, a low recurrence rate with less than 1% within the first 15 years, and required less aggressive treatment of lobectomy surgery only. There were no adverse events in 100% patients in the study. [5] In comparison, subjects with EFVPTC in the study required more aggressive treatment, with the majority receiving total thyroidectomy and radioactive iodine. In this group, 12% demonstrated adverse events during follow up.[5] Furthermore, the study proposed a new consensus diagnostic criteria so pathologists could use these guidelines to assist in diagnosing new nomenclature NIFTP. The study concluded that "this reclassification would affect more than 45,000 patients worldwide each year, thereby significantly reducing the psychological burden, medical over-treatment and expense, and other clinical consequences associated with a cancer diagnosis."[5]

The NIFTP study findings were published April 14, 2016, with a simultaneous companion article published in the *New York Times*.[5,6] A response was posted on the NAACCR website on April 20, 2016 discussing the significance of this study and its impact on cancer surveillance.[12] Per the response, the anticipated change based on the new diagnostic criteria would likely decrease thyroid cancer incidence for cases diagnosed in 2016 and later; however, "how rapid a decline will depend upon how quickly the new diagnostic criteria are adopted by clinicians and how our coding systems adapts to reflect the new designation."[12] The timeline and impact of the NIFTP study to the cancer surveillance community is outlined in Figure 2.

Following NAACCR's response, guidelines on "What You Need to Know for 2017, Version 1.1" were posted on NAACCR's website in March 2017.[11] The guidelines stated that all of the standard setters agreed to report NIFTP for cases diagnosed January 1, 2017, and later. In addition, the NAACCR document stated that "because NIFTP is a synonym for noninvasive EFVPTC, the standard setters have agreed to collect NIFTP as ICD-O-3 morphology code 8343/2."

On March 31, 2017, the NCCN included guidelines for NIFTP for the first time in their NCCN Guidelines for Thyroid Carcinoma version 1.2017. Per NCCN, NIFTP requires lobectomy only.[9] At the 2017 Annual NCRA Conference, which was held April 5–8, 2017, Dr. Michelle Williams presented "Staging Thyroid Cancers (8th Edition)", which included the new NIFTP diagnosis and its impact on treatment.[10] The indolent nature of noninvasive EFVPTC, which was reclassified to NIFTP, was presented. In addition, Dr. Williams indicated that the NIFTP classification will "identify the subset of patients not requiring total thyroidectomy, nor radioactive iodine (nor staging)."[10]

On July 2017, "Classification of Tumours of Endocrine Organs" 4th edition, published by the World Health Organization (WHO), assigned a histology code of 8349 to NIFTP, with a behavior code of 1.[13,22] This differed from the histology and behavior codes of 8343 and 2, respectively, that NCI/SEER had recommended in March 2017. Due to the difference in histology coding, a SEER inquiry was raised by the author in January 2019; SEER's response stated that all standard setters, including CoC, American Joint Committee on Cancer (AJCC), NAACCR, CDC/NPCR, and NCI/SEER, had all agreed to report NIFTP using the 8343 histology code with a behavior code of 2.[8] In addition, per NCI/SEER, any updates and changes to the histologies would be discussed with the NAACCR ICD-O-3 Implementation Taskforce. This taskforce meets with all standard setters to determine updates for reportability and histology coding. Once approved, an announcement would be sent via listservs for NAACCR, NCI/SEER, NCRA and CDC/NPCR. Any subsequent change in NIFTP histology coding and/or reportability would be communicated via the listserv.[8]

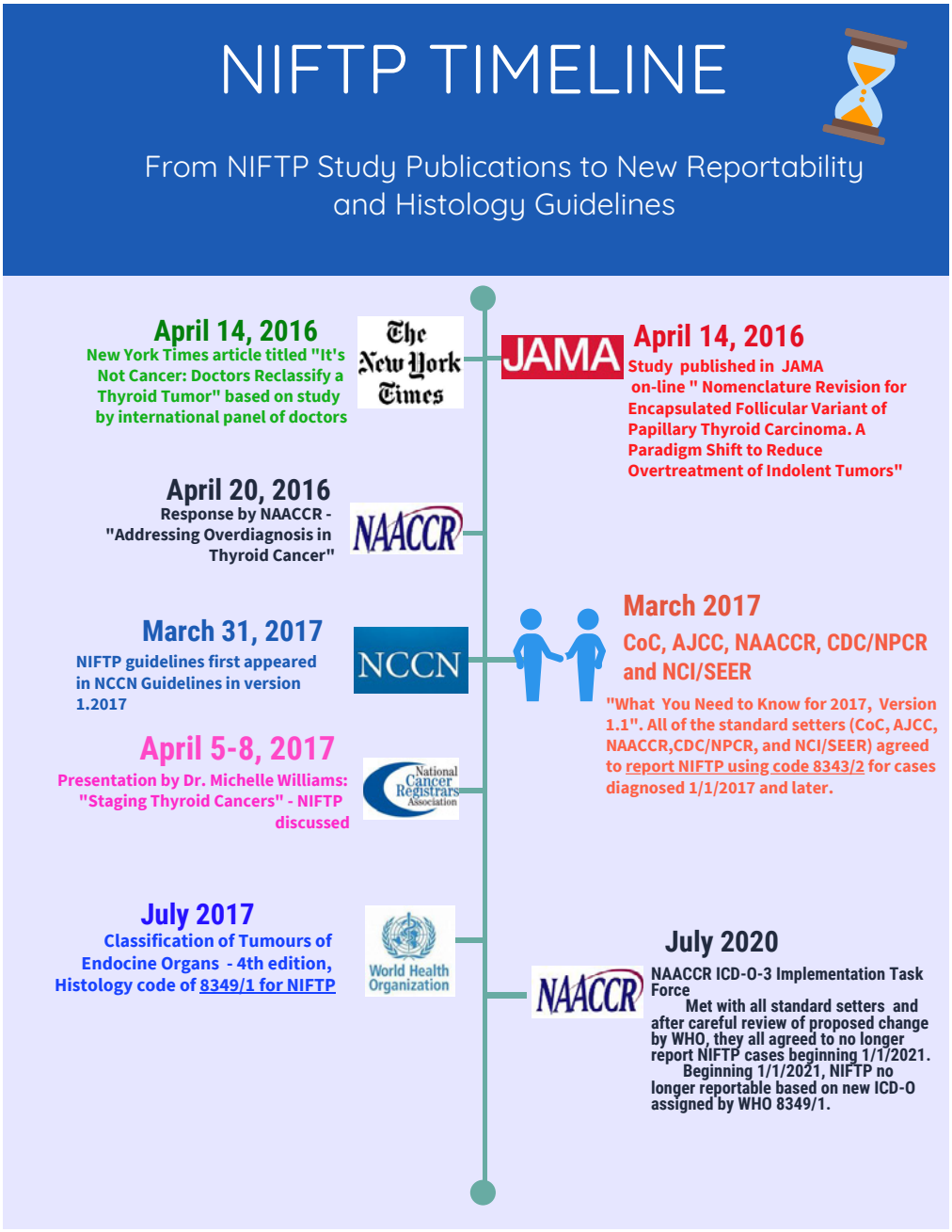
On July 16, 2020, SEER emailed listserv registrants that NIFTP would no longer be reportable for cases diagnosed January 1, 2021, and later. Additionally, a subsequent inquiry to NCI/SEER by the author confirmed that NIFTP diagnosed between January 1, 2017 and December 31, 2020 would continue to be reportable; however, any NIFTP diagnosed after January 1, 2021 would not be reportable based on the WHO's designation of 8349/1 for NIFTP.

Challenges for Processing NIFTP Cases

The CoC CAnswer Forum is a website forum that allows members in cancer programs all over the country to post questions about TNM staging, pathology, cancer program standards/reporting for Commission on Cancer programs and other cancer surveillance reporting items. During 2016–2019, 24 inquiries were posted on the CoC CAnswer Forum regarding NIFTP histology, its staging, incidence and reportability.[7] Many of the NIFTP questions on the CoC CAnswer Forum were regarding existence of and determination of AJCC TNM staging. The TNM is a staging system for adult cancers developed by the AJCC and the Union for International Cancer Control (UICC).[14] Per the CoC CAnswer Forum, NIFTP is not deemed an "in situ" cancer and was assigned a "1" behavior code per 4th Edition World Health Organization (WHO) *Classification of Tumors of Endocrine Organs* (Blue Book series) and cannot be staged.[23] Therefore, there is no AJCC TNM staging for NIFTP cases.

Additional inquiries were posted as to whether to code the WHO's histology of 8349 with a behavior code of 1, or to assign NCI/SEER's recommended histology code of 8343 with a behavior code of 2. Moreover, due to a behavior code of "1" for 8349/1 based on WHO's histology/behavior code for NIFTP, more inquiries were submitted questioning whether NIFTP cases should be reportable for a thyroid primary. The CoC CAnswer Forum responses suggested that registrars direct those questions to their standard setters. For cancer registries in North America, the primary resource for coding histology, reportability, and primary site is the ICD-O-3 with NAACCR updates.[15,16,20,21] Any queries regarding histology and reportability should be directed to NCI/SEER via the NCI/SEER inquiry system.[16] Therefore, due to the 2 different histology and behavior

Figure 2. Timeline of New Guidelines and Impact of the NIFTP (Noninvasive Follicular Thyroid Neoplasm with Papillary-like Features) Study to the Cancer Surveillance Community



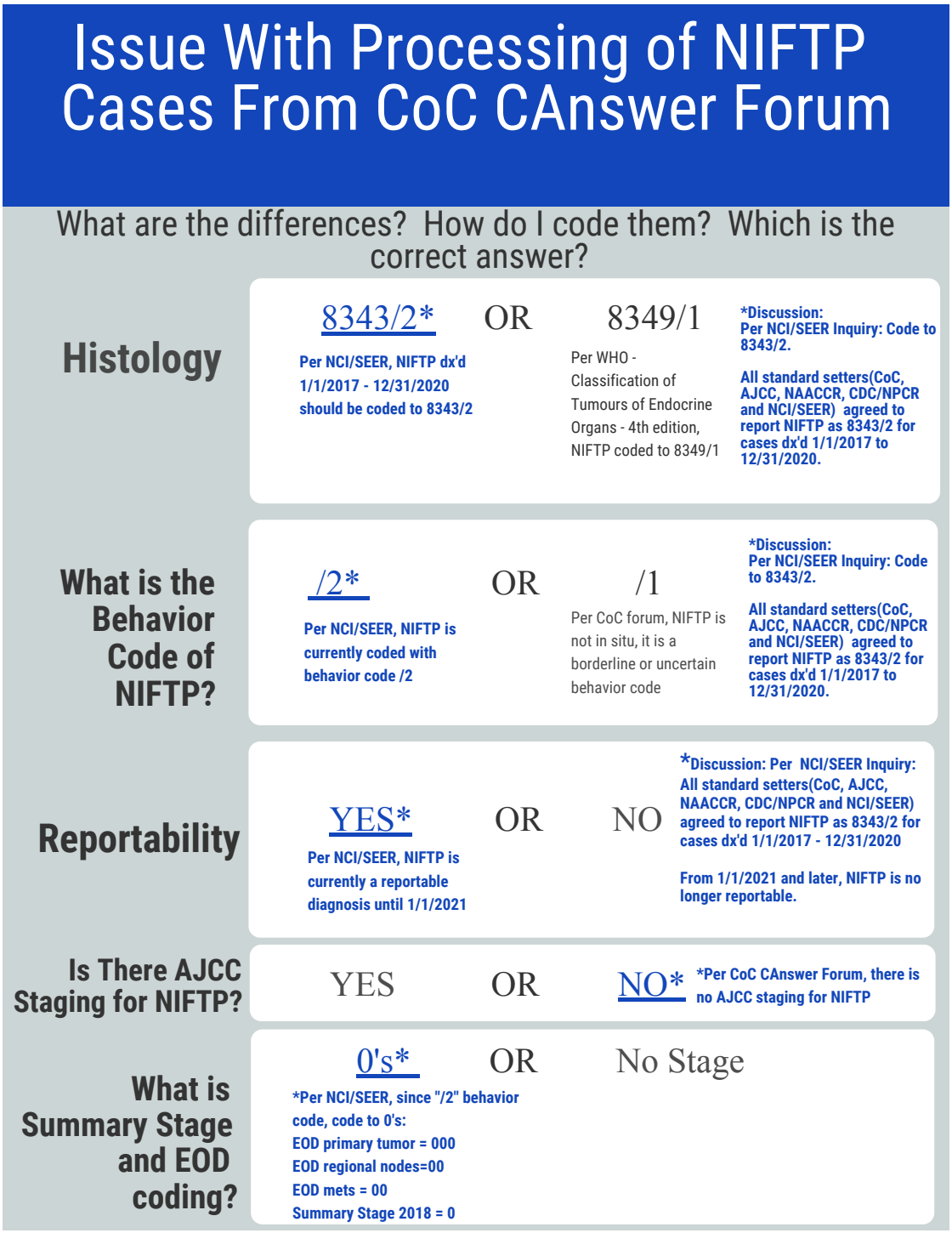
codes mentioned on the CoC CAnswer Forum, the author used the NCI/SEER inquiry system to query histology and reportability for NIFTP. Per the inquiry system, NIFTP should be coded to histology 8343 with a behavior code of 2 for cases diagnosed January 1, 2017 to December 31, 2020.[8]

Although TNM staging does not apply to NIFTP, the author queried NCI/SEER to confirm whether NIFTP is eligible for SEER Extent of Disease (EOD) and SEER Summary Staging. The SEER Summary Staging System is a second system utilized by population-based registries for tumor staging.[17] For EOD and Summary staging, registrars are instructed to query NCI/SEER via the NCI/SEER inquiry system. Per NCI/SEER, if the cancer has a "/2" behavior code, the summary stage must be coded as 0; extent of disease primary tumor must be coded as 000; extent of disease regional nodes must be coded as 000; and extent of disease metastasis must be coded as 00.[8] Furthermore, the definition for summary stage of "0" is "in situ, noninvasive, intraepithelial." Although NIFTP staging per TNM is unstageable, the EOD and Summary Stage is coded as an "in-situ" tumor.

Incidence Count for 2017 with Histology Code 8343/2

For informational purposes, the incident count for NIFTP with histology code 8343 and behavior code 2 is presented. With a response rate of 90%, 47 of 52 registries released 2017 incidence data and approved use of data for

Figure 3. Issues Registrars Face While Processing Cases of NIFTP (Noninvasive Follicular Thyroid Neoplasm with Papillary-like Features)



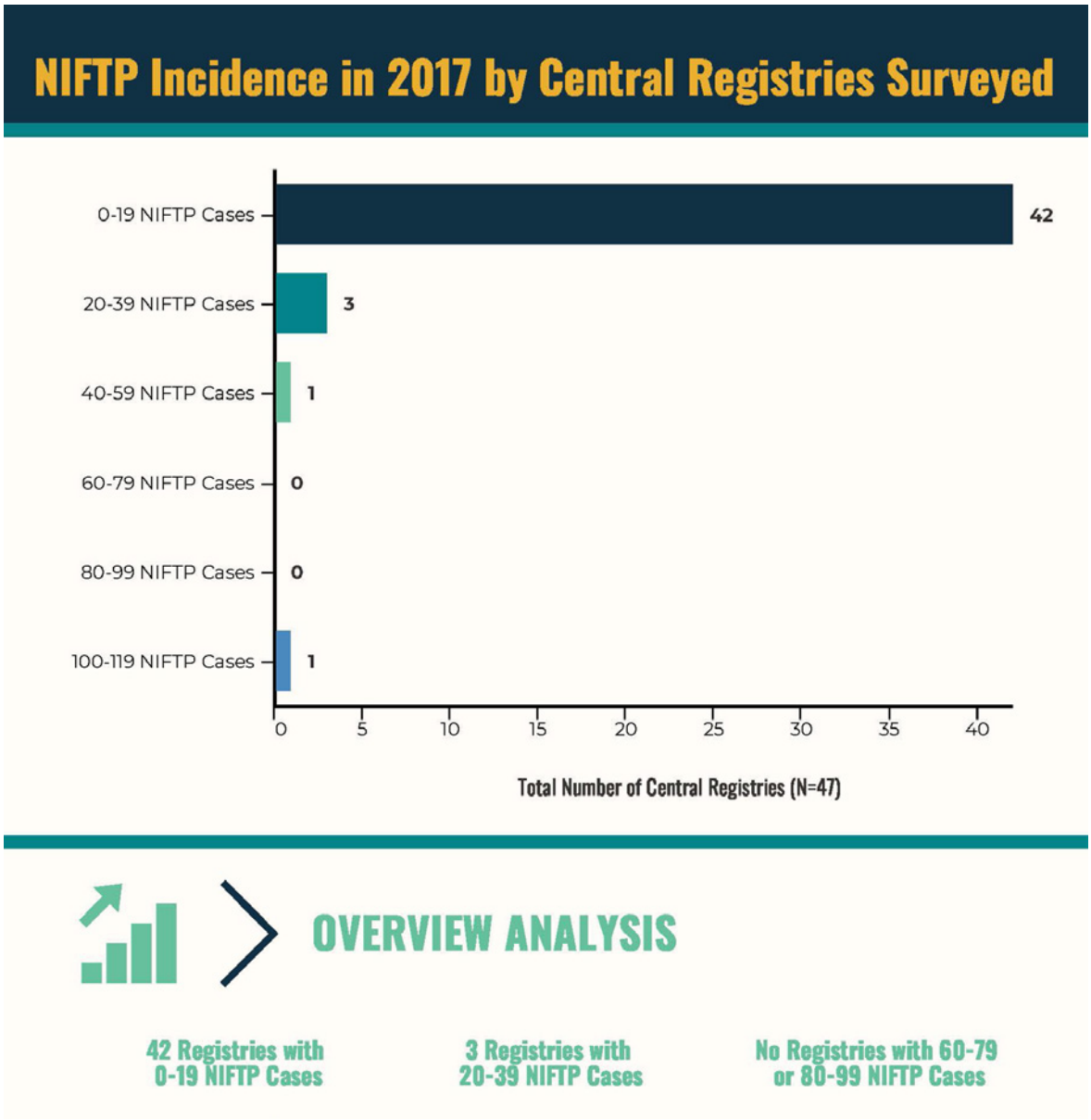
this publication. The case count range was 0–116. Forty-two of 47 registries had 0-19 NIFTP cases, 3 had 20-39, 1 had 40-59, and 1 had 100-119 NIFTP cases (Figure 4).

Discussion

The NIFTP nomenclature revision publications in *JAMA Oncology* and the *New York Times* highlighted the indolent behavior of noninvasive EFVPTC, described the consensus diagnosis criteria for NIFTP, and introduced the new nomenclature of NIFTP.[5,6] Thereafter, standard setters agreed to capture NIFTP as a reportable diagnosis for cases diagnosed January 1, 2017 and later, and a new histology was created for NIFTP (8343), with a behavior code of 2.[11] The new histologic and reporting guidelines for NIFTP were also noted on standard setters' websites and integrated into the NCCN guidelines in March 2017. However, per a recent update by NCI/SEER, NIFTP will no longer be reportable with cases diagnosed January 1, 2021, and later.

With any significant change, such as the addition of a new histology, issues with processing cases can arise. The

Figure 4. Incidence of NIFTP (Noninvasive Follicular Thyroid Neoplasm with Papillary-like Features) in 2017 by Registries Surveyed



first challenge faced by cancer registrars involves how to stay current with notifications regarding a new histologic classification like NIFTP. The first communications about NIFTP were posted on the NAACCR website on April 2016 ("Addressing overdiagnosis in thyroid cancer") and in March 2017 ("What you Need to Know for 2017").[11,12] In April 2017, NIFTP was presented at the NCRA Annual Conference. The first time the author was informed about NIFTP was via a colleague who attended the 2017 NCRA Conference. Since researching this article, the author has signed on to numerous listservs (ie, NAACCR, NCRA, NCI/SEER, NCCN) to keep abreast of updates. This is a key lesson learned to show the importance of staying connected and informed. In addition, national conferences that promote growth, knowledge, and connections is another means of staying well informed.

Another challenge is how to resolve reportability, histology, and staging discrepancies when answers seem to conflict from the various standard setters. The first example of inconsistency is the 2 histology and behavior codes for NIFTP, which were introduced in 2017. NCI/SEER issued the 8343 histology with the behavior code of 2 in March 2017, and then 4 months later in July 2017, the 4th edition *WHO Classification of Tumours of Endocrine Organs* listed 8349 histology with a behavior code of 1 for NIFTP.[13,22] For queries relating to TNM staging, registrars are routed to the CoC CAnswer Forum; and for histology and reportability queries, registrars are directed to the NCI/SEER Inquiry System. These resources usually respond in a timely manner; however, it does delay abstracting time when more than 1 site must be queried and knowing which site to query can be a challenge. Searches on the sites are usually done first to see if another participant has already asked the same questions and therefore a response already exists. However, if there is not a previous response, then a new query is created by the CTR. If there is a conflict with

standard setter responses, further research is required by the CTR to confirm the most accurate coding. AJCC staging questions answered by the CoC CAnswer Forum stated that NIFTP is not an in-situ cancer and has a behavior code of "1" and therefore does not have AJCC TNM staging. The CoC CAnswer Forum also stated that the histology and behavior code of 8349/1 is based on WHO's most recent publication. In contrast, NCI/SEER, indicated that NIFTP is reportable with a histology of 8343 and behavior code of 2, which makes the histology in-situ. Further analysis of these differences shows that ICD-O-3 with 2018 NAACCR ICD-O update is currently not synced with the most recent 4th edition of the *WHO Classification of Tumours of Endocrine Organs* publication.[23] Therefore, while the WHO Blue Book assigns 8349/1 for NIFTP which could already be used on pathology reports in 2017, the terminology and code updates were not yet approved by the NAACCR ICD-O Implementation Workgroup at that time. Although WHO has assigned the 8349/1 code, the ICD-O-3 with 2018 NAACCR updates continues to recommend histology and behavior code as 8343/2 for NIFTP diagnosed January 1, 2017, to December 31, 2020. However, when the new version ICD-O-3.2 is implemented in the United States in 2021, there will be more of an alignment with the most current 4th edition of the WHO Classification of Tumours publications. In a recent email query via the NCI/SEER Inquiry System sent by the author, NCI/SEER has confirmed that NIFTP will no longer be reportable for cases diagnosed January 1, 2021, and later, based on WHO's histology of 8349/1 for NIFTP.[8] Therefore, starting with 1/1/21 diagnosed cases, NIFTP cases are nonreportable and assigned to 8349 histology and "1"behavior code in both the WHO's Blue Book and ICD-O-3.2.

Finally, another issue identified with processing of cases were questions regarding stage. Although there is no TNM stage for NIFTP, the author was curious whether EOD staging and summary staging would be coded for NIFTP. The NCI/SEER email recommendation that EOD and summary staging be coded as 0 to reflect the in-situ nature of NIFTP was in contrast with a statement on the CoC CAnswer Forum that NIFTP is not an in-situ cancer. The behavior code of "1" based on WHO Blue Book versus the behavior code of "2" per NCI/SEER highlights another example of conflict on standard setter resources. In this instance, neither are in error. Per AJCC, there is no stage for NIFTP based on WHO histology of 8349/1 and per NCI/SEER, NIFTP does represent an "in-situ" tumor if diagnosed 2017 to 2020, and should be coded as "in situ" for EOD and summary. In yet another instance, WHO and AJCC are aligned, but the ICD-O-3 with 2018 updates does not align with WHO Classification of Tumours updates for cases diagnosed January 1, 2017, to December 30, 2020.

To summarize, in order to completely ascertain all the answers to questions regarding histology, staging and reportability, the questioner is advised to query NCI/SEER for histology and reportability and to query CoC CAnswer Forum for TNM staging. Querying several sites to process cases can take time; and when there are different answers, even more questions can arise. Being aware of when and how updates occur on the many resources registrars utilize, such as WHO, NAACCR, ICD-O-3, and AJCC is important to understand the effects of changes to reportability and how to accurately code histology, behavior, and staging.

Due to the challenges with processing of NIFTP cases, an analysis of the case count of NIFTP with histology of 8343 and behavior code of 2 diagnosed in 2017 were requested of central registries in all 50 US states, 1 US territory, and 1 federal district. The response rate was an impressive 90%, with 89% of respondents having 0–19 NIFTP case count, and only 5 central registries fell in the other ranges up to the highest range of 100–119 case count. The 2017 overall estimated count for NIFTP with 8343/2 from 47/52 registries was approximately 475 (Figure 4).

The incidence data for the first reporting year of NIFTP in 2017 are compared to predicted estimates of NIFTP in the United States. Based on an article published in October of 2016, the American Cancer Society "estimates that there will be more than 65,000 new cases of thyroid cancer diagnosed in the US this year, and the panel estimates 10,000 to 15,000 of these cases could be reclassified as NIFTP."[19] The panel referenced in the quote are international experts which include 24 pathologists, 2 endocrinologists, a thyroid surgeon, and psychiatrist who were the team behind the pivotal study headed by Dr. Nikiforov that created the new NIFTP nomenclature.[5,6] Should the estimated incidence count of NIFTP be higher than 475 in 2017 for the 47 locations that responded to our survey? Review of NIFTP estimates raises questions such as whether all NIFTP cases are being captured on the cancer surveillance data side or if NIFTP cases are being diagnosed on the clinical side. Was there a lower count due to questions regarding reportability of NIFTP? As this represents only incidence counts for 1 year, and responses were received from only 47 of 52 central registries, it is too early to determine the rate of NIFTP in the United States. The incidence count for 2017 is presented for informational purposes but does raise interesting follow-up questions.

Conclusions

A 2016 international study showed the indolent nature of noninvasive EFVPTC, creating a new nomenclature of NIFTP that became reportable for cases diagnosed January 1, 2017, to December 31, 2020, for all standard setters. How these new guidelines are disseminated for data collection across the nation for all reporting facilities and central registries is crucial for acquiring accurate incidence and survival data. CTRs face an immense task of keeping up to date with new and historical guidelines regarding histology, staging, treatment, and reportability. Challenges identified by the author for CTRs are awareness of the new NIFTP diagnosis, understanding of different standard setters' timelines for updating changes and identifying which standard setter to query regarding questions for processing cases. As CTRs continue to review and report NIFTP cases diagnosed 2017–2020, the importance of understanding the requirements for processing NIFTP is essential for capturing incidence, treatment, and outcome data. The journey for the author from learning about the study that coined NIFTP,

analyzing the time frame of NIFTP becoming a reportable diagnosis, and finally understanding each standard setter's role in establishing the requirement of specific data items was a light bulb moment. By providing this perspective by a CTR, the hope is that there will be 1 location that has been vetted by all standard setters with reporting requirements, announcements, and guidelines to support CTRs in accurately processing cases for cancer data reporting.

Acknowledgments

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Sources for NIFTP Incidence in 2017

1. Cancer registries participating in NCI SEER program.
2. Cancer registries participating in the National Program of Cancer Registries (NPCR) of the CDC.
3. The Florida cancer incidence data used in this report were collected by the Florida Cancer Data System (FCDS), the statewide cancer registry funded by the Florida Department of Health (DOH) and the CDC-NPCR. The views expressed herein are solely those of the author(s) and not necessarily reflect those of the DOH or CDC-NPCR.
4. Georgia Department of Public Health, Georgia Comprehensive Cancer Registry, 2020.
5. Minnesota Cancer Reporting System.
6. Nebraska DHHS Nebraska Cancer Registry.
7. NJSCR data were collected using funding from the Surveillance, Epidemiology, and End Results Program of the National Cancer Institute, the National Program of Cancer Registries, Centers for Disease Control and Prevention, the State of New Jersey, and the Rutgers Cancer Institute of New Jersey.
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10. Cancer data have been provided by the Texas Cancer Registry, Cancer Epidemiology and Surveillance Branch, Texas Department of State Health Services, 1100 West 49th Street, Austin, TX 78756. **https://www.dshs.texas.gov/tcr/**

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