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The Implementation of Nongynecologic Reporting Systems in Cytopathology Laboratories Is Highly Variable

Analysis of Data From a 2020 Supplemental Survey of Participants in the College of American Pathologists Interlaboratory Comparison Program in Nongynecologic Cytology

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Context.—In recent years, several reporting systems have been developed by national and international cytopathology organizations to standardize the evaluation of specific cytopathology specimen types.

Objective.—To assess the current implementation rates, implementation methods, and barriers to implementation of commonly used nongynecologic reporting systems in cytopathology laboratories.

Design.—Data were analyzed from a survey developed by the committee and distributed to participants in the College of American Pathologists Nongynecologic Cytopathology Education Program mailing.

Results.—Nongynecologic reporting systems with the highest rate of adoption were the Bethesda System for Reporting Thyroid Cytopathology, 2nd edition (74.1%; 552 of 745); the Paris System for Reporting Urinary Cytology (53.9%; 397 of 736); and the Milan System for Reporting Salivary Gland Cytopathology (29.1%; 200 of 688). The most common reason given for not adopting a reporting system was satisfaction with a laboratory’s current system. Implementation varied among laboratories with regard to which stakeholders were involved in deciding to implement a system and the amount of education provided during the implementation process.

Conclusions.—The implementation of nongynecologic reporting systems in cytopathology laboratories was highly variable.

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A shared language and framework of understanding are central components to the effective and safe practice of medicine. Although cytopathology shares some of the same language as histopathology, cytopathology specimens are inherently different than histopathology specimens. For example, some important diagnostic features, such as invasion, cannot be definitively assessed in cytopathology specimens, but cytomorphologic details may be more readily appreciated in cytologic preparations. Sometimes cytopathologic specimens lack a sufficient quantity of malignant cells to allow for an unequivocal diagnosis of malignancy. In other instances, the findings may be consistent for a neoplastic diagnosis, but the neoplasm cannot be further classified using cytopathology alone. Thus, the language of cytopathology differs somewhat from that of surgical pathology, and historically this language has differed among cytopathologists, owing to the different mentors and schools under which these cytopathologists were trained.

The Bethesda System for Reporting Cervical Cytology (TBSRCC) was the first widely accepted reporting system in the field of cytopathology. TBSRCC created a uniform language by defining distinct diagnostic categories and then assigned standardized diagnostic criteria for each category. This created a common language in which a diagnosis could be mutually understood regardless of from which pathologist...
or institution the diagnosis arose. This standardized terminology could then also be understood by clinicians, who could then integrate the specific diagnoses into clinical management algorithms. Standardized reporting also allowed for the performance of the Papanicolaou test to be more uniformly studied, resulting in studies that contributed to evidence-based improvements in subsequent editions of TBSRTC. Subsequent terminology systems have expanded into other organ systems and specimen sources, such as thyroid, pancreaticobiliary tract, urinary tract, salivary gland, breast, and serous fluids.

Although standardized terminology systems present many advantages, there can be barriers to their implementation. Although these systems aim to provide evidence-based diagnostic categories and criteria, existing evidence-based data may be limited. Updated terminology may be difficult to integrate with existing laboratory information systems and/or patient management algorithms. Changes in diagnostic reports may cause confusion for patients, clinicians, and other members of the health care team; this situation may be mitigated by education and interdisciplinary discussion prior to implementation. If a new terminology system is not perceived to have a clear advantage over the status quo, resistance to change may be significant.

In this survey, we sought to better understand the uptake of several commonly used standardized nongynecologic terminology systems, the methods laboratories have used to implement these systems, and the challenges that have been encountered.

MATERIALS AND METHODS

Description of Survey

The Nongynecologic Cytopathology Education Program (NGC) Terminology Systems Supplemental Questionnaire (SQ) was designed to assess laboratory use of the published terminology reporting systems. These systems included the 1st and 2nd editions of the Bethesda System for Reporting Thyroid Cytopathology (TBSRTC), the Paris System for Reporting Urinary Cytopathology, 1st edition (TPS), the Milan System for Reporting Salivary Gland Cytopathology (TMS), the Papanicolaou Society of Cytopathology (PSC) System for Reporting Pancreaticobiliary Cytopathology (PSCRPC), the Papanicolaou Society of Respiratory Cytopathology (PSCRPC), the Aspiration Biopsy Cytopathology (YBS) (Table 1). A subset of the College of American Pathologists (CAP) Cytopathology Committee members and CAP technical staff, including a staff biostatistician, developed a survey and reviewed the SQ for question clarity and data validity. The final survey included 19 questions (Supplemental Tables 1 and 2; see supplemental digital content). The survey was delivered in the 2020-D NGC Education Program mailing.

Statistical Analysis

Institution type and location were 2 independent variables used to examine associations with practice characteristics. Institution type and location were obtained from the 2020 CAP marketing demographic database and the NGC 2019-D Demographics Form. Demographic data were linked to laboratory responses using a unique laboratory identifier. Categories for institution type included veterans hospital, Army/Air Force/Navy hospital, hospital/medical center, academic hospital/medical center laboratory, independent/commercial reference laboratory, and, for the current analysis, “other” laboratories combined physician office laboratory/clinic and nonhospital site. Institution location was dichotomized as domestic (United States) and international laboratories.

Associations between independent variables and practice characteristics were examined using multiple logistic regression models, which controlled for both institution type and location. If the logistic regression model did not converge, the \( \chi^2 \) test of independence or Fisher exact test was performed. "Unsure" responses were excluded in all statistical calculations. The threshold for statistical significance was set to .05. Pairwise differences were computed for each level of institution type, with a Bonferroni correction to adjust for multiplicity in testing. All graphics and statistical analyses were performed using SAS 9.4 (SAS Institute, Cary, North Carolina).

RESULTS

Description of Respondents to the SQ

The questionnaire had 791 responses; 672 laboratories (85.0%) were in the United States, 28 (3.5%) in Canada, and the remaining 91 (11.5%) were from other countries (non-US, non-Canadian). Seven hundred twenty-nine respondents identified their institution type: 318 (43.6%) nonacademic medical center laboratory, 223 (30.6%) academic hospital/medical center laboratory, 97 (13.3%) independent/commercial reference laboratory, and 69 (9.5%) other.

Reporting System Adoption Rates

Of the reporting systems in the survey, those with the highest adoption rates were TBSRTC 2nd edition (74.1%; 552 of 745), TPS (53.9%; 397 of 736), and TMS (29.1%; 200 of 688) (Figure 1). Although the majority of laboratories using TBSRTC reported using the 2nd edition (74.1%), a sizable minority continued to use the 1st edition (28.3%; 186 of 657). Some laboratories reported adopting only partial recommendations of a given system, with a larger proportion of laboratories adopting partial recommendations for TPS and TMS compared with TBSRTC. Of the laboratories that reported using TBSRTC, a small fraction (18.3%; 119 of 649) reported using both the 1st and 2nd editions of TBSRTC.

Table 1. Chronology of the Survey’s Standardized Reporting Systems

<table>
<thead>
<tr>
<th>System</th>
<th>Year Released in the Literature</th>
<th>Year of Fascicle Publication</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Papanicolaou Society of Cytopathology System for Reporting Respiratory Cytopathology</td>
<td>1999</td>
<td>2019</td>
</tr>
<tr>
<td>The Bethesda System for Reporting Thyroid Cytopathology, 1st edition</td>
<td>2009</td>
<td>2010</td>
</tr>
<tr>
<td>The Papanicolaou Society of Cytopathology System for Reporting Pancreaticobiliary Cytopathology</td>
<td>2014</td>
<td>2015</td>
</tr>
<tr>
<td>The Bethesda System for Reporting Thyroid Cytopathology, 2nd edition</td>
<td>2017</td>
<td>2017</td>
</tr>
<tr>
<td>The Milan System for Reporting Salivary Gland Cytopathology</td>
<td>2018</td>
<td>2018</td>
</tr>
<tr>
<td>The International Academy of Cytopathology Yokohama System for Reporting Breast Fine-Needle Aspiration Biopsy Cytopathology</td>
<td>2019</td>
<td>2020</td>
</tr>
</tbody>
</table>
Obstacles in Adopting Reporting Systems

In addition to being asked about the adoption of reporting systems, respondents were asked to provide reasons why their laboratory did not adopt a particular system (Figure 3). Overall, the most common reason given for not adopting a reporting system was satisfaction with the laboratory’s current system. Other common obstacles included the lack of awareness of a system as well as lack of acceptance on the part of pathologists and/or clinicians. Lack of awareness was the second most common reason for all systems, but was highest among respondents in laboratories that did not adopt the PSCRPC, PSCRRC, and YBS (35.4% [151 of 427], 43.4% [219 of 505], and 42.4% [199 of 469], respectively). Although lack of acceptance by pathologists and/or clinicians was not a common obstacle, lack of acceptance by pathologists was highest for TPS and TMS (15.2% [35 of 231] and 11.1% [45 of 383], respectively), and lack of acceptance by clinicians was highest for TPS (10.0%; 23 of 231). Respondents that did not implement the TBSRTC 2nd edition reported the highest percentage of difficulty with laboratory information systems (LIS) integration (8.5%; 8 of 94) compared with other reporting systems.

Although lack of awareness was a common obstacle to adoption, lack of awareness also varied by institution type. Nonacademic hospital/medical center laboratories compared with academic hospital/medical center laboratories tended to report more unfamiliarity with TPS (36.2% [38 of 105] versus 14.5% [11 of 76]; \( P = .01 \)), TMS (44.3% [77 of 174] versus 19.7% [25 of 127]; \( P < .001 \)), PSCRPC (47.0% [85 of 181] versus 30.7% [42 of 137]; \( P = .03 \)), PSCRRC (55.3% [120 of 217] versus 34.0% [54 of 159]; \( P < .001 \)), and YBS (53.1% [103 of 194] versus 32.7% [49 of 150]; \( P = .001 \)) (Table 2). Compared with independent/commercial reference laboratories, nonacademic hospital/medical center laboratories also tended to report greater unfamiliarity with PSCRPC (12.5% [6 of 48] versus 47.0% [85 of 181]; \( P = .01 \)), PSCRRC (24.1% [13 of 54] versus 55.3% [120 of 217]; \( P = .003 \)), and YBS (29.8% [17 of 57] versus 53.1% [103 of 194]; \( P = .04 \)).

During the design of the survey, the International System (TIS) for Reporting Serous Fluid Cytology was being formulated but had not yet been released to the general public. However, several publications and presentations at national meetings had discussed TIS by the time the survey was released; therefore, participants were asked whether they were aware of TIS. A total of 747 participants responded to the question, and 177 respondents (23.7%) reported being aware of TIS. Academic hospital/medical center laboratories tended to report more awareness of TIS (32.4%; 69 of 213) compared with nonacademic hospital/medical center laboratories (16.2% [49 of 303]; \( P < .001 \)). International laboratories tended to report being aware of TIS more than domestic laboratories (36.2% [21 of 58] versus 22.1% [139 of 629]; \( P = .003 \)).

Process for Implementing Reporting Systems

To better understand how laboratories implement reporting systems, participants were surveyed regarding the most recent implementation of a reporting system in their laboratory. First, participants were asked about the persons involved in the decision to implement the most recent reporting system. The parties most often involved in this decision included the laboratory director (53.1%; 420 of 791), cytotechnologists (46.4%; 367 of 791), general pathologists (37.5%; 297 of 791), and cytopathologists (17.6%; 139 of 791). Academic hospital/medical center laboratories tended to report greater involvement of clinicians compared with nonacademic hospital/medical center laboratories (14.8% [33 of 223] versus 7.2% [23 of 318]; \( P = .03 \)) and greater involvement of cytopathologists (55.6% [124 of 223] versus 38.7% [123 of 318]; \( P = .001 \)) in the decision-making process (Figure 4). International laboratories also reported involvement of clinicians more than domestic laboratories (13.3% [8 of 60] versus 8.8% [59 of 669]; \( P = .04 \)).

Cumulative trends in the adoption of reporting systems were plotted for laboratories that reported the year of implementation (Figure 2). TBSRTC 1st edition had a gradual increase in adoption during several years. By contrast, TBSRTC 2nd edition were plotted for laboratories that reported the year of publication. Abbreviation: pub., year of fascicle publication.

Next, participants were asked whether formal training was provided to their pathologists, laboratory staff, or trainees as part of the reporting system implementation (Table 3). Of the 569 respondents, 31.5% (179) provided training to pathologists compared with 44.5% (253) of laboratories that did not, and 24.1% (137) of respondents were unsure; similar trends were found for the training of laboratory staff (22.1% [126] training provided, 56.9% [324] not provided, and 20.9% [119] unsure of training status). For trainees, training was provided by 15.2% of laboratories (47 of 309) and was not provided by 59.5% (184 of 309) with 25.2% (78 of 309) unsure of training status after exclusion of 260 laboratories that responded “not applicable.” Because of a high level of uncertainty among respondents, statistical testing results are not presented, although independent commercial/reference laboratories reported the highest percentage of training across roles compared with other laboratory types (Table 4). International laboratories reported higher percentages of training for pathologists (72.3% [34 of 47] versus 44.0% [200 of 455]), laboratory staff (55.0% [22 of 40] versus 27.7% [114 of 412]), and trainees (47.4% [9 of 19] versus 13.6% [26 of 191]) than domestic laboratories.

Finally, laboratories were asked whether clinicians associated with the given specimen types were notified of the newly implemented system prior to implementation. Of the 705 respondents, 269 (38.2%) indicated that their laboratory notified clinicians, 184 (26.1%) did not, and 252 (35.7%) respondents were unsure. Academic hospital/medical center laboratories (64.6%; 84 of 130) and independent/commercial reference laboratories (79.6%; 39 of 49) reported higher rates of notifying clinicians compared with nonacademic hospital/medical center laboratories (48.1%; 91 of 189).
TBSRTC Rate of Malignancy Reference Table

Reporting systems typically include evidence-based estimated rates of malignancy (ROMs) for each diagnostic category. Some laboratories choose to include an ROM table in their diagnostic reports. To identify how widespread this practice may be, participants using TBSRTC were asked whether an ROM table was included in their thyroid specimen reports, and the source of the ROM data. For the 730 respondents, 119 (16.3%) of laboratories included an ROM table and 611 (83.7%) did not. Of those including the ROM table, the majority of laboratories (82.5%; 94 of 114) used data from the fascicle; the remainder used laboratory-specific data (6.1%; 7 of 114), used ROMs reported in the literature (7.9%; 9 of 114), were unsure (2.6%; 3 of 114), or reported “other” as a source (0.9%; 1 of 114).

DISCUSSION

The SQ results found that the most widely implemented nongynecologic cytology reporting systems were TBSRTC, TPS, and TMS. Given that the SQ captured only one moment in time, it is difficult to know the uptake rate for TBSRTC 1st edition, as many laboratories had already switched to the 2nd edition at the time of the survey. However, the growth in implementation for the 2nd edition, as well as for TPS and TMS, was quite rapid compared with lesser implemented systems such as PSCRPC, PSCRRC, and YBS. These data suggest that the most predominant systems...
were rapidly implemented, rather than slowly, over time. TBSRTC, TPS, and TMS were all sponsored by the American Society of Cytopathology, the largest cytopathology organization within the United States, and thus likely benefited from being promoted by American Society of Cytopathology members within North America. Other factors impacting decision to implement a system may be laboratory specific, taking into account the potential benefit of having an implemented system versus the effort expended to implement that system. For instance, a laboratory receiving a large number of urine specimens may benefit more greatly than one receiving few urine specimens.

International laboratories indicated higher implementation rates for TPS, TMS, and YBS compared with domestic laboratories. Although the international laboratory cohort that participated in this SQ may not be representative of all international laboratories, the CAP-accredited laboratories taking the survey may be biased toward seeking international guidelines for laboratory improvement. Increased implementation of YBS may be due to the international nature of the sponsoring organization, which has a more limited presence within the United States. In addition, breast FNA specimens are less common in the United States but remain a common specimen outside of the United States. A minority of laboratories reported using modified versions of reporting systems, in which only partial recommendations were implemented. This trend was relatively uniform for all reporting systems surveyed. The SQ did not ask how particular systems were modified; modifications could include using different diagnostic category names or using different cytomorphologic criteria for a given category. Modified systems sometimes arise as a compromise among pathologists in each laboratory, where a reporting system is implemented but not fully accepted by all pathologists in the laboratory. The use of a modified reporting system can be problematic, as specific category nomenclature as well as cytomorphologic criteria can impact the overall performance of a reporting system. However, even the partial implementation of a system may be beneficial, as the implementation of a new system can increase discussion and awareness among pathologists in a laboratory.

The SQ identified several obstacles for laboratories attempting to implement systems. For laboratories that did not implement YBS and the PSC systems, lack of awareness was a significant obstacle. This supports the concept that a strong and early effort to increase awareness of a system is critical for a system’s widespread implementation. Although TPS was a widely implemented system, lack of acceptance by clinicians was a more common obstacle for it than for other reporting systems. Although respondents were not asked to explain why, lack of acceptance by clinicians may simply reflect the respondent’s perception of the system in general, or some specific aspects of TPS that were perceived as unacceptable. Finally, lack of pathologist acceptance was a more common obstacle for laboratories considering the implementation of TMS and TPS. This may be in part due to these systems being relatively new, with experienced pathologists not yet convinced that these systems are superior to their current practice.

This survey included both the 1st and 2nd editions of TBSRTC. The 2nd edition of TBSRTC emphasized the standardization of terminology within individual laboratories and updated the risk associations and clinical management recommendations for each category, but did not alter the names of the 6 diagnostic categories. The survey demonstrates that most but not all laboratories have made the switch to the 2nd edition of TBSRTC. Because many respondent laboratories were already using the 2nd edition of TBSRTC, this may explain why many respondents chose “No issues with current system” as a barrier for the 1st edition of TBSRTC, as they would not need or desire to revert back from the 2nd edition to the 1st edition.

The 2nd edition of TBSRTC had the highest number of respondents indicating difficulty with LIS integration (8.5%). Because the names of the categories did not change between editions, it is unlikely that LIS issues prevented those who had implemented TBSRTC1 from implementing TBSRTC2. LIS issues are likely to become known late in the implementation process, and thus those with LIS issues should already be aware of the system and are more likely to have had stakeholders (clinicians and pathologists) on board with the implementation. This phenomenon would be seen most prominently in TBSRTC, a system that had high levels of acceptance by pathologists and clinicians. By comparison, TPS had a slightly decreased amount of clinician and pathologist support, which may explain why LIS systems were less often identified as a barrier for TPS.
A uniform method for implementing a reporting system within a laboratory does not exist. However, literature has shown that providing educational materials and/or formal training can improve the performance of newly implemented reporting systems. The SQ results suggest great heterogeneity among laboratories regarding whether and to whom training is provided. The results of the SQ indicated that major stakeholders, such as clinicians, were often left out of this process. However, reporting systems often explicitly encourage the inclusion of major stakeholders early in implementation discussions. Implementation without clinical input could cause clinician dissatisfaction with a system that laboratories may not be representative of local laboratory clinicians. However, ROM values are known to vary among laboratories, and thus published ROM data from outside various locations. In the case of the second laboratory, receiving urine specimens from dozens of urologists in various locations. In the case of the second laboratory, designating a single or small group of urologists to serve as a proxy may be the best strategy.

The SQ identified a small percentage (16.3%) of laboratories that included an ROM table in their diagnostic report for thyroid FNA specimens. The majority of these used ROM data taken from the TBSRTC fascicle. Including the risk of malignancy for each category can be useful for patients and clinicians. However, ROM values are known to vary among laboratories, and thus published ROM data from outside laboratories may not be representative of local laboratory data. To avoid this pitfall, laboratories may consider providing laboratory-specific ROM values in their diagnostic reports.

This SQ took place prior to the release of TIS, which has been released since this manuscript was prepared. Four reporting systems are being prepared as part of the World Health Organization Classification of Tumours series. The IAC–International Agency for Research on Cancer Cytology Reporting Systems will include the International System for Reporting Lung Cytology; the International Reporting System for Lymph Node, Spleen, and Thymus Cytopathology; the International System for Reporting Pancreaticobiliary Cytopathology; and the International System for Reporting Soft Tissue Cytopathology. With the combined efforts of the IAC and the International Agency for Research on Cancer, these systems may experience a more widespread uptake than was seen for the initial PSC systems.

In summary, the implementation of reporting systems was highly variable among the surveyed laboratories. These data highlight the lack of a standardized process and specific recommendations for the implementation of reporting systems within a laboratory. Laboratories implementing reporting systems may benefit from guidelines regarding the identification of representative stakeholders during the preimplementation process, as well as a process for educating and communicating with all relevant stakeholders prior to and during implementation.

References