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Short communication

A practice analysis of toxicology

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ABSTRACT

In 2015, the American Board of Toxicology (ABT), with collaboration from the Society of Toxicology (SOT), in consultation with Professional Examination Service, performed a practice analysis study of the knowledge required for general toxicology. The purpose of this study is to help assure that the examination and requirements for attainment of Diplomate status are relevant to modern toxicology and based upon an empirical foundation of knowledge. A profile of the domains and tasks used in toxicology practice was developed by subject-matter experts representing a broad range of experiences and perspectives. An on-line survey of toxicologists, including Diplomates of the ABT and SOT members, confirmed the delineation. Results of the study can be used to improve understanding of toxicology practice, to better serve all toxicologists, and to present the role of toxicologists to those outside the profession. Survey results may also be used by the ABT Board of Directors to develop test specifications for the certifying examination and will be useful for evaluating and updating the content of professional preparation, development, and continuing education programs.

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1. Introduction

The science of toxicology is advancing at a record pace, where new knowledge increases daily. With advances in our understanding of the toxicity of new materials like nano-sized particles coupled with the use of new technologies involved in high-throughput screening, genomics, and adverse pathway analysis, the manner and methods scientists use to determine mechanisms and effect levels are constantly changing. Along with these changes comes the need to be able to understand and utilize the advancing science as a professional within the toxicology discipline.

The American Board of Toxicology (ABT), the largest professional toxicology credentialing organization in the world, strives to identify, maintain, and evolve a standard for professional competency in the field of toxicology. It is the vision of ABT to establish a globally recognized credential in toxicology that represents competency and commitment to human health and the environmental

sciences. The purpose of ABT is to: 1) encourage the study and science of toxicology, 2) stimulate advancement in the field of toxicology by establishing standards of practice and keeping these standards current with advances in toxicology, and 3) confer recognition upon members of the profession who, when measured against such standards, demonstrate competence in the science and practice of toxicology.

The first ABT exam was administered on August 4, 1980 resulting in the certification of 217 Diplomates (Rinehart, 2000). Today there are approximately 2300 certified Diplomates of the American Board of Toxicology (DABT) world-wide. The benefits of attaining Diplomate status indicate that certification in toxicology continues to play an important role in employment opportunity, compensation, and professional advancement (Gad and Sullivan, 2016).

As mentioned, the science of toxicology is undergoing continued advancements in knowledge and techniques since the inception of professional certification by American Board of Toxicology. In order to assess these changes and evolve accordingly, the ABT Board of Directors (BoD) has embarked upon an evaluation of the current practice and standard of knowledge of toxicology relevant to the evolution of toxicology in the twenty-first century.

The purpose of this analysis is to help assure that the examination and requirements for attainment of Diplomate status are

Abbreviations: ABT, American Board of Toxicology; DABT, Diplomates of the American Board of Toxicology; ABT BoD, The American Board of Toxicology Board of Directors; PATE, Practice Analysis Task Force; SOT, Society of Toxicology.

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relevant to modern toxicology practice and based upon an empirical foundation of knowledge. To this end, the ABT BoD has taken the steps presented here to ensure that these requirements and the testing content of the ABT exam reflect the knowledge required in the professional practice of toxicology and comply with the standards and recommendations outlined by the National Commission for Certifying Agencies (NCCA) standards (National Commission for Certifying Agencies, 2014).

2. Methods

2.1. Selection of the Practice Analysis Task Force

The ABT BoD, together with the Society of Toxicology (SOT), selected a 10-member Practice Analysis Task Force (PATF). In determining the composition of the PATF, key stakeholders from the ABT BoD and SOT leadership considered critical demographic and professional background variables such that the toxicologists selected to serve on the PATF represented the diversity of toxicology in practice settings and roles. Three members of the PATF held the DABT credential and seven did not. Members of the PATF are listed in Table 1.

The PATF was charged with the following activities over the course of the study:

- Develop an initial model or organizational structure describing general toxicology practice and delineate the tasks performed in practice;
- Review and incorporate the work of the additional subject-matter experts (SMEs) contributing to various qualitative data collection initiatives;
- Develop survey rating scales and a demographic and professional questionnaire for the quantitative survey of toxicologists; and
- Review the data obtained via the survey to create the final delineation of practice.

The PATF was responsible for developing the delineation of domains and tasks of general toxicologists. In a process-based description of practice, the work performed by professionals is organized into domains, which are the major areas of responsibility that make up the role of a toxicologist. Domains encompass all of

the tasks performed in practice. Tasks are the distinct, identifiable, and specific job-related activities performed in the course of work in the profession of toxicology.

Professional Examination Service (ProExam; New York, NY) is a recognized expert in the development, implementation, and evaluation of credentialing programs, including the conduct of practice analysis studies and the development of test specifications on which to base credentialing program activities. The ABT BoD contracted with ProExam to conduct the practice analysis study of general toxicologists in order to develop and validate a process-based delineation of the competencies of general toxicologists.

2.2. Task force meetings

ProExam facilitated eight two-hour virtual meetings of the PATF over the course of the study. ProExam provided introductory materials (for the first meeting) or the current iteration of the delineation to be discussed (for subsequent meetings) and a brief agenda outlining the meeting goals for each virtual meeting. After each meeting, the work output was distributed to PATF members for comment and review; email feedback was circulated among PATF members for consideration at each subsequent meeting.

The PATF developed the delineation through this iterative process, working from an initial model developed during the first two meetings. The domain structure and tasks were refined and augmented during subsequent meetings based on input from subject matter experts, as well as feedback received from the complementary data collection initiatives described below and the results of a pilot test of the on-line survey.

2.3. Thought leader interviews

ProExam conducted telephone interviews with four thought leaders in the toxicology profession who were selected to represent key perspectives in practice (Table 1). These thought leaders responded to a series of questions under a protocol designed to elicit information about major trends in the profession, recent and anticipated changes in the roles and work functions of toxicologists, and the impact of these changes on the competencies and knowledge base required of general toxicologists. Thought leaders also commented on the delineation of practice and provided feedback on the domain structure and tasks. The PATF reviewed the feedback

Table 1
Members of the Practice Analysis Task Force (PATF), thought leaders, and independent reviewers.

| PATF | Thought leaders | Independent reviewers |
|--------------------------------------------------------------------------|----------------------------------------------------------------------------------------|---------------------------------------------------------------------|
| Myrtle Davis, PhD., DVM National Cancer Institute | Melvin E. Anderson, PhD., DABT The Hamner Institutes for Health Sciences | Desmond I. Cannon, PhD., DABT US Army Institute of Public Health |
| Yvonne Dragan, PhD. Haskell Labs | Linda Birnbaum, PhD., DABT, ATS National Institute of Environmental Health Sciences | Janet Clarke, PhD., DABT Newid Consulting |
| Jodi A. Flaws, PhD. University of Illinois | Jack H. Dean, PhD., DABT University of Arizona | Jamie DeWitt, PhD. East Carolina University |
| Jeff Fowles, PhD. CA Dept. of Public Health | Lois Lehman-McKeeman, PhD, ATS Bristol-Myers Squibb Company | Janice Lansita, PhD., DABT ToxStrategies, Inc. |
| Michael Holsapple, PhD., ATS Michigan State University | | John Snawder, PhD., DABT CDC-NIOSH |
| Lewis B. Kinter ^a , PhD., DABT AstraZeneca Pharmaceuticals | | |
| Serrine Lau, PhD. University of Arizona | | |
| David Mayfield, MS., DABT Gradient | | |
| E. Spencer Williams, PhD. Baylor University | | |
| Adam Woolley, DABT, FRCPATH, ERT, ATS ForthTox Limited | | |

^a Currently with Green Lawn Professional Scientific Consulting.

and suggestions and incorporated these into the revisions of the delineation during the course of the meetings.

2.4. Independent review

After the initial PATF meetings and the thought leader interviews had been completed, ProExam circulated the delineation of domains and tasks to five additional external SMEs for an independent review. The members of the independent review panel were selected by the ABT BoD to be representative of the toxicology profession, and are listed in Table 1. ProExam compiled all feedback and comments, and the PATF reviewed the results and further refined the delineation of practice.

2.5. Survey development and rating scales

The delineation was uploaded into an on-line survey platform for validation. Rating scales were used to enable survey respondents to rate the elements of the delineation and to collect data about the respondents via a professional and demographic questionnaire.

2.5.1. Tasks

Two rating scales were used by respondents to evaluate the tasks, one designed to assess the respondents own work patterns (*Frequency*) and the other designed to assess the task in the context of the work of toxicologists in general (*Importance*). The frequency with which each task was performed as part of a respondent's job was rated on a 5-point scale with the following choices: never, rarely, occasionally, frequently, or very frequently. Values used to calculate mean importance of each task used a 4-point scale which included the following: not, minimally, moderately, or highly important.

2.5.2. Domains

Two rating scales were used by respondents to evaluate the domains. One assessed the percentage of work time during the past 12 months spent performing the tasks in each domain and the other assessed the importance of the tasks in each domain to an individual's work as a toxicologist. Five response options were included on the importance scale for domains: 1 = never, 2 = rarely, 3 = occasionally, 4 = frequently, or 5 = very frequently.

2.5.3. Feedback on the delineation

As a check on the completeness of the delineation, respondents answered one quantitative and two qualitative questions:

- How completely did the delineation represent the work of toxicologists in general?
- Are there any other tasks you perform in your work as a toxicologist that were not included in the survey?
- Please provide any other feedback you may have regarding the delineation of toxicology practice.

2.6. Pilot test of the survey

The survey was pilot-tested in June 2015. Eleven external pilot testers, members of the Task Force, and the ABT BoD and SOT president were invited to review the online survey. Based on their comments, a number of tasks were modified, one was moved to a different sub-domain, and the rating scales and demographic questionnaire were finalized.

2.7. Survey dissemination

The large-scale validation survey was launched in mid-July 2015 and was open for three weeks. All 2285 certified DABTs were included in the survey invitation list, and a random sample of 500 non-DABT members of SOT were also invited to participate. ABT and SOT sent pre-survey emails to all invitees, and followed up with an invitation containing a unique link. Additional reminders were sent over the course of the survey.

3. Results

3.1. Demographics

One thousand fifty-nine respondents completed the survey, for an overall response rate of nearly 40%. Approximately 44% of DABTs and nearly 20% of the SOT members completed the survey (Table 2). Fig. 1 summarizes the demographics of survey respondents. Respondents had a mean of 21 years of experience as a toxicologist, with 16% having less than 10 years, 32% having 11–20 years, and 27% having 21–30 years of experience. Eighty-four percent of respondents held a doctoral degree, 12% a master's level degree, and 3% a bachelor's level degree. Overall, the largest percentage of respondents (45%) worked in industry, followed by 12% in academia, 11% in independent consulting, 10% for the federal government and 8% in consulting for a firm. The primary area of practice for the largest percentage of total respondents was pharmaceutical (41%) followed by regulatory (13%) and academic (11%). Sixty-two percent indicated they currently specialized in general toxicology, 49% in regulatory toxicology, and 43% in risk assessment.

Seventy-nine percent of respondents were from the United States, representing 42 states or territories, and 21% were from outside the US, representing 27 countries. The greatest number of non-US respondents were from Canada (41), followed by India (32).

3.2. Delineation of toxicology

The delineation of the practice of general toxicology developed by the PATF is shown in Table 3. As a result of the iterative development process, the delineation was organized into a domain structure consisting of six domains, one of which has four related sub-domains, and includes 66 tasks and 3 sub-tasks.

Respondents indicated how completely they thought the delineation represented the work of toxicologists. These responses further validated that the domain structure developed over the course of this study well represented the work of general toxicologists. As shown in Fig. 2, 91% of respondents thought the delineation completely or mostly did so.

3.2.1. Highlights related to the tasks

Summary responses for the respondents rating of each task under each domain were calculated for *Frequency* and *Importance* as shown in Table 3.

Five of the 66 tasks/3 subtasks were performed at least weekly (mean ≥ 4.0). The most frequently performed task was *Interpret and*

Table 2
Survey response rate.

| | ABT | SOT | Total |
|-----------------------------------------|--------------|--------------|--------------|
| Invitations sent | 2285 | 500 | 2785 |
| Undeliverable (invalid email addresses) | 93 | 2 | 95 |
| Valid invitations | 2192 | 498 | 2690 |
| Completed surveys | 961 | 98 | 1059 |
| Response rate | 43.8% | 19.7% | 39.4% |

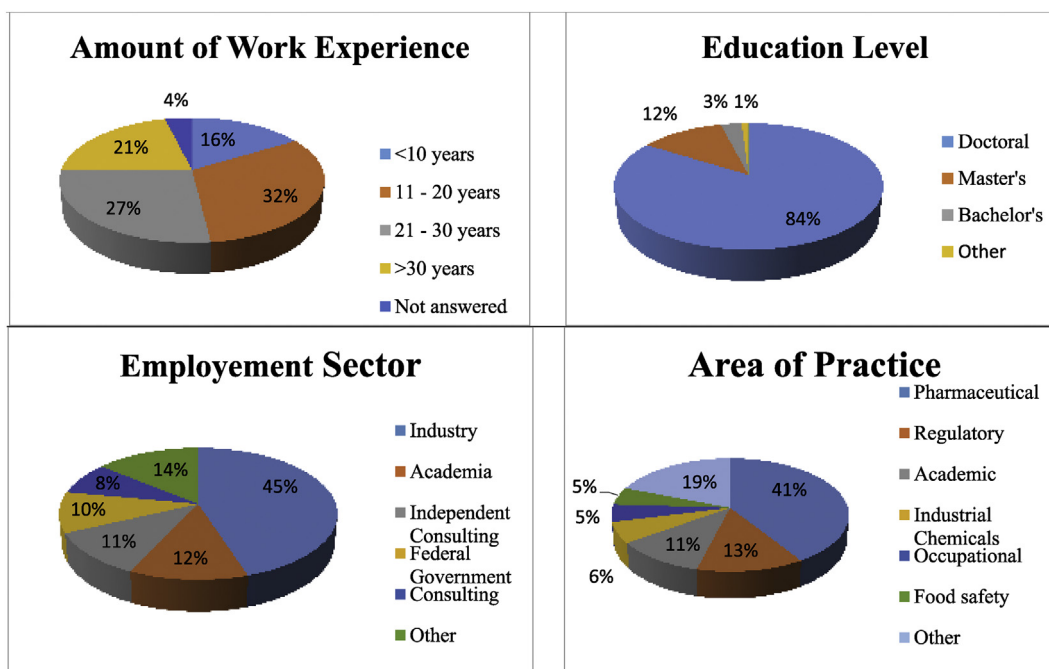


Fig. 1. Background Information on work experience, area of employment, areas of toxicology practice, and education level.

integrate study results into a scientifically cogent narrative to develop conclusions and/or inform next step (mean = 4.2 ± 1.0); the next most frequently performed task was *Characterize, describe and interpret effects and test system endpoints of toxicological concern* (mean = 4.1 ± 1.2).

Seven of the tasks achieved mean frequency ratings below a mean of 2.0, indicating they are performed less than monthly. The least frequently performed tasks were *Use population-based biomonitoring studies to ascertain temporal trends in chemical exposures* (mean = 1.5 ± 0.9) and *Develop or provide treatment recommendations for poisoning incidents (including antidotes)* (mean = 1.5 ± 1.0).

Despite not all tasks being performed frequently, all tasks were rated highly important relative to the importance scale used in the analysis. Twenty-nine tasks achieved mean ratings of 3.5 or higher, meaning they were between moderately and highly important. The most highly rated task on this scale was also the one rated highest in frequency: *Interpret and integrate study results into a scientifically cogent narrative to develop conclusions and/or inform next steps* (mean importance = 3.9 ± 0.4). Five tasks had mean importance ratings of 3.8 including: *Design scientifically valid studies to answer questions or address defined hypotheses* (± 0.5); *Characterize toxicological effects in vivo* (± 0.5); *Characterize, describe and interpret effects and test system endpoints of toxicological concern* (± 0.4); *Identify systemic effects and/or target organs, dose response, and thresholds of effect* (± 0.5); and *Quantitatively and/or qualitatively characterize relationships between dose (or concentration) and incidence and severity of health effects or toxicological endpoint* (± 0.5).

Only three tasks were rated as less than moderately important to the work of toxicologists, however, all three achieved a mean rating of 2.9. These were *Characterize toxicological effects in silico* (± 0.8); *Use differential mechanistic information to develop products* (± 0.8); and *Use population-based biomonitoring studies to ascertain temporal trends in chemical exposures* (± 0.5).

A careful review of the write-in responses to the question regarding missing tasks found that in general, respondents wrote in tasks that were either specific examples of existing tasks, unique to their own work, not germane to their role as a toxicologist, or

knowledge-based rather than task-based. The PATF did not find any suggestions that would warrant inclusion of any additional tasks in the delineation based on these responses.

3.2.2. Highlights related to the domains

Table 4 shows the mean survey responses to the questions of percentage of time spent in each domain, as well as the importance rating of each domain. The delineated domain structure was overwhelmingly validated by the indication that a significant percentage of the respondents' toxicology work time was spent in each domain, and that all domains were at least moderately to highly important to professional toxicologists.

The domain in which respondents spent the most time was *Risk Assessment* (34% of time), followed by *Design, Execute, and Interpret Toxicology Studies* (26%). Respondents spent the least amount of time in *Applied Toxicology: Public, Environmental, and Occupational Health and Contribution to the Profession* (both about 8%). Review of the write-in responses to the question of time spent in other non-delineated domains found that most such time was related to managerial/administrative duties or to educational activities. No write-in responses indicated that a domain was missing from the structure.

The domain ranked as being most important to toxicologists in general was *Design, Execute, and Interpret Toxicology Studies* (mean = 4.1 ± 1.1). Two sub-domains in the Risk Assessment domain, *Hazard Identification* and *Dose Response Assessment*, were next most important (mean = 4.0 ± 1.0 for both).

4. Discussion

The field of toxicology is a matrixed one that integrates chemistry, biochemistry and physics into various levels of biological organization that span from molecular and cell biology to tissue, organism, population, community and, ultimately, biosphere level effects. It strives to understand the importance of exposure to various chemical and biological stressors in a complex environment in which science continues to make significant advances.

Table 3
Delineations of general toxicology with mean *Frequency* and *Importance* ratings.

| Domains and tasks | Frequency (5-pt scale) | Importance (4-pt scale) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|----------------------------|
| I. Design, Execute, and Interpret Toxicology Studies | | |
| 1. Design scientifically valid studies to answer questions or address defined hypotheses. | 3.5 | 3.8 |
| 2. Comply with applicable regulations and guidelines specific to the agent under study. | 3.9 | 3.7 |
| 3. Select and characterize the chemical and physical identity of the test agent. | 2.5 | 3.1 |
| 4. Characterize toxicological effects in vivo. | 3.8 | 3.8 |
| 5. Characterize toxicological effects in vitro. | 3.1 | 3.5 |
| 6. Characterize toxicological effects in silico. | 2.3 | 2.9 |
| 7. Characterize toxicological effects in a field or clinical setting. | 2.3 | 3.3 |
| 8. Develop, qualify, and validate new testing methods and techniques. | 2.3 | 3.2 |
| 9. Analyze test results and integrate existing data using informatics, statistics, and modeling. | 3.3 | 3.4 |
| 10. Interpret and integrate study results into a scientifically cogent narrative to develop conclusions and/or inform next steps. | 4.2 | 3.9 |
| 11. Prepare research report or summary that is fit for purpose. | 4.0 | 3.7 |
| II. Descriptive Toxicology: Environmental, Clinical, Non-clinical, and Forensic Investigations | | |
| 1. Analyze and integrate toxicology data obtained from diverse sources to identify toxicological patterns of concern (molecules, cells, tissues, target organs, individuals, populations, communities, ecosystems). | 3.7 | 3.7 |
| 2. Identify hazards, risks, and putative mechanisms. | 3.8 | 3.7 |
| 3. Develop strategies to test hypotheses. | 3.2 | 3.5 |
| 4. Perform weight of evidence analyses. | 3.4 | 3.5 |
| 5. Develop strategies to mitigate toxicity. | 3.0 | 3.3 |
| 6. Translate results of descriptive toxicological investigations between species. | 3.5 | 3.6 |
| III. Mechanistic Toxicology | | |
| 1. Develop mechanistic hypotheses. | 2.8 | 3.3 |
| 2. Assess role of toxicokinetics in mechanism of toxicity. | 3.3 | 3.5 |
| 3. Assess role of toxicodynamics in mechanism of toxicity. | 3.1 | 3.4 |
| 4. Identify susceptibility factors. | 2.8 | 3.2 |
| 5. Distinguish direct and indirect action. | 3.1 | 3.3 |
| 6. Use differential mechanistic information to develop products. | 2.1 | 2.9 |
| 7. Translate results between mechanistic studies and toxicological outcomes, prevention, and clarification of risk (human, environmental, animal). | 3.1 | 3.5 |
| 8. Develop and apply mechanistic information to disease models. | 2.4 | 3.0 |
| 9. Apply principles of systems toxicology. | 2.9 | 3.2 |
| IV. Risk Assessment | | |
| A. Hazard Identification | | |
| 1. Characterize, describe and interpret effects and test system endpoints of toxicological concern - including but not limited to acute and repeat dose toxicity, reproductive effects, genotoxicity, carcinogenicity, local effects/tolerance, and ecotoxicology | 4.1 | 3.8 |
| 2. Apply appropriate test systems and study types for safety evaluation. | 3.7 | 3.7 |
| 3. Identify systemic effects and/or target organs, dose response, and thresholds of effect. | 4.0 | 3.8 |
| 4. Assess mechanisms of action and relevance to humans or other target species, including sensitive sub-populations and individuals. | 3.6 | 3.6 |
| 5. Identify toxicological endpoints using the actual route, or appropriate surrogate of primary exposure. | 3.7 | 3.6 |
| B. Exposure Assessment | | |
| 6. Select appropriate endpoints with which to document exposure to toxicants in test systems and populations. | 3.3 | 3.5 |
| 7. Assess toxicant exposure in the general public, occupationally exposed individuals, populations, and the environment using appropriate technologies (including but not limited to analytical, bioassay, biomonitoring). | 2.3 | 3.3 |
| 8. Assess relevance of biomarkers of exposure in individuals, populations and the environment. | 2.5 | 3.2 |
| 9. Characterize absorption (A), disposition (D), metabolism (M), excretion (E), and kinetics (PK or TK) of toxicants." | 2.9 | 3.5 |
| 10. Assess and document behavior, fate, and transport of chemicals entering the environment (for example, biotransformation, bioavailability, bioaccumulation, biomagnification). | 2.1 | 3.1 |
| 11. Consider issues of disproportional, unique, and reactive metabolites arising in specific species. | 2.6 | 3.2 |
| 12. Identify primary and secondary interactions between agents and biological systems. | 2.6 | 3.1 |
| 13. Assess impact of target and off-target interactions on cellular, tissue, organ, organism, population, and environmental functions. | 2.9 | 3.3 |
| C. Dose Response Assessment | | |
| 14. Quantitatively and/or qualitatively characterize relationships between dose (or concentration) and incidence and severity of health effects or toxicological endpoint. | 3.9 | 3.8 |
| 15. Analyze toxicity data to determine a safe dose (or concentration) or protective threshold (for example, benchmark dose). | 3.7 | 3.7 |
| 16. Analyze toxicity data to determine an effective or toxic dose (or concentration). | 3.7 | 3.7 |
| D. Risk Characterization and Management | | |
| 17. Integrate toxicity and exposure information to characterize potential health risks and margins of safety. | 3.7 | 3.7 |
| 18. Assess health risks and management options to protect environmental or public health (including but not limited to cleanup goals, emission limits, safe concentrations, efficacious concentrations). | 2.4 | 3.3 |
| a. Evaluate and implement alternatives to reduce risks. | 2.3 | 3.1 |
| b. Derive safety limits that are protective of environmental or public health. | 2.5 | 3.4 |
| c. Identify and implement emergency risk management options to reduce chemical exposures or risks. | 1.8 | 3.0 |
| V. Applied Toxicology: Public, Environmental, and Occupational Health | | |
| 1. Characterize, describe and interpret effects of toxicological and ecotoxicological concern – in individuals, populations, communities, and ecosystems. | 2.4 | 3.4 |
| 2. Identify critical effects and thresholds from dose-response assessment. | 3.0 | 3.5 |
| 3. Respond to public health issues, including new or emerging public health concerns. | 2.1 | 3.2 |
| 4. Assess public health impacts from ecosystem effects of environmental toxicants. | 1.7 | 3.1 |
| 5. Investigate health outcomes in specific groups with respect to measured or modeled chemical exposures. | 1.9 | 3.1 |
| 6. Use population-based biomonitoring studies to ascertain temporal trends in chemical exposures. | 1.5 | 2.9 |
| 7. Identify sensitive or susceptible subpopulations. | 2.2 | 3.2 |
| 8. Design or implement programs to reduce the exposure to hazardous substances. | 1.8 | 3.0 |
| 9. Evaluate products and communicate potential environmental, health, or safety issues (including product stewardship). | 2.5 | 3.3 |

Table 3 (continued)

| Domains and tasks | Frequency (5-pt scale) | Importance (4-pt scale) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|-------------------------|
| 10. Evaluate the safety or risk of toxic agents for the treatment of diseases (including but not limited to drug development). | 2.7 | 3.5 |
| 11. Evaluate the signs and symptoms of toxicity. | 3.2 | 3.5 |
| 12. Develop or provide treatment recommendations for poisoning incidents (including antidotes). | 1.5 | 3.1 |
| VI. Contribution to the Profession | | |
| 1. Perform work in accordance with regulatory guidance and good laboratory practice standards (as applicable). | 4.0 | 3.7 |
| 2. Improve regulatory guidelines to ensure guidelines reflect current scientific advances. | 2.6 | 3.4 |
| 3. Provide testimony about toxic agents and products. | 1.8 | 3.0 |
| 4. Communicate the results of toxicological or risk evaluations to technical, governmental, or public groups (including but not limited to publications (peer reviewed and otherwise), technical reports, summary documentation (reviews), abstracts, presentations and posters). | 3.4 | 3.6 |
| 5. Establish, facilitate, or support programs to educate the public on environmental or public health issues. | 2.0 | 3.2 |
| 6. Provide education, training, and mentorship for students, colleagues, and others in the field. | 3.2 | 3.4 |
| 7. Respond to requests from organizations (companies, government/regulatory authorities, scientific societies) for technical expertise and comments about toxins/toxicants. | 2.9 | 3.3 |
| 8. Disseminate information to trainees, colleagues, management, and appropriate organizations. | 3.4 | 3.3 |
| 9. Incorporate new approaches to toxicology by using emerging technologies. | 2.7 | 3.3 |
| 10. Participate in professional scientific or not-for profit organizations. | 3.5 | 3.3 |

Frequency of tasks rated on a 5-point scale: 1 = Never/Not applicable to my job, 2 = Rarely (less than once per month), 3 = Occasionally (at least once per month), 4 = Frequently (at least once per week), 5 = Very frequently (at least daily).

Importance of tasks rated on a 4-point scale: 1 = Not important, 2 = Minimally important, 3 = Moderately important, 4 = Highly important.

Professionals in this field are becoming increasingly specialized to stay current with these advances and the need to understand what qualifications are necessary to conduct such work is a moving target.

One of the guiding principles of the ABT is to assure that advancement in the field of toxicology is based upon sound standards of practice. Keeping these standards current in a dynamic professional environment presents an important and ever-evolving challenge to the ABT BoD. With this review and analysis, ABT strives to serve Diplomates, employers, and the profession of toxicology as a whole by systematically acquiring insights from science thought leaders, practicing toxicologists, and other reviewers with interests, expertise and experience in toxicology. It is not surprising that the results are indicative of an evolving profession. The ABT BoD is committed to using these results to continue the role of establishing certification standards that are commensurate with evolution of the field. Use and implementation of the data generated by this effort are entirely at the discretion of the ABT BoD.

This survey will have a significant impact on the design and construction of the ABT certification examination. One of the primary goals of the practice analysis study was the development of test specifications for the ABT certification program using data from the survey to generate the preliminary test specifications. The analysis indicated the percentage of the examination that should focus on content related to each domain. The empirically-derived test specifications developed via this process are shown in Table 5. Using this test specification, the two domains of Risk Assessment and Design, Execute, and Interpret Toxicology Studies

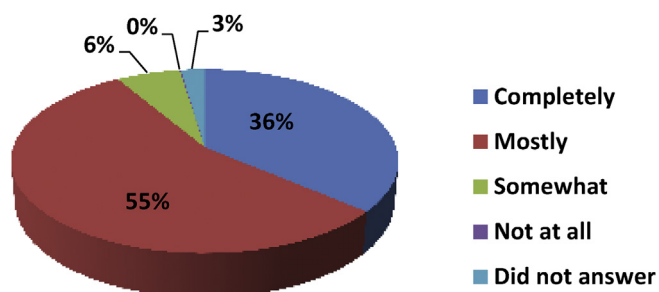


Fig. 2. Assessment of delineation for representing the work of toxicologists.

would make up slightly greater than 60% of the ABT certification examination.

However, ABT will first consider whether any adjustments to these data-derived test specifications are warranted. For those individuals just meeting eligibility requirements for the examination, not all validated tasks in the delineation may be suitable for inclusion. For example, some of the tasks in Domain VI. Contribution to the Profession (e.g., follow regulatory guidance, communicate with the public or disseminate information, and be a mentor), may be beyond what the toxicologist would be expected to be responsible for at the point of certification.

In response to a series of questions regarding information about major trends in the profession and the impact of these changes on the competencies and knowledge required by general toxicologists, the emphasis was on a broad knowledge base with fundamentals in cell biology and physiology and the ability to work in teams. While *in vivo* animal testing remains one of the major tools to evaluate potential toxicities of a given agent, increased importance of cellular and mechanistic studies, alternative animal models, and high technology areas such as “omics” are perceived. Increased interest was also noted in assessment of combinations of stressors

Table 4

Domains of toxicology: Percentage of time spent and the importance of each.

| Domains | % Of time spent | Mean importance (5-point scale) |
|------------------------------------------------------------------------------------------------|-----------------|---------------------------------|
| I. Design, Execute, and Interpret Toxicology Studies | 26.4% | 4.1 |
| II. Descriptive Toxicology: Environmental, Clinical, Non-clinical, and Forensic Investigations | 11.7% | 3.6 |
| III. Mechanistic Toxicology | 8.5% | 3.5 |
| IV. Risk Assessment (Total, A through D) | 33.7% | |
| A. Hazard Identification | 11.1% | 4.0 |
| B. Exposure Assessment | 6.9% | 3.7 |
| C. Dose Response Assessment | 8.3% | 4.0 |
| D. Risk Characterization and Management | 7.4% | 3.8 |
| V. Applied Toxicology: Public, Environmental, and Occupational Health | 8.0% | 3.4 |
| VI. Contribution to the Profession | 8.4% | 3.5 |
| Other | 3.3% | 2.8 |
| Total | 100.0% | |

Importance of domains rated on a 5-point scale: 1 = never, 2 = rarely, 3 = occasionally, 4 = frequently, or 5 = very frequently.

Table 5
Test specifications.

| Domain | % Of exam |
|------------------------------------------------------------------------------------------------|---------------|
| I. Design, Execute, and Interpret Toxicology Studies | 28.8% |
| II. Descriptive Toxicology: Environmental, Clinical, Non-clinical, and Forensic Investigations | 11.7% |
| III. Mechanistic Toxicology | 8.5% |
| IV. Risk Assessment (Total, A through D) | 34.8% |
| A. Hazard Identification | 11.5% |
| B. Exposure Assessment | 7.0% |
| C. Dose Response Assessment | 8.6% |
| D. Risk Characterization and Management | 7.7% |
| V. Applied Toxicology: Public, Environmental, and Occupational Health | 8.1% |
| VI. Contribution to the Profession | 8.1% |
| TOTAL | 100.0% |

and chemicals, and exposure issues relating to low doses and sensitive subpopulations. The ABT BoD will use this information to identify gaps in the existing evaluation process. These may include evaluating the current database of questions, updating question writing practices based upon empirically-derived test specifications for the examination, and transitioning to an online system for banking examination questions.

These empirically-derived test specifications may serve as the starting point for evolution of the certification examination, and can be adjusted (i.e., have percentage allocations increased or decreased) based on a number of factors. Such factors include but are not limited to:

- The number of tasks in each domain;
- If tasks within a domain are time consuming or repetitive, and do not require a wide range of competencies or knowledge, so that test items might be redundant;
- If there is overlap across domains (so as not to overweight some areas of practice);
- If the characteristics of the sample population may have influenced the ratings;

- The potential or difficulty for developing test questions related to the tasks in each domain;
- The suitability of the task for developing test questions for candidates just meeting the eligibility requirements for the certification; and
- If the domain included emerging areas of practice.

The American Board of Toxicology continues its dedication to serve the public and practice of toxicology world-wide. With these analyses, it is the intent of the ABT BoD to continue its progress in service and dedication to the science of toxicology, those who devote their professional lives to that science, and the employers who expect excellence from Diplomates of the American Board of Toxicology.

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Transparency document

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