ORIGINAL COMMUNICATION

Development of the Anatomical Quality Assurance (AQUA) Checklist: Guidelines for Reporting Original Anatomical Studies

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The rise of evidence-based anatomy has emphasized the need for original anatomical studies with high clarity, transparency, and comprehensiveness in reporting. Currently, inconsistencies in the quality and reporting of such studies have placed limits on accurate reliability and impact assessment. Our aim was to develop a checklist of reporting items that should be addressed by authors of original anatomical studies. The study steering committee formulated a preliminary conceptual design and began to generate items on the basis of a literature review and expert opinion. This led to the development of a preliminary checklist. The validity of this checklist was assessed by a Delphi procedure, and feedback from the Delphi panelists, who were experts in the area of anatomical research, was used to improve it. The Delphi procedure involved 12 experts in anatomical research. It comprised two rounds, after which unanimous consensus was reached regarding the items to be included in the checklist. The steering committee agreed to name the checklist AQUA. The preliminary AQUA Checklist consisted of 26 items divided into eight sections. Following round 1, some of the items underwent major revision and three new ones were introduced. The checklist was revised only for minor language inaccuracies after round 2. The final version of the AQUA Checklist consisted of the initial eight sections with a total of 29 items. The steering committee hopes the AQUA Checklist will improve the quality and reporting of anatomical studies. Clin. Anat. 00:000–000, 2016. © 2016 Wiley Periodicals, Inc.

Key words: anatomy; checklist; reporting guideline

Additional Supporting Information may be found in the online version of this article.

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INTRODUCTION

Although it is a descriptive basic science, anatomy will always remain a cornerstone of medicine. The study of anatomy has progressed significantly over the years at both macroscopic (gross) and microscopic levels. Although the fundamentals of the discipline are well established, research in many other areas of medicine (pathology, surgery, etc.) continually reports important and unique anatomical findings. Moreover, the field has gained greater attention in the light of evidence-based approaches in modern medicine (or evidence-based medicine).

The methods adopted in anatomical research have also advanced greatly, from cadaveric or dissection studies to modern medical imaging and electrophysiological studies. In addition, with the current development of evidence-based anatomy (Yammine, 2014; Henry et al., 2016), in which evidence-based principles are applied to epidemiological anatomy research, it is crucial that anatomical studies be conducted and reported systematically and with a high degree of accuracy. The reporting quality is particularly important if the methodological quality of such studies is to be assessed, and for subsequently ensuring the validity and reliability of its findings and their clinical impact or relevance, if any.

As in all other types of research, anatomical studies should be reported as transparently and accurately as possible to preclude uncertainty or confusion in readers' minds. All aspects of the study and the manuscript, from the study design and methods to the conclusion, should allow for critical assessment of the credibility and reproducibility of the research. Therefore, recommendations and guidelines for authors on reporting research are helpful. Outside the field of anatomical research, many other checklists such as the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement-Checklist for reporting systematic reviews (with or without metaanalyses) (Moher et al., 2009), the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) Statement-Checklist for reporting observational studies (von Elm et al., 2008), the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) Statement-Checklist for reporting protocols of clinical trials (Chan et al., 2013), the Standards for Reporting Diagnostic accuracy studies (STARD) Checklist for reporting diagnostic accuracy studies (Bossuyt et al., 2015), and the Consolidated Standards of Reporting Trials (CONSORT) Statement-Checklist for reporting clinical trials (Schulz et al., 2010), have become standards in their fields, ensuring the clarity and transparency of reporting. They also serve as a framework for researchers to conduct and report their studies.

Some of these checklists have been endorsed by prominent medical journals as they have improved the quality of reporting of studies (Plint et al., 2006; Turner et al., 2012; The PLOS Medicine Editors 2013). In that context, the authors of the present study have developed the Anatomical Quality Assurance (AQUA) Checklist, the aim of which is to improve the quality of reporting of anatomical studies. From our extensive

experience of evidence-based anatomical studies (Andall et al., 2015; Henry et al., 2015a, 2015b; Ramakrishnan et al., 2015; Roy et al., 2015a, 2015b; Tomaszewski et al., 2016a, 2016b, 2016c, 2016d, 2016e, 2016f; Vikse et al., 2016), we have found that such studies are often poorly reported, thus decreasing their reliability and increasing the risk of bias. A high reporting quality is imperative since understanding and knowledge of anatomy allows for successful clinical interventions.

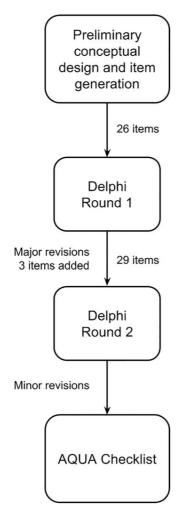
The aim of the AQUA Checklist is to present a list of items that should be addressed by authors of articles reporting original anatomical studies. It was designed to help authors to present their work in a comprehensive and systematic way with minimum ambiguity. Its only aim is to strengthen the reporting of original anatomical studies, not to provide a step-by-step guide to anatomical research or serve as a replacement for author guidelines in journals. Furthermore, the AQUA Checklist is not designed as a tool for assessing the quality of anatomical studies.

MATERIALS AND METHODS

Development of the AQUA Checklist began in 2015 with the formation of a steering committee comprising the authors of the present article. Following a careful review of the literature, probing the quality of reporting in anatomical studies, the steering committee developed a preliminary conceptual design and began to generate items, eventually developing a preliminary checklist. The committee then performed a Delphi protocol to assess the face validity of the checklist, and to edit, refine, and improve the preliminary version on the basis of feedback from eminent anatomists around the world. Figure 1 presents an overview of the development process.

Preliminary Conceptual Design and Item Generation

Using reviews of the anatomical literature and existing checklists (STROBE, CONSORT, etc.), and the extensive background of the steering committee in conducting meta-analyses and systematic reviews of anatomical studies (Andall et al., 2015; Henry et al., 2015a, 2015b; Ramakrishnan et al., 2015; Roy et al., 2015a, 2015b; Tomaszewski et al., 2016a, 2016b, 2016c, 2016d, 2016e, 2016f; Vikse et al., 2016), we developed a preliminary conceptual design for the AQUA Checklist. In addition to items considered standard in reporting all medical studies (sample size, demographics, results, etc.), we aimed to focus on the reporting of elements unique to anatomical research (e.g., aspects of descriptive anatomy, techniques and instrumentation) and aspects that are common weaknesses in anatomical research reporting (study design, sample size calculations, etc.), as identified from our own research experience. These aspects are often ambiguously or inconsistently reported, and this translates into studies with poor reporting quality. The steering committee unanimously agreed that a well-reported study should ideally



 $\begin{tabular}{ll} \textbf{Fig. 1.} & Overview of the process of developing the AQUA checklist. \end{tabular}$

have the power to allow for easy reproducibility and that the results (baseline characteristics, statistics, figures, etc.) are presented clearly, unambiguously, and consistently throughout the manuscript.

The Delphi Procedure

The steering committee selected potential panel members for the Delphi procedure on the basis of their experience in anatomical research and invited them via email to participate in the study. The panel members included editors-in-chief of major anatomical journals and their editorial boards, committee members of reputable anatomical societies, editors-in-chief of major anatomical textbooks and atlases, and other distinguished experts in the fields of anatomy or evidence-based research methods. The Delphi panel members were invited from all major continents in order to obtain a global input into the development of the checklist. Following each round of the Delphi procedure, the steering committee examined the

responses from panel members and revised the checklist accordingly. All decisions about revising the checklist were made following unanimous agreement among steering committee members. Following the revisions, all panelists received a revised version of the checklist and detailed responses to the comments they had made during the first round of the Delphi procedure, plus justifications for the revisions. The panelists were requested to judge the revised checklist while considering the revisions on the basis of their individual responses and those of other panelists. This was to allow for a thorough and comprehensive evaluation of the revised checklist. The Delphi procedure employed in our study was devised and modified from that used in the development of the QUADAS tool (Whiting et al., 2003).

Delphi Round 1

The Delphi round 1 consisted of an online survey to assess the validity and quality of the AQUA Checklist. Reviewers were asked to rank each checklist item on a 5-point Likert Scale (5—Strongly agree, 4—Moderately agree, 3—Neutral, 2—Moderately disagree, 1—Strongly disagree). The authors set an a priori mean score of >4 for an item requiring minor revision, 2–4 for an item requiring major revision, and <2 for an item requiring either major revision or serious reconsideration for inclusion in the checklist. Panelists were also given the opportunity to comment on each item to suggest edits or provide feedback (strengths and weaknesses), and to comment at the end of the survey on ways of improving the overall quality and usefulness of the AQUA Checklist.

Delphi Round 2

After all the amendments related to round 1 of the Delphi procedure had been made, the steering committee sent a revised version of the checklist to all the panelists who had participated in the first round, together with point-by-point responses to all the comments they had made. The panelists were asked for edits or comments on the revised version and were encouraged to provide further feedback to the steering committee.

RESULTS

The preliminary checklist generated consisted of 26 items divided into eight sections (Title, Abstract, Introduction, Methodology, Results, Discussion, Conclusions, and Other Information) (Supporting Information 1). After this preliminary checklist had been reviewed and approved by the entire steering committee, it was deemed ready for assessment through the Delphi procedure.

For the first round of the Delphi procedure, 20 experts in anatomy were invited by email to participate. Of these, 12 agreed and completed the round 1 survey. The mean score for all items was 4.23 (out of 5), with four items receiving scores <4 (Setting, Reference Standard, Outcomes and Parameters, and

TABLE 1. List of Items with their Descriptions and Recommendations as Included in the Final Version of the AQUA Checklist

Checklist component	#	Description and recommendation:
Title		
Title	1	Identify the main objective or key characteristic of the study in the
Abstract		title.
Structured Summary	2	Provide a clear and structured summary of the study with emphasis on the aims, methodology, key findings, and conclusions directly supported by study findings.
Introduction Background/Rationale	3	Provide a rationale for the study including a concise, updated scientific background, appropriately referenced. Identify any relevant knowledge gaps to support the study rationale.
Objective	4	Indicate clearly the main objective(s) of the study, and state any hypotheses to be tested.
Methodology Study Design and	5	1. Provide precise details with respect to the design and fundamen-
Fundamentals		tals of the study, including but not limited to the following: 2. Study design: prospective, retrospective, cross-sectional, etc. 3. Study type: cadaveric (e.g., formalin fixed or fresh frozen), imaging, intraoperative, etc.
Setting	6	Describe clearly the location where the study was conducted and dates (month/year) between which the data were collected.
Samp l e Size	7	When appropriate, statistical power analysis should be used to calculate sample size or effect size. If relevant, justification for the study sample size should be briefly stated.
Subjects	8	Define clearly the eligibility criteria and methods of subject selection and inclusion, with details of the baseline and demographic selection criteria of the subjects (age, sex, healthy or diseased, etc.) included in the study.
Reference Standard	9	Define clearly and accurately all anatomical definitions (normal anatomy, variations, classifications, etc.) by which data will be collected, analyzed, and compared. Citations should be included when appropriate.
Outcomes and/or Parameters	10	Define clearly the outcomes and parameters (e.g., prevalence of a variation, mean length and diameter of a structure, etc.) assessed in the study. When present, confounders should be clearly stated.
Measurement and Assessment	11	Indicate clearly the group of subjects included in each measurement/ assessment (source of data). Provide clear details about the methods of measurement/assessment of each outcome and/or parameter (e.g., reference points for length measurements, internal or external diameter, etc.).
Modality	12	Describe clearly the materials, equipment, and instruments used (with manufacturer/supplier details) to conduct the specific study design.
Technique	13	Describe precisely the methods (e.g., dissection technique, image reconstruction, etc.) applied in the study to allow for reproducibility. Relevant details (profession, years of experience) regarding the individual(s) performing the technical aspect of the study are recommended.
Bias	14	Identify any potential source of bias and, when present, describe measures implemented to assess the risk of bias.
Statistical Approach	15	Describe all statistical methods for analyzing the data, including those of confounders. Statistical methods for additional analyses (e.g., subgroup/sensitivity analyses), when performed, should be described.
Ethics	16	Provide the details of compliance with ethical guidelines, including the name of the review board or agency, approval number, and date. AQUA endorses the Helsinki Declaration and its later amendments. When appropriate, details of written, informed consent should be clearly stated.
Results		·
Subjects	17	Report the numbers of subjects included in the study, including data on their baseline and demographic characteristics. When needed, provide reason(s) and data on characteristics of the subjects excluded from the study at any stage.
Main Results	18	from the study at any stage. Provide unaltered/non-manipulated summary data (number [percentage]) or estimates (with confidence intervals and values of consistency when applicable) from the analyses performed. Tabular presentation of the results is highly recommended.

TABLE 1. Continued

Checklist component	#	Description and recommendation:
Descriptive Anatomy	19	Present clear and comprehensible figures (i.e., images, illustrations, diagrams, etc.), labeled as appropriate, to explain the results where needed AND describe clearly any anatomical findings that could be ambiguous, questionable, or atypical. New classifications of anatomical variations should be complemented by representative figures and corresponding dissection/imaging photographs.
Confounders	20	Present precise data from assessment/measurement of confounders, if any.
Additional analyses	21	Provide clear results of additional analyses (e.g., subgroup/sensitivity analyses), if performed. Tabular presentation of the results is highly recommended.
Discussion		
Key Findings	22	Include summary of key evidence/findings from the study pertaining to the rationale/objectives of the study. No new study results should be presented in the discussion.
Interpretation and Comparison(s)	23	Provide comprehensive (but judicious) interpretation of the results from the study, and comparison and/or reference to the results from other studies on the topic, appropriately cited. Meaningful clinical impact/significance of the findings from the study should be discussed where relevant.
Implication(s)	24	State briefly the implications of the findings or potential areas of the study that require further research.
Limitation(s)	25	Discuss briefly limitations of the study at any stage, including risk of bias, potential confounders, or intraobserver and/or interobserver variability.
Conclusions		,
Summary	26	Summarize the key information (i.e., "take-home message") directly supported by the findings/evidence from the study.
Other Information		
Acknowledgement	27	Acknowledge individual(s), institution(s), or third parties who significantly contributed to the study.
Conflict of interest	28	Disclose any conflicts of interests related to the study for all contributing authors.
Funding	29	Describe sources of funding for the study and any other support.

Measurements). On the basis of feedback from the panel members, these items underwent major revisions but were not eliminated from the checklist. Also, three new items (Sample Size, Ethics, and Conflicts of Interests) were added to checklist, bringing the total number of items in the revised version to 29. All 12 reviewers who completed the round 1 survey received a copy of the revised checklist and instructions for the round 2 survey of the Delphi procedure. Following this second round, the panelists suggested only minor grammatical revisions.

The final version of the AQUA Checklist, consisting of eight sections with a total of 29 items, is presented in Table 1 (Supporting Information 2).

USER'S GUIDE TO THE AQUA CHECKLIST

The AQUA Checklist was designed to enhance the clarity of reporting of original anatomical studies. It was not designed as a guide to writing anatomical research papers or to replace journal guidelines, but authors may still want to consult it before drafting their manuscripts. It could help them by providing a foundation for structured reporting. After their

manuscript has been drafted, authors should complete the AQUA Checklist by filling in the manuscript page numbers corresponding to each item. If an item is not reported in or applicable to their study, the authors may write "NA" (Not Applicable) in the page number box. The AQUA Checklist is freely available for all users on the International Evidence-Based Anatomy Working Group website (http://www.eba.cm.uj.edu. pl/aqua). Authors should submit the completed checklist form as a supplement to their manuscript. We also encourage them to submit their raw datasets as a supplement to enhance the clarity of reporting in their study.

DISCUSSION

Anatomical studies are primarily descriptive and observational and can be labeled as basic or translational research. From our extensive experience of evidence-based anatomy (i.e., meta-analyses and systematic reviews), many studies are seen to have incomplete and/or unclear methodological descriptions and results. Anatomical data obtained from poorly-reported studies, which can also be poorly-designed, could result in dissemination of erroneous information, which could ultimately lead clinicians into

making premature or false interventions. For these reasons, the checklist has been designed and arranged similarly to that for a scientific research article, with 29 items crucial for reporting anatomical studies. These items should allow the report to be clear, unambiguous, and transparent in describing vital information, while being complete in reporting key elements applicable to all types of medical research. The authors are aware that anatomical studies are diverse and interdisciplinary, so we have endeavored to maintain the applicability of the checklist to different types of studies in the field: gross, microscopic, surface, surgical, radiological, developmental, electrophysiological, etc. In short, the AQUA Checklist aspires to define the reporting standards and quality of anatomical studies.

The checklist should not be viewed as an attempt to promote reporting of anatomical studies in a rigid and uncompromising format. In fact, the checklist items are included on the basis of a consensus and recommendations by experts in anatomical research. Moreover, the checklist provides only a general description and a recommendation for each item without defining any specific methodological rigor. We strongly encourage authors to abide by the scope and requirement of the journal, direction and feedback provided by the editors and reviewers, and their own preferences wherever applicable. Nor does the checklist require authors to describe the essential aspects of their study as per the order numbered on the checklist document. It merely provides an idea on how to translate such aspects of their research into a solid and sound manuscript. Furthermore, it could allow for improved objectiveness in reporting and for conveying the impact and usefulness of studies, regardless of research paradigm and methodological approach. It could also prevent authors from omitting important information from their report, thus decreasing the risk of bias and enhancing the reliability of their study. Nevertheless, we reemphasize that it is not intended to standardize the content or structure of anatomical reporting.

Poor reporting in anatomy has also been observed by the pioneers of evidence-based anatomy (Yammine, 2014; Henry et al., 2016). The standard of reporting that the checklist proposes simply reflects the quality of study design and conduct of an individual study. Although we generally agree that a poorlyreported study might not imply a poor methodological approach, studies with obscure, incomplete, and inconsistent descriptions do not allow for accurate evaluation of quality, or any implications and clinical relevance they may hold. This is particularly imperative for anatomical journal reviewers who have a scientific obligation to appraise manuscripts critically and provide constructive feedback prior to deciding whether to recommend acceptance. Universal application of the AOUA Checklist would allow for transparency in reporting anatomical research and help identify potential areas of a study that could be at high risk of bias or needing additional analyses. This is relevant to every field of research, including anatomy, as overenthusiastic reporting of premature or erroneous findings could lead to rejections or mislead other researchers and clinicians. The checklist also stresses

the importance of comprehensiveness in reporting, which permits replication. We firmly believe that reproducibility is one of the hallmarks of a study with high methodological and reporting quality. Hence, the AQUA Checklist could elevate and preserve the future quality of anatomical research, and shed light on areas in the field that need to be addressed.

The AQUA steering committee did not perform a comprehensive literature review of each item in the checklist. However, we reached a unanimous consensus with our expert panelists regarding inclusion of every item. Although it is intended to be applicable to all types of anatomical studies, the AQUA Checklist might be less useful in qualitative studies, which are more descriptive. However, qualitative anatomical studies share many of the essential reporting items with more quantitative ones. Authors also have the option to assign "NA" to items in the checklist that might not be applicable to their particular study. Furthermore, some of the checklist items are currently not methodologically standardized in anatomical research (e.g., sample size and confounders). The panelists for the Delphi procedure and the AQUA steering committee feel that these items should be included, wherever appropriate, to help ensure accurate reporting of anatomical studies.

Finally, the underreporting of the methods or results of a study is in itself a form of scientific misconduct, which can lead to inappropriate decisions or interpretations based on the study's reported findings (Chalmers 1990). As such, we suggest that authors be forthright regarding the weaknesses and limitations of their research, as this can serve to enhance the reliability of their study, and encourage investigators, reviewers, and journal editors to all work to reduce underreporting in anatomical research. The AQUA steering committee strongly feels that the checklist is an evolving guideline requiring continuing appraisal and modification. As such, we welcome any comments, feedback, or recommendations from the scientific community to improve it.

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