Reporting guidance for violence risk assessment predictive validity studies

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Reporting Guidance for Violence Risk Assessment Predictive Validity Studies: The RAGEE Statement

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Available reporting guidelines for prognostic and diagnostic accuracy studies apply primarily to biological assessment and outcomes, overlooking behavioral issues with major public health and safety implications such as violence. The present study aimed to develop the first set of reporting guidance for predictive validity studies of violence risk assessments: the Risk Assessment Guidelines for the Evaluation of Efficacy (RAGEE) Statement. A systematic search of 8 electronic databases prior to September 2012 identified 279 reporting guidelines for prognostic and diagnostic accuracy studies. Unique items were extracted and modified to make them relevant to risk assessment. A 4-wave Delphi process involving a multidisciplinary team of 37 international experts resulted in a 50-item reporting checklist. The panelists endorsed the RAGEE Statement checklist as being highly satisfactory and as indicating study features that should be reported routinely in manuscripts. Use of these proposed standards has the potential to improve the quality of the risk assessment literature.

Keywords: reporting guidance, risk assessment, violence, checklist, RAGEE

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Study quality has been shown to account for variation in clinical research findings (Rutjes et al., 2006). Because it is difficult to assess and compare study quality without transparent and consistent reporting of methodology, investigators in prognostic (McShane et al., 2006) and diagnostic medicine (Bossuyt et al., 2003) have developed well-received guidelines for methodological reporting in accuracy studies. Evidence suggests that the implementation of such guidelines has resulted in an improvement in reporting practices (Plint et al., 2006; Prady, Richmond, Morton, & MacPherson, 2008; Smidt et al., 2006; Smith et al., 2008). However, available guidance of this type is limited to research assess-

ing the risk of biological outcomes, overlooking behavioral issues with major public health and safety implications such as violence.

Given the mortality rate and economic burden associated with violence, the World Health Organization (2002) has designated violence prevention as one of its priorities. This perspective is shared both by the mental health and criminal justice systems of numerous countries, including the United States and the United Kingdom, and is reflected in clinical guidelines for psychologists (American Psychological Association Presidential Task Force on Evidence-Based Practice, 2006), psychiatrists (American Psychiatric Association, 2004; National Institute for Health & Clinical

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Declaration of Interest: The first author reports being occasionally hired as an expert for giving talks or workshops about risk assessment.

Typically, this is done as part of the author's regular university duties but depending on the nature of the task and constituents, such activities are sometimes commissioned with additional remuneration. The second author was supported by the U.S. Department of Veterans Affairs, Office of Academic Affiliations, Advanced Fellowship Program in Mental Illness Research and Treatment. Contents do not represent the views of the Department of Veterans Affairs or the U.S. Government. Since completion of the manuscript, Dr. Yang has been employed at General Dynamics Information Technology. The third author is an author of a commercially available violence risk assessment tool. These potential conflicts did not influence the design, conduct, findings, or manuscript preparation for this report.

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Excellence, 2009), and nurses (Nursing & Midwifery Council, 2004) that recommend using evidence-based methods to assess violence risk. While the research base on the predictive validity of structured risk assessment instruments has grown exponentially (Buchanan, Binder, Norko, & Swartz, 2012), recent evidence from systematic reviews suggests that this literature has not achieved the same transparency and consistency as fields with established reporting guidelines. Considerable variability has been found in the reporting of essential sample- and study-level information in risk assessment studies published between 1990 and 2011 (Singh, Desmarais, & Van Dorn, 2013), making it difficult to assess the internal and external validity of their findings.

The development of reporting standards for violence risk assessment predictive validity studies could allow more informed comparisons between primary investigations, as well as sounder meta-analyses. This would, in turn, support the development of a cumulative science and potentially increase the reliability, utility, and impact of research in this area (Simera et al., 2010). Hence, to address the limitations of available reporting guidelines for prognostic and diagnostic accuracy studies when applied to the area of violence risk assessment, we used the Delphi technique to develop a novel reporting checklist: the Risk Assessment Guidelines for the Evaluation of Efficacy (RAGEE) Statement. Following published guidelines for developers of health research reporting guidance (Moher, Schulz, Simera, & Altman, 2010), our aim is to promote consistency and transparency for this important area of the behavioral sciences.

Method

Design

Consistent with the development of previous reporting standards (Hutchings, Raine, Sanderson, & Black, 2006), a multi-wave Delphi process was used to select the item content of the RAGEE Statement. The Delphi method is based on the premise that group decisions are necessary when the scope of a problem is such that no single individual has sufficient expertise and knowledge to effect a solution. It is a structured communication technique that relies on the anonymous feedback of a panel of experts in an iterative process to establish consensus (Powell, 2003). By maintaining the anonymity of panelists and controlling their interactions, the Delphi technique avoids the disadvantages of more conventional consensus-based roundtable discussions and committees (Hasson, Keeney, & McKeena, 2000). Ethical review was waived by the University of South Florida Institutional Review Board; therefore, informed consent was not sought.

Participants

The Delphi panel consisted of 37 experts in the field of violence risk assessment (Table 1). This group included a multidisciplinary set of clinicians, researchers, legal professionals, and journal editors from 10 countries: Australia, Belgium, Canada, Germany, The Netherlands, Norway, Sweden, Switzerland, the United Kingdom, and the United States. The principal investigator (JPS) and coinvestigators (SY, EPM) organized, but were not members of, the Delphi panel. Potential panel members were identified by using

recent reviews of the risk assessment literature (e.g., >; Hanson & Morton-Bourgon, 2009; Singh, Serper, Reinharth, & Fazel, 2011; Skeem & Monahan, 2011) and were recruited to serve as experts if they met Farmer and Richman's (1965) criteria for Delphi panelist selection:

1. Extensive knowledge of the problem area and the ability to apply that knowledge
2. Good performance record in their particular area
3. High degree of objectivity and rationality
4. Time available to participate
5. Willingness to participate

Materials

To identify a pool of items for consideration by the Delphi panel, a systematic search was performed to identify existing reporting guidance for prognostic and diagnostic accuracy studies. We searched the Cochrane Methodology Register, Database of Abstracts of Reviews of Effects, NHS Economic Evaluation Databases, Health Technology Assessment Databases, US National Criminal Justice Reference Service Abstracts, PROSPERO, PsycINFO, and MEDLINE prior to September 2012 using combinations of the following Boolean keywords: *prognos**, *diagnos**, *guid**, *checklist*. Additional guidelines were identified using the EQUATOR (Enhancing the Quality and Transparency of Health Research) Network (Altman, Simera, Hoey, Moher, & Schulz, 2008), annotated bibliographies (e.g., Sanderson, Tatt, & Higgins, 2007), and discussion with experts.

Using this search strategy, we identified 279 published checklists (Figure 1). Items from each were extracted by the first and second authors with a high level of interrater agreement as established using a randomly selected subsample of 28 (10.0%) checklists ($\kappa = 0.92$). Items addressing the same methodological principle (e.g., the inclusion of a structured abstract) were combined, and the wording of select items was modified to make them relevant to risk assessment (e.g., descriptions of biological tests were changed to descriptions of risk assessment instruments). This procedure, combined with a review of the literature on violence (including sexual violence) and criminal recidivism risk assessment, resulted in the identification of 130 unique items.

Procedure

A four-wave Delphi process was conducted between September 2012 and February 2013 to select which of the 130 initially identified items would be included in the final RAGEE Statement. The Delphi process was conducted electronically using Qualtrics survey software (www.Qualtrics.com), thus effectively managing the geographic dispersion of panelists and overcoming the time constraints related to physical meetings. Qualtrics has been used in recent research with forensic mental health professionals (e.g., Kimonis Fanniff, Borum, & Elliott, 2011; Singh, 2013) and has a number of benefits, including data collection through a secure server, libraries of customizable question templates, and a continuous file saving function to minimize data loss because of browser crashes.

In both the first and second waves of the Delphi process, panelists voted to definitely include, definitely exclude, or abstain from voting

Table 1
Members of the RAGEE Statement Delphi Panel

Name	Affiliation at time of publication
Stål Bjørkly, PsyD	Institute of Health Sciences, Molde University College, Molde, Norway
Marcus T. Boccacini, PhD	Department of Psychology and Philosophy, Sam Houston State University, Huntsville, Texas
Randy Borum, PsyD	School of Information, University of South Florida, Tampa, Florida
Alec Buchanan, PhD, MD	Department of Psychiatry, Yale University, New Haven, Connecticut
David J. Cooke, PhD	Psychology Department, Glasgow Caledonian University, Scotland, United Kingdom
Sarah L. Desmarais, PhD	Department of Psychology, North Carolina State University, Raleigh, North Carolina
Kevin S. Douglas, LLB, PhD	Department of Psychology, Simon Fraser University, Burnaby, BC, Canada
Michael Doyle, PhD, RMN	Institute of Brain, Behaviour and Mental Health, University of Manchester, Manchester, United Kingdom
John F. Edens, PhD	Department of Psychology, Texas A&M University, College Station, Texas
Eric B. Elbogen, PhD	Department of Psychiatry, University of North Carolina-Chapel Hill School of Medicine, Chapel Hill, North Carolina
Jerome Endrass, PhD	Department of Justice, Psychiatric/Psychological Service, Canton of Zurich, Switzerland
Seena Fazel, MD	Department of Psychiatry, University of Oxford, Warneford Hospital, Oxford, United Kingdom
Martin Grann, PhD, MBA	Department of Medical Epidemiology and Biostatistics, Karolinska Institute, Stockholm, Sweden
Laura S. Guy, PhD	Department of Psychiatry, University of Massachusetts Medical School, Worcester, Massachusetts
R. Karl Hanson, PhD	Public Safety Canada, Ottawa, ON, Canada
Robert D. Hare, PhD	Department of Psychology, University of British Columbia, Vancouver, BC, Canada
Grant T. Harris, PhD	Waypoint Centre for Mental Health Care Penetanguishene, ON, Canada
Stephen D. Hart, PhD	Department of Psychology, Simon Fraser University, Burnaby, BC, Canada
Kirk Heilbrun, PhD	Department of Psychology, Drexel University, Philadelphia, Pennsylvania
Mark A. Larsen, JD	Committee for Public Counsel Services, Commonwealth of Massachusetts, Boston, Massachusetts
John Monahan, PhD	School of Law, University of Virginia, Charlottesville, Virginia
Daniel F. Montaldi, PhD	Sexually Violent Predator Program, Florida Department of Children and Families, Tallahassee, Florida
Douglas Mossman, MD	Department of Psychiatry and Behavioral Neuroscience, University of Cincinnati College of Medicine, Cincinnati, Ohio
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James R. P. Ogloff, JD, PhD	Centre for Forensic Behavioural Science, Monash University and Forensicare, Victoria, Australia
Randy K. Otto, PhD	Department of Mental Health Law & Policy, University of South Florida, Tampa, Florida
John Petrila, JD, LLM	Department of Health Policy and Management, University of South Florida, Tampa, Florida
Thierry H. Pham, PhD	Centre de Recherche en Defense Sociale, Tournai, Belgium
Martin Rettenberger, PhD	Department of Psychology, Johannes Gutenberg University Mainz, Mainz, Germany
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Corine de Ruiter, PhD	Faculty of Psychology and Neuroscience, Maastricht University, Maastricht, The Netherlands
Astrid Rossegger, PhD	Department of Justice, Psychiatric/Psychological Service, Canton of Zurich, Switzerland
Nicholas Scurich, PhD	Department of Psychology & Social Behavior and Department of Criminology, Law & Society, University of California, Irvine, California
Jennifer L. Skeem, PhD	Department of Psychology & Social Behavior, University of California, Irvine, California
Robert L. Trestman, PhD, MD	Correctional Managed Health Care, University of Connecticut Health Center, Farmington, Connecticut
Frank Urbaniok, PhD	Department of Justice, Psychiatric/Psychological Service, Canton of Zürich, Switzerland
Jodi L. Viljoen, PhD	Department of Psychology, Simon Fraser University, Burnaby, BC, Canada

on each of the items. An inclusion threshold of 75% approval and an exclusion threshold of 25% disapproval were set (cf. Campbell, Piaggio, Elbourne, Altman, & the CONSORT Group, 2000). Items falling between these thresholds were retained for a further round of voting. Panelists had the opportunity to suggest new items, as well as to recommend modifications in wording. In the third wave, the panel was asked to dichotomously vote to either include or exclude remaining items. In the final wave, panelists used seven-item Likert scales to register their degree of satisfaction with the finished checklist (1 = *very dissatisfied*; 7 = *very satisfied*), as well as whether the guidance statement should be routinely used as reporting standards for risk assessment predictive validity studies (1 = *strongly disagree*; 7 = *strongly agree*). Upon the completion of each wave, approved items were summarized and panelists were given access to the voting results for each item if requested.

Response rates in each wave were maximized using the Dillman Total Design Method (Dillman, Smyth, & Christian, 2009). In accordance with this approach, an initial e-mail with an active Qualtrics link was sent to panelists on a Friday requesting participation in the

given wave. Three reminder e-mails were sent at seven day intervals after the initial distribution. Using this strategy, a 100% panelist response rate was achieved for each wave (Figure 2).

Results

The RAGEE Statement Checklist Criteria

The completed RAGEE Statement includes 50 items and contains minimal reporting standards for the abstract (k items = 4), introduction (k = 2), methods (k = 30), results (k = 6), and discussion (k = 4) sections of risk assessment predictive validity manuscripts, as well as guidance on recommended disclosures (n = 4; Table 2). The methods criteria are divided into six subsections: participants (k = 5), instrument design (k = 7), instrument administration (k = 5), study design (k = 5), predicted outcome (k = 2), and statistical analysis (k = 6). The results criteria are divided into two subsections: participant outcomes (k = 2) and predictive validity (k = 4). The checklist version of the

Figure 1. Identification of methodological reporting checklists for prognostic and diagnostic accuracy studies.

RAGEE Statement criteria can be found in the Supplemental Materials (Supplement 1). All criteria in the most comprehensive section of the checklist, concerning methods, can be met in fewer than 250 words (a sample methods section is available upon request), suggesting that the checklist does not place a substantial burden on authors. An elaboration document including exemplars for each item from the peer-reviewed predictive validity literature on risk assessment instruments was also developed to increase the usefulness of the checklist (Supplement 2).

Perceived Usefulness of the RAGEE Statement Checklist

Using 7-point Likert scales, the average satisfaction rating with the checklist was 6.00 ($SD = 1.04$), and the average support rating for using the checklist as reporting standards for risk assessment predictive validity studies was 5.84 ($SD = 1.31$). Narrative comments revealed that lower ratings were due to the desire of some panelists to include mandatory reporting of calibration performance indicators (e.g., positive and negative predictive values) as an item rather than just discrimination performance indicators (e.g., area under the curve and correlation coefficients), the belief

that no guidance should be given for introduction and discussion sections, and uncertainty about whether minimum reporting standards would exclude from consideration studies that merit publication.

Discussion

The development of health research guidance has resulted in increased transparency and consistency in the methodological reporting of diagnostic and prognostic accuracy studies. None of this work, however, has been done in the critical and rapidly growing area of violence risk assessment. The creation of general guidelines for research studies such as the American Psychological Association *Journal Article Reporting Standards* (American Psychological Association Publications and Communications Board Working Group on Journal Article Reporting Standards, 2008) has been a positive development for the social sciences, but such standards do not provide adequately specific guidance on sample- and study-level characteristics that should be reported to maximize the clinical relevance of the risk assessment literature.

In the present report, we developed the first set of methodological reporting standards for predictive validity studies in violence

Figure 2. Development of the Risk Assessment Guidelines for the Evaluation of Efficacy (RAGEE) statement.

risk assessment. A four-wave Delphi process involving 37 international experts from diverse fields resulted in a 50-item reporting checklist. Because the guidance statement was voted highly satisfactory and appropriate for routine use as a reporting standard for risk assessment predictive validity studies, researchers may wish to reference the RAGEE Statement checklist while preparing manuscripts. In addition to being useful for manuscript authors, the use of the checklist by reviewers has the potential to expedite and increase agreement in the peer-review process.

Just as health research reporting guidance for other specialties has been adapted to related fields (Campbell, Piaggio, Elbourne, Altman, & the CONSORT Group, 2012; Ioannidis et al., 2004), the RAGEE Statement checklist may provide a useful basis for the development of methodological standards in other fields of behavioral prediction, such as suicide risk assessment. In its current form, however, the RAGEE Statement is designed for use only in studies of violence (including sexual violence) and criminal recidivism risk assessment.

Adherence to the RAGEE Statement guidance has the potential to resolve and overcome these obstacles to innovation, rigor, and relevance. It is important to note that the items on the RAGEE

Statement checklist represent a *minimum* of what should be reported in risk assessment predictive validity studies at this time. Other valuable demographic, design, and performance information should continue to be reported where appropriate. For example, it is reasonable to assume that a brief summary of past predictive validity and reliability information will be reported in manuscripts. And as the field continues to develop, additional statistical approaches may enrich our picture of an instrument's predictive validity and expand the domain of study features that are desirable to report. It is our aim to update the RAGEE criteria as these developments arise. Hence, the RAGEE should be viewed as a living document. Meanwhile, when RAGEE Statement reporting criteria conflict with a journal's *Instructions for Authors*, please follow the latter.

Conclusion

Mental health professionals are routinely called upon to assess the violence risk presented by their clients, frequently aided by structured instruments. Though a considerable literature exists on the predictive validity of these instruments, such studies are often

Table 2

Risk Assessment Guidelines for the Evaluation of Efficacy (RAGEE) Statement Checklist

Section	Item	Description	Endorsed (N of 37, %)
Abstract	1	Include a structured abstract describing the study	30 (81.1%)
	2	Identify the article as a risk assessment study in which predictive validity is measured	30 (81.1%)
	3	Identify the risk assessment instrument(s) whose predictive validity is measured	37 (100.0%)
	4	State the nature of the principal outcome (e.g., violence, sexual violence, criminal offending, institutional misconduct)	33 (89.2%)
Introduction	5	Provide the rationale and a summary of the scientific/theoretical background for the study	37 (100.0%)
	6	State the research questions and/or study aims	37 (100.0%)
Methods			
Participants	7	Report the sample size	37 (100.0%)
	8	Report the sex/gender composition of the sample	37 (100.0%)
	9	Report the average age at assessment (with dispersion parameter)	31 (83.8%)
	10	Report the index offense composition of the sample	29 (78.4%)
Instrument design	11	Report the characteristics of groups that underwent subgroup analysis	28 (75.7%)
	12	Report the acronym(s) and full name(s) of the instrument(s) under investigation with appropriate reference to source document	37 (100.0%)
	13	Report the number of items on the instrument(s) under investigation	30 (81.1%)
	14	Report the approach by which the assessment information from the instrument(s) under investigation is organized into an overall evaluation of risk	28 (75.7%)
	15	Report the population for which the instrument(s) under investigation was intended to be used	34 (91.9%)
	16	Report the outcome(s) that the instrument(s) under investigation was intended to assess	35 (94.6%)
	17	Report the length of follow-up for which manual-recommended probability estimates of risk were derived for the instrument(s) under investigation	30 (81.1%)
	18	Report the cut-off score(s) and/or risk categories that the instrument(s) under investigation was designed to use to classify risk level	30 (81.1%)
Instrument administration	19	Report whether risk assessments were conducted in the context of research or practice	28 (75.7%)
	20	Identify when risk assessments occurred (e.g., pre-admission, admission, release, post-release)	37 (100.0%)
	21	Report the number of assessors in the study as well as their training in the administration of the instrument(s) under investigation	34 (91.9%)
	22	Identify the source(s) of information used to administer the instrument(s) under investigation	37 (100.0%)
Study design	23	Describe any modifications made to the instrument(s) under investigation	37 (100.0%)
	24	Report the geographical location and clinical setting in which risk was assessed	34 (91.9%)
	25	Describe the method(s) used to recruit participants	34 (91.9%)
	26	Identify the temporal design of the study (prospective or quasi-prospective)	36 (97.3%)
	27	Identify the setting in which participants were followed to ascertain whether the outcome(s) of interest had occurred	37 (100.0%)
	28	Report the average length of follow-up and time at risk (with dispersion parameter, if not fixed), including a description of periods subtracted from follow-up time (e.g., incarceration and/or hospitalization)	35 (94.6%)
Predicted outcome	29	Specify the event(s) coded as meeting outcome criteria (e.g., assault, rape, homicide)	34 (91.9%)
	30	Identify the type (e.g., arrest, charge, conviction, incarceration) and source (e.g., criminal records, self-report, collateral) of information used to detect outcome occurrence	37 (100.0%)
Statistical analysis	31	Describe the statistical methods used to conduct all analyses, and report the purpose of each analysis	30 (81.1%)
	32	Report whether risk scores and/or risk categories of the instrument(s) under investigation were used as an independent variable in analyses	32 (86.5%)
	33	Identify the statistical significance level used	34 (91.9%)
	34	Describe any subgroup analyses planned <i>a priori</i>	32 (86.5%)
	35	Report inter-rater reliability for administration of the instrument(s) under investigation (if conducted). If inter-rater reliability was not assessed, clarify why not	28 (75.7%)
	36	Include at least one discrimination performance indicator when measuring predictive validity	32 (86.5%)
Participant outcomes	37	Report the rate of attrition	32 (86.5%)
Predictive validity	38	Report the outcome occurrence rate for the entire sample as well as for relevant subgroups	34 (91.9%)
	39	Report predictive validity performance indicators for each outcome of interest as specified in the Methods with associated dispersion parameters	36 (97.3%)
	40	Report the number of participants with each risk score and/or in each risk category and how many went on to engage in the outcome(s) of interest	29 (78.4%)
	41	Report the results of subgroup analyses planned <i>a priori</i> as specified in the Methods	32 (86.5%)
	42	Describe and report the findings of any <i>post hoc</i> analyses conducted	28 (75.7%)

Table 2 (continued)

Section	Item	Description	Endorsed (N of 37, %)
Discussion	43	Provide a summary of the principal findings, including a discussion of their relevance in the context of the current literature	35 (94.6%)
	44	Discuss limitations of the study design	35 (94.6%)
	45	Discuss the generalizability of study findings	30 (81.1%)
	46	Discuss future research directions based on study findings	29 (78.4%)
Disclosures	47	Report any commercial interests and/or source(s) of funding as well as their role(s) in the conduct of the study	30 (81.1%)
	48	Report whether an author or translator of the risk assessment instrument(s) under investigation was also a study author	29 (78.4%)
	49	Report whether the study presented in the article has been published in an alternative form (e.g., government report)	28 (75.7%)
	50	Report whether the sample or a portion thereof has been studied in other publications	33 (89.2%)

plagued by inconsistent methodological reporting, limiting their reproducibility and clinical utility. The use of reporting guidelines has the potential to resolve and overcome these obstacles to innovation, rigor, and relevance.

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