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CHARMS and PROBAST at your fingertips

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CHARMS and PROBAST at your fingertips: a template for data extraction and risk of bias assessment in systematic reviews of predictive models

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Abstract

Background Systematic reviews of studies of clinical prediction models are becoming increasingly abundant in the literature. Data extraction and risk of bias assessment are critical steps in any systematic review. CHARMS and PROBAST are the standard tools used for these steps in these reviews of clinical prediction models.

Results We developed an Excel template for data extraction and risk of bias assessment of clinical prediction models including both recommended tools. The template makes it easier for reviewers to extract data, to assess the risk of bias and applicability, and to produce results tables and figures ready for publication.

Conclusion We hope this template will simplify and standardize the process of conducting a systematic review of prediction models, and promote a better and more comprehensive reporting of these systematic reviews.

Keywords CHARMS, PROBAST, Systematic review, Prognostic model, Template

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Background

Systematic reviews of clinical prediction model studies are becoming increasingly popular. Prediction models are covered by the type III prognostic research studies proposed by the PROGRESS (PROGnosis RESearch Strategy) partnership [1, 2]. The most common aims of these systematic reviews are to identify and summarize all available models for a particular target population, condition or outcome, and to summarize the predictive performance of a specific prognostic model while identifying potential sources of heterogeneity [3]. During the systematic review process, it is crucial for reviewers to extract key data from the relevant studies. Data extraction provides the reviewer the necessary information for describing and summarizing the findings, and examining the risk of bias and any applicability concerns of the models. Risk of bias refers to the likelihood that a primary predictive model study leads to a distorted, usually



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overly optimistic, estimate of predictive performance. Applicability concerns arise when a primary study question differs from the specific review question in terms of population, predictors or outcomes. Several checklists and toolkits have been developed to guide the process of data extraction and risk of bias assessment for different types of review questions [4].

The CHARMS checklist (CHecklist for critical Appraisal and data extraction for systematic Reviews of prediction Modelling Studies) provides guidance for both formulating the review question, and for extracting data the primary studies reporting prediction models [5].

The PROBAST tool (Prediction model Risk Of Bias Assessment Tool) is a checklist for assessing the risk of bias and the applicability of prognostic model studies [6, 7]. The PROBAST includes four domains: participants, predictors, outcome, and analysis. For each domain the tool provides signalling questions for determining whether the risk of bias and the applicability should be graded as low, high or unclear.

With the aim of facilitating the use of these two tools (i.e. CHARMS and PROBAST) for reviewers performing a systematic review of clinical prediction model studies, we have created an Excel template for extracting data and assessing the risk of bias and the applicability of predictive models.

Implementation

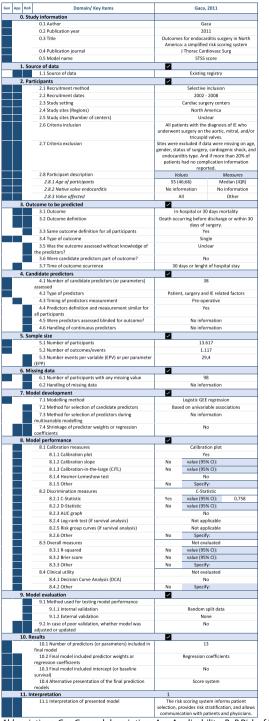
The Excel file (named CHARMS and PROBAST template.xls) consists of eight sheets. The first sheet "Home" provides a description of the Excel file, instructions for its use and links to relevant papers and forms. The following three sheets ("Summary", "CHARMS" and "PROBAST") correspond to the collection of data from the studies included in the systematic review, and the following three sheets ("Study Characteristics", "Model characteristics ", and "PROBAST summary") contain the tables and figures generated from the data collected. The final sheet ("CHARMS. Drop-down response lists") allows tailoring of the template to the systematic review. A more detailed description of each sheet is presented next.

To start with the data extraction process, for each predictive model presented in each study included in the systematic review, the user should tick the "new model" box on the "Summary" sheet. This operation enables the CHARMS and PROBAST forms for this new model in the corresponding sheets. The Excel template assumes that each study in the review reports a single prognostic model, but it can easily be generalized to a study reporting two or more models. In that case, the reviewer shall enable as many rows in the template as models are reported in that study. In the "Summary" sheet the following basic information of the new study should be filled in: author, year, title or an identifier (i.e. PMID or DOI), journal of publication and name of the model, if applicable. An identifier for each model is automatically created based on author name and year. In the last two columns of this summary sheet, the reviewer finds information on the status (i.e. complete or incomplete) of the CHARMS and PROBAST sheets.

The "CHARMS" sheet contains the template from Moons et al. [4]. The data extraction sheet is structured according to the eleven CHARMS domains: source of data, participants, outcome to be predicted, candidate predictors, sample size, missing data, model development, model performance, model evaluation, results and interpretation. To complete the data extraction process reviewers should fill in all the cells shaded in yellow. Depending on the item, the reviewers can choose from a drop-down list of options, or they can enter a free-text response. The items with available drop-down lists are showed in the last sheet of the Excel file (sheet named "CHARMS. Drop-down response lists"). The categories of these default lists can be tailored by the reviewer. When the information in the study report is not available, the reviewer has to fill in the cell with "No information". In the participant description section, reviewers can specify the relevant characteristics that they plan to extract from the primary studies, tailored to the target population in the review. These characteristics will be the same for all models included in the review. For each domain within CHARMS, its status is incomplete whenever a cell within that domain remains empty (marked in vellow). In the observations section of the CHARMS checklist table (bottom part of CHARMS sheet), the reviewer will find a status line that flags each model as "All information has been successfully registered" when all domains are complete, or "Incomplete data extraction" otherwise. Additional information of the model could be extracted and filled in as free text on an additional information field at the bottom line. When all relevant information from a model has been extracted for all domains in the form, the CHARMS checklist for that model is flagged as complete in the "Summary" sheet.

The "*PROBAST*" sheet contains the template from Wolff et al. [6]. To make information of the model accessible to the reviewers, relevant information

Table 1 Example of CHARMS sheet using data from a primary study included in the systematic review of prognostic models for mortality after cardiac surgery in patients with infective endocarditis [8]



Abbreviations: Gen General description, App Applicability, RoB Risk of Bias

Table 2 Example of PROBAST sheet using data from a primarystudy included in the systematic review of prognostic modelsfor mortality after cardiac surgery in patients with infectiveendocarditis [8]

0. Study information	Gaca, 2011
0.1 Author	Gaca
0.2 Publication year	2011
0.3 Title	Outcomes for endocarditis surgery in Nort America: a simplified risk scoring system
0.4 Publication journal	J Thorac Cardiovasc Surg
0.5 Model name	STSS score
1. Participants	
1.1 Were appropriate data sources used?	Probably Yes
1.2 Were all inclusions and exclusions of participants appropriate? Risk of bias introduced by selection of participants	Probably No High RoB
Applicability	Low concern
Relevant information extracted from CHARMS:	Low concern
Source of data	Existing registry
Recruitment methods	Selective inclusion
Recruitment dates	2002 - 2008
Study setting Inclusion criteria	Cardiac surgery centers All patients with the diagnosis of IE who
in course in concerne	underwent surgery on the aprtic, mitral.
	and/or tricuspid valves.
Exclusion criterio	Sites were excluded if data were missing o age, gender, status of surgery, cardiogeni
	shock , and endocarditis type. And if more
	than 20% of patients had no complication information reported.
Rationale of bias and applicability rating:	Excluding complete sites if data were
	missing in some variables, likely to have
	introduced bias but it is less important tha to exclude individual participants.
2. Predictors	to exclose manifular participants.
2.1 Were predictors defined and assessed in a similar way for all participants?	Yes
2.2 Were predictor assessments made without knowledge of outcome data?	No Information
2.3 Are all predictors available at the time the model is intended to be used?	Yes
Risk of bias introduced by predictors or their assessment	Low RoB
Applicability Relevant information extracted from CHARMS:	Low concern
Predictors definition and measurement similar for all participants	Yes
Were predictors assessed blinded for outcome?	No information
Timing of predictors measurement	Pre-operative
Rationale of bias and applicability rating:	Excluded complete sites if data were missir in some variables, likely to have introduce
	bias but less important than excluding
	individual participants.
3. Outcome 3.1 Was the outcome determined appropriately?	Yes
3.2 Was a pre-specified or standard outcome definition used?	Yes
3.3 Were predictors excluded from the outcome definition?	Yes
3.4 Was the outcome defined and determined in a similar way for all	Yes
3.4 Was the outcome defined and determined in a similar way for all articipants?	
3.4 Was the outcome defined and determined in a similar way for all articipants? 3.5 Was the outcome determined without knowledge of predictor information?	No Information
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Gray shaded cells are automatically filled based on the information included in the CHARMS sheet

Table 3 Example of the table with study characteristics automatically produced by the Excel file using data from the systematic review of prognostic models for mortality after cardiac surgery in patients with infective endocarditis [8]

Author, Year	Source of data	Enrolment	Study setting	Study region	Participant characteristics				
		period			Age of participants	Native valve endocarditis	Valve affected		
Gaca, 2011 [10]	Existing registry	2002—2008	Cardiac surgery centers	North America	55 (46;66)	No information	All		
De Feo, 2012 [11]	Retrospective cohort	1980—2009	Cardiac surgery center	Italy	49 (16)	440 (100)	All		
Martínez-Sellés, 2014 [12]	Existing registry	2008—2010	Cardiac surgery centers	Spain	61.4 (15.5)	267 (61.1)	All		
Madeira, 2016 [13]	Retrospective cohort	2007—2014	Cardiac surgery center	Portugal	60 (47;70)	94 (73.4)	All		
Gatti (a), 2017 [14]	Other (specify)	2000—2015 (Italy) 2008 (France)	Cardiac surgery centers	Italy and France	59.1 (15.4)	285 (78.9)	All		
Gatti (b), 2017 [14]	Other (specify)	2000—2015 (Italy) 2008 (France)	Cardiac surgery centers	Italy and France	59.1 (15.4)	285 (78.9)	All		
Di Mauro, 2017 [15]	Retrospective cohort	2000—2015	Cardiac surgery centers	Italy	59.6 (15.1)	2.221 (82)	All		
Gatti (c), 2017 [<mark>16</mark>]	Retrospective cohort	1999—2015	Cardiac surgery center	Italy	60.6 (8.5)	103 (74.6)	All		
Olmos, 2017 [17]	Retrospective cohort	1996—2014	Cardiac surgery centers	Spain	62 (14)	259 (61.1)	Aortic / Mitral		
Fernández- Hidalgo (a), 2018 [18]	Retrospective cohort	2000—2011	Cardiac surgery centers	Spain	58 (15.1)	No information	All		
Fernández- Hidalgo (b), 2018 [18]	Retrospective cohort	2000—2011	Cardiac surgery centers	Spain	58 (15.1)	No information	All		

(such as source of data, inclusion and exclusion criteria, validation methods, performance measures, etc.) from CHARMS domains are automatically transferred into the "PROBAST" sheet. Reviewers should fill in signalling questions for all PROBAST domains: participants, predictors, outcome and analysis. These questions are shaded in yellow and responses should be selected from a drop-down list with the following categories "Yes", "Probably yes", "Probably no", "No" or "No information". Once all signalling questions for one domain have been filled, the risk of bias and applicability assessment cells become editable. Reviewers should rate risk of bias and concerns for applicability of the model as "Low", "High" or "Unclear" for both. When the risk of bias assessment and the applicability of a model have been rated for all domains in the form, the PROBAST assessment for the model is flagged as complete in the "Summary" sheet.

Results

In this section we present a worked example of the template file. This example is based on the data from a systematic review of prognostic models for mortality after cardiac surgery in patients with infective endocarditis [8].

Once we have extracted the data of the models included in the review using the corresponding CHARMS sheet (see Table 1 with data extracted from one of the models as an example) and after completion of the risk of bias assessment using PROBAST sheet (see Table 2 with the risk of bias assessment of the same model), the reviewers could obtain a number of tables and figures aimed to assist in the process of reporting adequately the review findings. All tables and figures can be copied and pasted for further editing.

The first result table automatically created (sheet named: "*Study characteristics*") shows a summary of the characteristics of included studies listed in

the "Summary" sheet. It presents information covered by methods section (items 4 and 5) and results section (item 13) of the TRIPOD (Transparent Reporting of a multivariable prediction model for Individual Prognosis Or Diagnosis) statement [9]. The headers of the table include the source of data, the enrolment period, study setting and regions, and the participant characteristics previously predefined in the CHARMS sheet, in our example, these characteristics includes age, specification of native valve endocarditis and valves affected (see Table 3 with characteristics of the studies included in the review).

The second table of results (sheet named: "Model characteristics") shows the relevant information of the

predictive models included in the review. It presents information about the methods section (items 7, 8 and 10) and the results section (item 14) of the TRIPOD statement. In addition, for each included model, a summary of the results of the risk of bias assessment and applicability is shown (see Table 4 with the characteristics of the models reviewed).

The sheet named "*PROBAST summary*" presents a table and a graph with the results of the risk of bias and applicability assessments (Table 5 and Fig. 1).

The template as well as a filled in file with an example is provided as supplementary material, and this version and further updates can be downloaded from https:// github.com/Fernandez-Felix/CHARMS-and-PROBA ST-template.

Table 4 Example of the table with model characteristics automatically produced by the Excel file, using data from the systematic review of prognostic models for mortality after cardiac surgery in patients with infective endocarditis [8]

Author, Year Gaca, 2011	Modelling		Events	No pre	dictors	EPV or	Selection of candidate predictors Based on univariable	Selection of final	Number (%) and handling of	Type of	Performance measures	Critical appraisal (PROBAST)								
	method	size	n (%)	Cand.	Final	EPP		predictors	missng data	validation			Ρ	Pr	0	Α				
	Logistic GEE	13.617	1117 (8,2)	38	13	29,4		No information	n (%): 98 (0,7) Method:	Int: Random split data	Cal: Calibration plot Disc : C-Statistic	RoB	-	+	+	-				
	regression						associations		No information	Ext : None	Ov: Not evaluated	Арр	+	+	+					
De Feo, 2012 Logistic Z	De Feo, 2012 Logistic regression		440	40 (9,1)				19	6	2,1	Based on univariable	No information	n (%): 22 (5,0) Method:	Int: None (Apparent performance)	Cal: HL test Disc : C-Statistic / AUC graph	RoB	-	?	+	-
			(9,1)				associations	information	No information	Ext : None	Ov: Not evaluated	App	-	+	+					
Martínez-Sellés,	Logistic	437	106	Unkown	7	Unknown	Based on univariable	n (%): Unkown (Appar le Stepwise Method: (Appar	Int: None (Apparent	arent Disc : C-Statistic / AUC graph		+	+	+	-					
2014	regression		(24,3)				associations	selection	No information	performance) Ext : None	Ov: Not evaluated	App	+	+	+					
Madeira, 2016	Logistic	128	21	15	2	1,4	Based on univariable	No	n (%): Unkown Method:	Int: None (Apparent	Cal: Calibration plot / Slope / CITL / HL test	RoB	?	+	+	-				
Madella, 2010	regression	120	(16,4)	15	2	1,4	associations	information	No information	performance) Ext : None	Disc : C-Statistic / AUC graph Ov: Brier score	App	?	+	+					
	Logistic	_ogistic	56		_		Based on	Backward	ion Method: Ext :	Int: Bootstrap	Cal: HL test	RoB	+	+	+	-				
Gatti (a), 2017	regression	361	(15,5)	57	5	1,0	univariable associations	elimination		Ext : Geographical	Disc : C-Statistic / AUC graph Ov: Not evaluated	Арр	+	?	+					
	Logistic	tic 56	56				Based on	n Backward	n (%): Unkown	Int: Bootstrap	Cal: HL test Disc : C-Statistic / AUC graph Ov: Not evaluated	RoB	+	+	+	-				
Gatti (b), 2017	regression	361	(15,5)	57	3	1,0	univariable associations	elimination	Method: No information	Ext : None		Арр	+	+	+					
		tic 209	200				Based on		n (%): Unkown	lat. De statue e	Cal: Comparison with the	RoB	?	+	+	?				
Di Mauro, 2017	Logistic regression	2.715	298 (11,0)	32	15	9,3	univariable associations	No information	Method: No information	Int: Bootstrap Ext : None	ideal values Disc : C-Statistic / AUC graph Ov: Brier score	App	?	+	+					
	1		20				Based on	De al second	n (%): 45 (32,6)		Cal: HL test	RoB	+	+	+	-				
Gatti (c), 2017	Logistic regression	138	28 (20,3)	56	5	0,5	univariable associations	Backward elimination	Method: No information	Int: Bootstrap Ext : None	Disc : C-Statistic / AUC graph Ov: Not evaluated	Арр	+	+	+					
	11-11-		124				Based on univariable	Chamming		Int: Random	Cal: Calibration plot / HL test	RoB	+	+	+	-				
Olmos, 2017	Logistic regression	424	124 (29,2)	37	8	3,4	associations and clinical relevance	Stepwise selection	Method: No information	split data Ext : Geographical	Disc : C-Statistic / AUC graph Ov: Not evaluated		+	+	+					
		202				Based on		n (%): 4 (0,5)		Cal: Calibration plot / Slope /	RoB	+	+	+	+					
Fernández-Hidalgo (a), 2018	Logistic regression	779	208 (26,7)	26	10	8,0	prior knowledge	Bootstrap selection	Method: Complete-case analysis	Int: Bootstrap Ext : None	CITL Disc : C-Statistic / AUC graph Ov: Brier score	App	+	?	+					
Fernández-Hidalgo	Logistic	779	208	27	9	77	Based on	Bootstrap	n (%): 4 (0,5) Method:	Int: Bootstrap	Cal: Calibration plot / Slope / CITL	RoB	+	+	+	+				
(b), 2018	regression	//9	(26,7)	21	э	7,7	prior knowledge	selection	Complete-case analysis	Ext : None	Disc : C-Statistic / AUC graph Ov: Brier score	Арр	+	+	+					

Abbreviations: GEE Generalized Estimating Equation, n: number of event and number of missing data, Cand Number of candidate predictors assessed, EPV Events per variable, EPP Events per parameter, Critical appraisal domains (P Participants, Pr Predictors, O Outcome, A Analysis), Int Internal validation, Ext External validation, Disc Discrimination, Cal Calibration, Ov Overall, CITL Calibration-in-the-large, C: C-Statistic, AUC Area under curve, HL Hosmer–Lemeshow, RoB Risk of Bias, App Applicability

 $+ \operatorname{Low} \operatorname{RoB}$ or low corcern for applicability

- High RoB or high concern for applicability

? Unclear RoB or applicability

Author, Year	Risk of Bias				Applicability		Overall		
	1. Participants	2. Predictors	3. Outcome	4. Analysis	1. Participants	2. Predictors	3. Outcome	Risk of Bias	Applicability
Gaca, 2011 [10]	-	+	+	-	+	+	+	=	+
De Feo, 2012 [11]	-	?	+	-	-	+	+	-	-
Martínez-Sellés, 2014 [12]	+	+	+	-	+	+	+	-	+
Madeira, 2016 [13]	?	+	+	-	?	+	+	-	?
Gatti (a), 2017 [14]	+	+	+	-	+	?	+	-	?
Gatti (b), 2017 [14]	+	+	+	-	+	+	+	-	+
Di Mauro, 2017 [15]	?	+	+	?	?	+	+	?	?
Gatti (c), 2017 [16]	+	+	+	-	+	+	+	-	+
Olmos, 2017 [17]	+	+	+	-	+	+	+	-	+
Fernández- Hidalgo (a), 2018 [18]	+	+	+	+	+	?	+	+	?
Fernández- Hidalgo (b), 2018 [18]	+	+	+	+	+	+	+	+	+

Table 5 Example of the table with the summary of PROBAST tool automatically produced by the Excel file using data from the systematic review of prognostic models for mortality after cardiac surgery in patients with infective endocarditis [8]

Discussion

We present in this manuscript an Excel template for extracting data and assessing the risk of bias and applicability of predictive modelling studies.

This template is the first to combine the CHARMS and PROBAST tools into one file. The template simplifies and standardizes the tasks of data extraction and risk of bias assessment, reducing the risk of errors and increasing reliability between data extractors. Having the relevant information at hand while assessing the risk of bias will make the review process more efficient. The template is easy to use and allows the reviewers to fill the forms using drop-down lists that are easily customisable. Such customisation makes our template versatile and adaptable to meet users' needs. The template generates several summary tables that can be used directly for publication with minor edits. All these characteristics will speed up the process of performing some of the steps of a systematic review and reporting its findings; surely, systematic reviewers will appreciate its usefulness.

There are some limitations to our template. First, it has been designed to include up to 30 existing models only (or 30 validation studies of a model). Second, the summary tables we produce are generic and might not fit every purpose. However, the tables could be edited outside the template to incorporate other aspects of interest for a specific review.

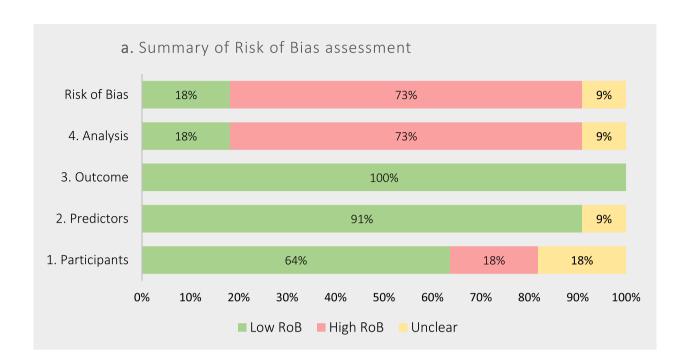
Conclusion

We have designed a useful template for extracting data and assessing the risk of bias and the applicability of clinical prediction models using the CHARMS and PROBAST checklists. The template makes it easier for reviewers to manage these tools, and to produce results tables ready for publication with minor edits. We hope this template will promote a better and more comprehensive reporting of systematic reviews of prediction models. We encourage piloting the template and providing feedback to improve the template in future versions.

Availability and requirements

Project name: None.

Project home page: None.



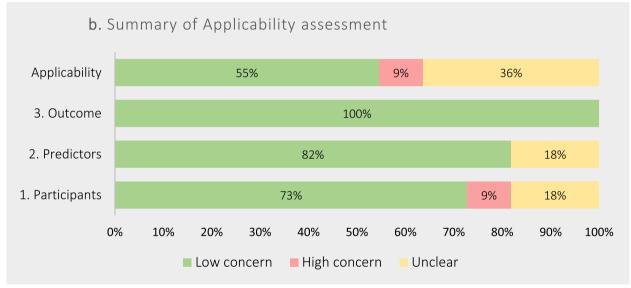


Fig. 1 Example of the graph with the summary of PROBAST tool automatically produced by the Excel file using data from the systematic review of prognostic models for mortality after cardiac surgery in patients with infective endocarditis [8]

Operating system(s): Operating system with Microsoft Office.

Programming language: Only formulae available in Excel are employed.

Other requirements: None.

License: None required.

Any restrictions to use by non-academics: None.

Abbreviations

PROGRESS	PROGnosis RESearch Strategy
CHARMS	CHecklist for critical Appraisal and data extraction for systematic
	Reviews of prediction Modelling Studies
PROBAST	Prediction model Risk Of Bias Assessment Tool
TRIPOD	Transparent Reporting of a multivariable prediction model for
	Individual Prognosis Or Diagnosis

Supplementary Information

The online version contains supplementary material available at https://doi. org/10.1186/s12874-023-01849-0.

Additional file 1. CHARMS & PROBAST template.

Additional file 2. Example CHARMS and PROBAST template.

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Authors' contributions

BMFF contributed to develop the template; the template's validation was done by JZ, AM, JLA, MR; the original draft was written by BMFF and JZ; and all authors contributed to reviewing and editing the article. The authors read and approved the final manuscript.

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Availability of data and materials

All data generated or analysed during this study are included in this published article [and its supplementary information files]. CHARMS and PROBAST template.xls. Example CHARMS and PROBAST template.xls.

Declarations

Ethics approval and consent to participate Not applicable.

Consent for publication

Not applicable.

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