

Closing the Regulatory Gap: A National Policy Framework for Transparent and Reproducible Radiology AI

Colin Wu¹, Edward Pettyjohn², MD, Youyou Cheng¹, Justin Kuyn, Ravi Patel¹, Sina Ashraf¹, Zhuangwei Kang⁴, PhD, Sarah Pettyjohn, MD⁵

¹University of the Incarnate Word School of Osteopathic Medicine; ²University of Illinois College of Medicine Peoria (UICOMP); ³University of Colorado Boulder; ⁴Independent Researcher; ⁵Rutgers Robert Wood Johnson Medical School

Purpose

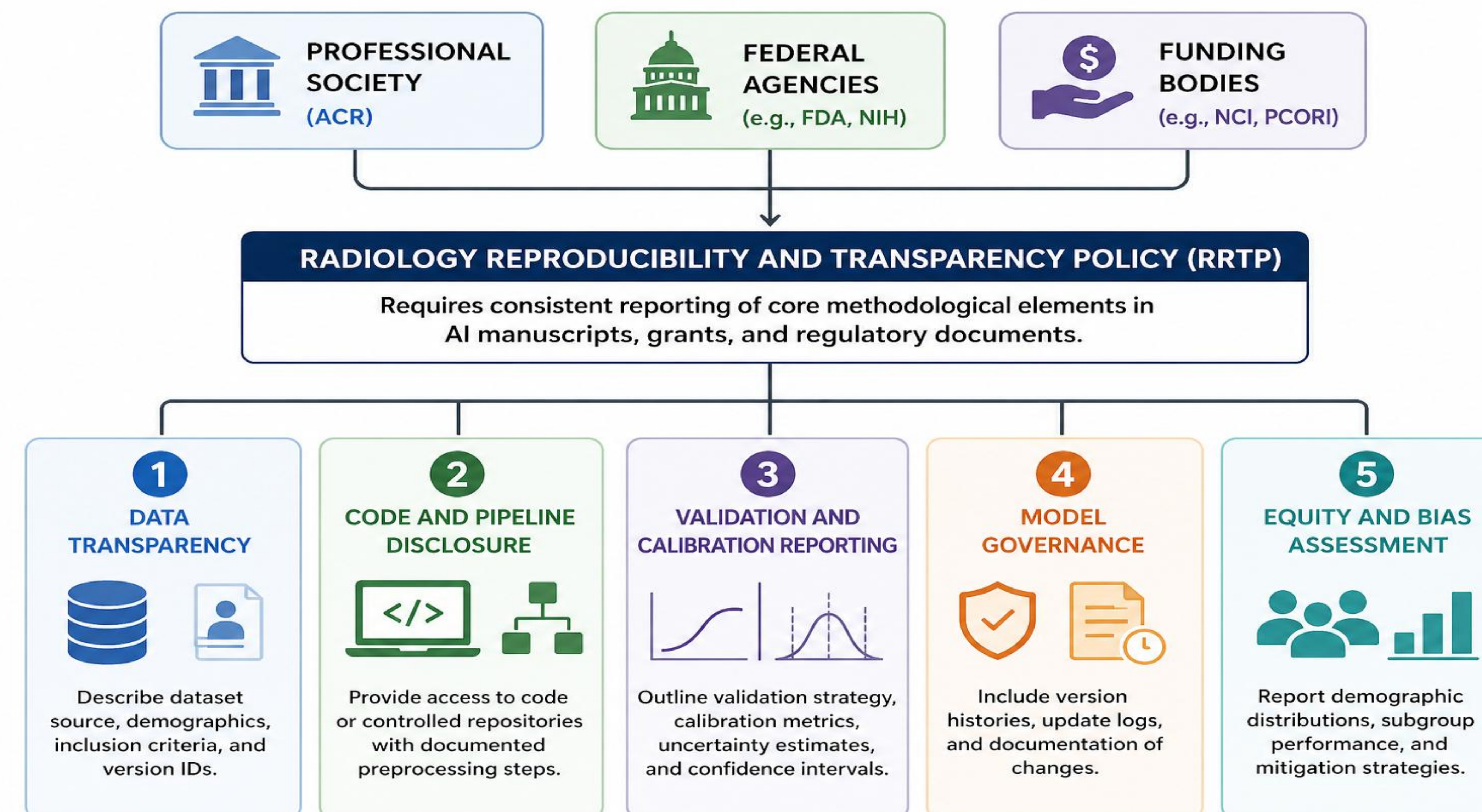
To recommend national policy actions, led by ACR and aligned with federal priorities, that establish clear and enforceable standards for transparency and reproducibility in radiology AI research and evaluation.

Methods/Materials

We reviewed FDA guidance, ACR draft practice parameters, journal standards, and research frameworks to assess transparency expectations for radiology AI. Although FDA and ACR encourage transparency, there is no required standard across U.S. journals, grant agencies, or clinical practice to disclose dataset sources, preprocessing steps, validation methods, or model calibration. FDA draft guidance expects limited information for AI-enabled devices, but these expectations do not apply to academic research. We compared these gaps with Transparent Reporting of a multivariable prediction model for Individual Prognosis Or Diagnosis–AI (TRIPOD-AI), Minimum Information for Medical AI Reporting (MINIMAR), and the ACR Data Science Institute (ACR DSI) to define policy elements needed for reproducible radiology AI.

Results

1. Data Transparency: Describe dataset source, demographics, inclusion criteria, and version IDs.
2. Code and Pipeline Disclosure: Provide access to code or controlled repositories with documented preprocessing steps.
3. Validation and Calibration Reporting: Outline validation strategy, calibration metrics, uncertainty estimates, and confidence intervals.
4. Model Governance: Include version histories, update logs, and documentation of changes.
5. Equity and Bias Assessment: Report demographic distributions, subgroup performance, and mitigation strategies.



Conclusions

A unified reproducibility policy would strengthen peer review, reduce misleading claims, improve patient safety, and support responsible deployment of AI tools. Establishing an enforceable national framework will help ensure radiology AI is transparent, reliable and ready for clinical use.

References

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