

# **Evidence in Action between Science and Society**

Constructing, Validating, and  
Contesting Knowledge

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## **On Top of the Hierarchy: How Guidelines Shape Systematic Reviewing in Biomedicine**

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# 6 On Top of the Hierarchy: How Guidelines Shape Systematic Reviewing in Biomedicine

*Alexander Schniedermann, Clemens Blümel,  
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## **Certifying Biomedical Evidence**

Evidence practices in biomedicine have changed profoundly since the postwar era. After medical treatments ceased to reveal “blockbuster” effects at the beginning of the twentieth century, experts developed and promoted more systematized attempts to determine the most effective “therapeutic interventions.”<sup>1</sup> They redefined the ways of how knowledge can be legitimately produced and claimed. In this manner, the randomized-controlled-trial (RCT) combined different methods and techniques and has become the main template for generating biomedical knowledge. Full of ethical and epistemic promises, proponents turned this research design into a marker for “evidence” in biomedical policy and practice, and one which allows for certificating knowledge claims irrespective of the various complexities in their making.<sup>2</sup>

But not only experimental designs became part of the evidence movement in biomedicine. Also, research syntheses summarizing and synthesizing primary research were highly demanded. By using systematic reviewing to find and appraise the relevant trials, as well as meta-analyses as a reliable statistical technique to pool trial data, researchers started to aggregate multiple trial results into overall conclusions about treatment effectivity.<sup>3</sup> Facing the growing output of the “clinical trial industry,”<sup>4</sup> experts hoped that these methods would help to cope with a huge load of information. Further, it was hoped that the aggregation of studies would solve contradictive results and sufficiently represent scientific consensus. These steps toward fact making would then ultimately allow for drawing conclusions and recommendations as to what knowledge should be perceived as “evidence” and which interventions are to be considered effective.<sup>5</sup>

Like clinical trials, systematic reviews were ascribed evidencing qualities based on the intended purpose of the genre as identifying and presenting the most convincing research. Displaying such authority claims, meta-analysis and systematic review have been coined the “platinum standard of evidence,”<sup>6</sup> in comparison to RCT as the “the gold standard.”<sup>7</sup> In addition, synthesis formats have been placed at the top of what was called the

“hierarchy of evidence.”<sup>8</sup> They have become the main input to “evidence-based medicine,” and one of the core areas of international organizations that deal with quality assurance in health care, such as the Cochrane Collaboration which essentially produces and disseminates systematic reviews about medical interventions.<sup>9</sup>

Likewise, the roles of meta-analysis and systematic review in biomedicine became a benchmark for other agoras where research and intervention meet. With generous references to biomedicine, researchers and practitioners from social policy, education or climate science discuss the benefits and potentials of these formats for their areas of expertise.<sup>10</sup> As a result, systematic research syntheses also shaped concepts like “evidence-based policy” and informed the work of the Campbell Collaboration or the Collaboration for Environmental Evidence, organizations that are very similar to Cochrane. Despite the efforts to establish systematic review and meta-analysis in other fields, their diffusion was rather limited which is why biomedicine remained the only research community with a wider adoption of these standardized research formats.<sup>11</sup> For this reason, we consider in more detail what makes systematic reviewing an evidence practice in biomedicine, and the ways in which this practice was established and stabilized.

In order to shed light on how systematic reviews are attributed to represent evidence, we focus on the exploration of methods and guidelines that play a crucial role during the writing of such reviews. Today, systematic reviews are a widely accepted subtype of review articles, the latter often being perceived as a very diverse and little standardized genre in scientific literature.<sup>12</sup> Criticism related to the writing of review articles in science argued that those would suffer from little methodological control and a lack of transparency (e.g. how primary research is included, how to evaluate research, etc.).<sup>13</sup> Against this background, the systematic review article was positioned as a more controlled format of research synthesis, where strict and transparent criteria assure the quality of conduct and reporting. Method experts have developed distinct conceptions of what systematic reviews are, and how they can be separated from other forms of synthesizing research.<sup>14</sup>

As systematic reviews spread among the sciences, their status hinges on the agreed upon standard ways of writing and doing such reviews, that is, guidelines.<sup>15</sup> The epistemic authority of systematic reviews is based on the idea that various forms of biases can be ruled out by providing a strict set of procedures to follow. Since meta-analysis alone was perceived to be incapable of ruling out various biases, systematic reviewing as a higher-order method became pervasive.<sup>16</sup> It is against this background that we intend to explore the systematic review guideline documents in more detail. In steering the author through various stages in the conduct of a systematic review, the method promises to reduce the influence of the author’s individual preferences and viewpoints. Rather than defining or certifying the outcome, the systematic reviewing method defines the practices and steps

taken within the process. Therefore, the epistemic authority is based on a procedural conception of objectivity, that is, a set of procedural rules which authors need to follow if they want their article to be certified as systematic review.<sup>17</sup>

We are focusing our analysis on more recent guidelines for systematic reviewing, as these can be best understood as solutions for what was called the “new worries of science.”<sup>18</sup> In addition to the sometimes detrimental influence of the pharmaceutical industry on the outcome of trials,<sup>19</sup> experts also criticized how the pressure to publish influences which knowledge is reported how and where.<sup>20</sup> Reporting guidelines such as the “preferred reporting items for systematic reviews and meta-analyses,”<sup>21</sup> (PRISMA) inform the methodologies for *reporting* systematic reviews, thus the writing of the reports. We have therefore chosen to focus our analysis on these guidelines, in order to explore the ways in which the renegotiating of evidence practice took place in the biomedical field.

Effectively being a checklist for review authors, PRISMA represents the claims for procedural conception of objectivity that is common to systematic review methodologies. Yet, at the same time PRISMA seems to be different from the rather extensive methodological frameworks for systematic reviewing, for example, defined by the Cochrane Collaboration which guides the whole process of registering, writing and publishing reviews. Different to these large infrastructures, PRISMA consists of a small checklist of rules that, if followed by the author, promise to ensure the credibility of the decisions made during the systematic review process.

In contrast to clinical treatment guidelines, PRISMA influences the practices of researchers rather than doctors. As such, its successful dissemination and implementation seems to depend on the voluntary acceptance of a wider community, rather than the enforcement of a clinical director or a healthcare system. Treatment guidelines may not be accepted, and instead create lines of conflict between the social contexts of the guideline developers and the guided individuals.<sup>22</sup> In addition, because the making of treatment guidelines incorporates various actors—such as researchers, practitioners, industry agents, or healthcare officers—the resulting definition of a medical practice is shaped by a multitude of interests and values correspondingly.<sup>23</sup> Likewise, actors and corresponding values define the evidence practice of systematic reviewing when issuing guidance for systematic reviews. Thus, the making and dissemination of PRISMA entangles characteristics of scholarly communication, evidence practices, and practices from clinical guideline making. To understand the processes leading to the production of PRISMA guidelines and the justification of their status as evidence practices, we address the following questions.

First, how and by whom was PRISMA constructed, and which factors and arguments were negotiated to make it persuasive and acceptable? Second, how was PRISMA disseminated in biomedical communities, and how has it become so pervasive for authors of systematic reviews? Third, if

the social and practical configurations that led to the construction of PRISMA mirror the making of medical practice guidelines, how do procedural and interventionist paradigms interfere with the prevailing modes of evidence practices or academic cultures?<sup>24</sup>

We believe that understanding these processes can shed light on how evidencing practices are constructed. Interestingly, the case of guidelines for systematic reviews provides an example of how instruments initially designed to guide practitioners outside academia (guidelines) were taken back and adapted to what is central for the research enterprise, the art of presenting evidence in scientific writing. In the next section, we present our approach to tackle the questions mentioned above. Presenting and discussing our results, we provide five sections that are based on different aspects in constructing PRISMA: the creation of a narrative, making the guidelines credible, applicable, and explaining how the guidelines were disseminated, and implemented. Finally, we present a conclusion based on our research questions.

## **Methods and Theoretical Background**

To tackle the research questions above, we conceptualized reporting guidelines as a specific genre of literature, that lies between typically academic and also more performative modes of narrating.<sup>25</sup> Based on this conception, we performed a document analysis to reveal the guideline's rationales and aims as well as the reported methodology that led to its construction. To further deepen our understanding, we developed and performed expert interviews based on the findings.

In a first document search, we explored the environment of the PRISMA guidelines by identifying relevant publications listed on the guideline's website as well as the website of the EQUATOR network, which collects and disseminates various reporting guidelines.<sup>26</sup> We further used the Web of Science bibliometric database to identify all guideline updates, translations, and guideline forks. Focusing on the main PRISMA publications, we performed an exploratory document analysis to study not only its bibliographic but also the textual characteristics.<sup>27</sup> This analysis was guided by a framework which focused on issues of scholarly communication, such as publication formats, authors, referencing, or number of pages.

Key to understanding guidelines such as PRISMA as a genre of their own is the idea that they offer a specific and shared set of communicative purposes which are different from that of traditional research articles.<sup>28</sup> First of all, guidelines appear to be more technical than other forms of scientific writing, providing a list of rules to follow. Yet for these rules to be followed and have an impact, guideline publications needed to be granted legitimacy by community members.<sup>29</sup> Therefore, guidelines also contain textual elements designed for persuasion, that is, a narrative or rationale why

guidelines and standards are needed and why the concrete effort appears to be plausible. For this reason, the document analysis focused on exploring the ways in which the guidelines and the process of creating them were designed to create academic credibility.

To further deepen our understanding of what has been found in the document analysis, we planned and performed semi-structured interviews with six guideline experts during the first quarter of 2021. Interview participants were sampled from authors, translators, or workgroup members of one or more of the PRISMA publications or its updates. While interviews have been anonymized for ethical reasons, the interviewees have been asked to provide substantial information about their role in the development process. Analyzing the interviews, we used deductive coding based on the key themes identified in the document analysis as well as theoretical accounts of standardization, the construction of clinical practice guidelines, and communication in academic communities.

Each of the interview participants had different roles in the making of the earliest version of the guidelines—QUOROM—or one of its later updates. Two were involved as authors in the 1999 version (Participants B and C), and its 2020 version (Participants E and F), while only one authored the 2009 version of the guidelines' explanatory document (Participant A). Most interviewees were part of the expert group that developed PRISMA, yet all of them were researchers active in various fields, such as information retrieval, research ethics, clinical research, or research design. In the 2009 version of PRISMA, two participated in the guidelines (Participants A and B) and one also contributed to the explanatory document (Participant B). Although many workgroup members were listed as authors in the 2020 update, two interviewees remained mere workgroup members (Participants A and B). While all of the interviewees have at least some background in the biomedical sciences, one participant is especially known for his work as an editor of an academic journal (Participant B). Several are also associated with the Cochrane Collaboration (Participants A, B, and F). In addition, one interviewee has substantial experience in the medicine related industry (Participant C).

Our analysis is guided by a framework that focuses on “the multiple ‘worlds’ of a guideline.”<sup>30</sup> It consists of four “worlds,” or repertoires, that express the discursive forces in the construction of guidelines. First, the repertoire of science consists of argumentative strategies about the identification and appraisal of relevant evidence and mainly comes in the form of systematic reviews or meta-analyses.<sup>31</sup> Second, the repertoire of practice, which attempts to link a guideline text to the practices in a clinic in order to evaluate its usefulness. Third, in the repertoire of politics, guideline developers envision different stakeholders to discuss the acceptability of the included statements, and how the guideline embodies political positions that may affect power relations. Last, the repertoire of process understands the group as an apparatus of knowledge generation, which constructs guidelines by employing a reliable methodology.<sup>32</sup>

By identifying such dimensions in the creation of PRISMA, we can analyze substantial similarities between the construction of clinical practice guidelines and reporting guidelines for researchers.

However, we must consider the substantial differences between clinical practices and evidence practices in scholarly communication, and inform the analytical framework proposed above accordingly. Different to other fields, biomedicine has a well-established set of research techniques which lead to determinable and replicable outcomes. When facing new research problems, biomedical researchers can rely on an agreed upon set of practices and tasks to establish knowledge claims. This low level of task uncertainty is characteristic of what Richard Whitley has termed “professional ad-hocracy,”<sup>33</sup> an organizational configuration of professions which are characterized by their degree of division of labor. We are interested in how these task uncertainties are reduced and accepted due to technical standardization and formal training. Such standards enable the communication between distant communities by changing local disciplinary practices in relation to overarching goals and aims.<sup>34</sup> But how does such standard-setting take place?

Scientific communities are structured by disciplinary authorities that define standards and practices in their local domain.<sup>35</sup> In order to retain their status, such authorities eventually become more resistant to overarching standardizations. In comparison to other scientific fields, biomedical communities in particular are more fragmented into local centers of authority that have to negotiate new forms of standards on a dynamic level.<sup>36</sup> In recent years, biomedicine and its subfields have also been influenced by the strengthening of role models to act more autonomously in negotiating priorities between research and application—or bench and bedside.<sup>37</sup> For this reason, establishing standards has become more complicated and requires more rhetoric and discursive effort, in order to not only to be accepted by researchers, but also to compete against other potential forms of standardization, for example, provided by the Cochrane Collaboration. In addition, standard conflicts may not be avoided or resolved by overarching or central authorities, as in the case of clinical practice in which checklists and treatment guidelines are implemented by clinical directors or healthcare policies.<sup>38</sup> Rather, the standard must be made highly compatible with existing and agreed upon disciplinary as well as local regulatory authorities, for example editors of academic journals as the gatekeepers of scientific fields.<sup>39</sup>

Given these theoretical considerations, we extended the “multiple worlds framework,” proposed by Tiago Moreira, to fit the specific characteristics that can be found in academic practices and scholarly communication. First, we put a much stronger emphasis on how the standard employs a narrative for the profession to provide rationales for application and build the “repertoire of science.” Second, we focused on the role of academic journals in disseminating the guideline, for example publishing the guidelines as well as enforcing it by implementation. And we further

investigated how a “repertoire of journals” also influenced the creation of the guidelines in order to fit it into the role of the gatekeepers of science.

### ***Results and Discussion: Invoking the Crisis***

PRISMA attempts to influence the practice of writing systematic reviews. It is dependent on making authors aware of the genre’s shortcomings, and creating acceptance for change. To understand how PRISMA constructs such acceptance and calls for change, we analyzed its argumentative strategies and their evolution. Essentially, in order to persuade readers, the guidelines establish a narrative which makes the practice of systematic reviewing problematic.

PRISMA creates a story about the current state of systematic reviewing, the problems, and the potential solutions—of which the PRISMA guidelines are only one. As such, they not only construct a profession and “enroll” the reader into their reasoning,<sup>40</sup> but also employ an operational mode that calls for action.<sup>41</sup> The professional story unfolds with the role of systematic reviews and meta-analyses for contemporary biomedicine:

Systematic reviews and meta-analyses have become increasingly important in health care. Clinicians read them to keep up to date with their specialty, and they are often used as a starting point for developing clinical practice guidelines.<sup>42</sup>

Beyond iterating the functions and epistemic promises of systematic reviews, this story also creates narrative links to the actors who value and promote them to shape a community.<sup>43</sup> While guideline developers, doctors or healthcare systems are mentioned in all versions of PRISMA, in its first iteration (the QUOROM guideline), it also mentions the Cochrane Collaboration.<sup>44</sup>

In a second step, the guideline texts explain the various flaws in the reporting of systematic reviews. In doing so, the text refers to the common variance in the quality of scientific publications, rather than accusing systematic reviewing or review authors more explicitly.

“As with other publications, the reporting quality of systematic reviews varies, limiting readers’ ability to assess the strengths and weaknesses of those reviews.”<sup>45</sup> In addition, the text refers to several observations to support these claims, and persuades the reader that applying the guidelines will provide a viable solution to the presented problems. In citing studies that either prove the lacking reporting quality of reviews, or evaluate how a guideline can improve reporting, the PRISMA document combines two strands of research into a new story.<sup>46</sup> Utilizing the repertoire of science, it gathers the support of several researchers and their studies to become a technical document itself. This makes rejecting its statements and



conclusions more tedious, since critics have to reject all supporting references and claims.<sup>47</sup>

Each version—QUOROM in 1999, and PRISMA in 2009 and 2020—witnessed roughly a decade of development in systematic reviewing. While the main rationale and several arguments can be found in each version in a similar way, their differences relate to the genre's role for scientific communication. With QUOROM as its first version,<sup>48</sup> the narrative of the responsible profession was built particularly around meta-analyses—the statistical aggregation technique—even though the guideline mentions the conceptual differences between meta-analysis and systematic reviewing by referring to the Potsdam consultation held in 1994, which was one of the earlier international gatherings to discuss the state of research syntheses:<sup>49</sup>

Several queries addressed the distinction between the meta-analysis and systematic review. As we indicate in the introduction, and throughout the statement, the QUOROM group agreed to observe the distinction as defined by the Potsdam consultation on meta-analysis.<sup>50</sup>

In the later versions this was changed.<sup>51</sup> A more inclusive wording was used to explicate a wider methodological scope and applicability. Besides renaming the guideline from QUOROM to PRISMA to actually include the words “systematic review,” its narrative sections now mentioned how the systematic review has become important to actors other than healthcare decision makers or researchers. It adds guideline makers, clinicians, funders, and even journal editors, and thereby claims that the guidelines' role in changing practices is relevant to a wider array of publics and communities.

The updates in 2020 renew the original intentions and target audiences but still mention wide applicability, even for nonmedical practices such as “social or educational interventions.”<sup>52</sup> Although its narrative employs an overall more neutral tone, it distinctively establishes links to other actors that gather around the guidelines. Most notably, it mentions the wide array of PRISMA extensions that modify the 2009 version in order to account for specific review methods, study types, or disciplinary specialties. In addition, the document refers to the EQUATOR network of reporting guidelines, and explains its compliance with the network's guidance on creating reporting guidelines.<sup>53</sup> It thereby stabilizes the PRISMA guidelines by situating them in a network of standardization organizations.

Similar to how the narratives within clinical guidelines evolved from healthcare decision making to other uses of knowledge syntheses, guideline developers aligned PRISMA's story with current topics in the research community. Most notably, several participants elaborated on the relation between PRISMA and the problem of reproducibility or replicability of systematic reviews.<sup>54</sup> Subordinating the problems of systematic reviews under those “new worries of science,”<sup>55</sup> and with PRISMA as a weapon in

the “credibility revolution,”<sup>56</sup> the overall endeavor is equipped with substantial intellectual value and societal legitimization.

The stories, and their evolution during the development of PRISMA and its updates, construct multiple professions. In the early versions, a diverse set of actors such as researchers, practitioners, or policymakers are narrated into a community of users and producers of systematic reviews. Furthermore, PRISMA’s terminology and selection of items for inclusion shapes this community’s genuine understanding of what a systematic review is. Framing the epistemic crises in and around systematic reviewing, the story fuels the quality assurance movement in contemporary biomedicine. This consists of academic researchers and publication experts, who address the problems of reviews by scientifically evaluating the genre. Similar to how traditional review articles narrate topics, assumptions, and results into a scientific field,<sup>57</sup> the guidelines connect topics, arguments, studies, and even institutions.<sup>58</sup> How this profession was shaped into an active discourse community will be elaborated in the next section, in more detail.

### **Guidelines in the Making**

In order to be granted legitimacy, the guidelines had to present the process by which the different items relevant for the practice of systematic reviewing, the contributing guideline authors, and the description of the tasks were articulated. As such, the content of the PRISMA guidelines and its updates were drafted and discussed in several meetings, surveys, and conferences. Based on interviews with the guideline authors and document analysis, we will now further elaborate on the processes that shaped the making of PRISMA. Beside the role of the steering committee, the formation of expert groups, and formal consensus practices, the enrollment of various actors effectively fostered the dissemination of the guidelines and initiated a network of what might be considered as PRISMA’s own professional community.

We first analyzed how, and in what ways, experts were invited, and what role they played in convincing communities to change their practices. The core of the guidelines was formulated by a small group of actors. A central role was taken by the steering committee—as the method sections of the guidelines and our interviews have revealed. As the first iteration of PRISMA was built from scratch, this committee collected available knowledge about reporting, and drafted the first items. It was this group which also coordinated later revisions or versions of the guidelines. Although the updates were built upon each other and involved additional actors, a few core experts still led the development by writing substantial parts of the texts, and dealing with comments. Recalling experiences with other guidelines, interviewees stressed how the steering committee’s efforts can benefit or harm the overall workflow:

When the team is very capable, they would have done a lot of prep (aration) work ahead of time, before they engage with you to solicit input on the specific things. When the team is less capable ... it's going around and around and you never get to what needs to be done or how this can be done in a way that not only incorporate most people's feedback but also efficiently ... in terms of time-wise and how many rounds of revision we need.<sup>59</sup>

Crucial to the construction of PRISMA were the involved experts. Starting with 29 contributors in 1999, growing to 42 in 2009, and finally to 139 in 2020, PRISMA and its network grew substantially over time. Similar to what Latour has called "bringing friends in" to explain the argumentative force of referencing,<sup>60</sup> the number and status of the involved experts provides the guidelines with intellectual and social authority. Since most intended recipients and readers of PRISMA are authors of systematic reviews, the group must achieve a proper representation of disciplinary and methodological plurality to avoid conflicts with local authorities, such as prolific specialists or groups that usually establish disciplinary practices and standards:

So we did the first guideline and it was an interdisciplinary group of people. There were statisticians. There were trialists, people who run randomized controlled trials. And perhaps most importantly, we had some influential journal editors.<sup>61</sup>

Authoring a guideline document such as PRISMA can boost one's academic impact, due to the high citation rates of this genre.<sup>62</sup> In addition to selecting experts based on their skills and roles of contribution, selection criteria must warrant the expert's proper motivation to participate: "As you probably know, these guidelines are highly cited. People want to have them on their CVs. It's beneficial to your career. Sure, if you have something that's been cited a thousand times."<sup>63</sup>

Analyses of each individual author's affiliation reveal that these were carefully selected, each representing different fields of expertise. Negotiating and defending their boundaries against other experts, prolific researchers take a central role and make local authority claims, for example, about valid methods or canonical interpretations. By agreeing or disagreeing on the narratives, other disciplinary researchers gather around these new cores, and build social structures and networks.<sup>64</sup> The disciplinary experts who contributed to the new standard can transform the perception of who (or what) the local authorities are. The local integration of PRISMA devalues systematic reviews that do not comply with this standard. Therefore, as with other standardizations, the negotiation and integration of PRISMA may reshuffle authority claims in biomedical disciplines.<sup>65</sup> Yet, according to our interviewees, the effects of guidelines are often less glamorous than expected

though we have indication from our fieldwork that PRISMA has achieved to become a particularly reputed way of reporting systematic reviews, especially when it is planned as a collaborative endeavor.

But the selection of experts focused not only on the intellectual contribution of experienced researchers but also on the effective dissemination of the guidelines. By bringing experts from different fields into the process of formulating the guidelines, the guidelines become related to these different fields of which these authors were part of. Therefore, the representation of targeted groups is crucial for the acceptance and dissemination of guidelines, as it creates awareness and supports “marketing.”<sup>66</sup> The involvement of journal editors particularly served this role, as one interviewee pointed out:

I remember we would be looking at who were the key stakeholders and journal editors were key with the view that both you’ve got the voice of the journal editor influencing [the] guideline, but you’ve (also) got the ability for other journal editors to say, “Oh, somebody of my type was involved. Maybe I should pay more attention to it.” And then it was a bit of lobbying of the journals to say, “This is a good thing to be doing. It will help your transparency.”<sup>67</sup>

By establishing cross-disciplinary narratives and enrolling various disciplinary authorities, PRISMA can be disseminated and implemented into several biomedical subcommunities. Furthermore, since there is no central authority that issues regulations and standards—setups that can be found, for instance, in clinical practice—guidelines must enroll and cooperate with local authorities in order to become pervasive.<sup>68</sup> In representing the shared efforts of such connected local authorities, the PRISMA documents establish the network of group members and their institutional affiliations. To display this expert group, members were turned into a composite author called “the PRISMA group,” that was listed as last author.<sup>69</sup> In contrast to merely listing the contributors’ names in the acknowledgement, this rather uncommon type of authorship stresses that members contributed in multiple ways in addition to the writing of text. Yet at the same time, the text employs a personal tone which makes not only the authors visible but also the wider group.<sup>70</sup>

How the different experts collaborated with each other on PRISMA is outlined as a method section in the guideline document. This establishes a textual link between the procedure and the resulting guideline items. Additionally, the resemblance to other reports of empirical research presents guideline making as a research process itself. As such, PRISMA attempts to create causal links between the group meetings and the resulting rules for reporting.<sup>71</sup> By unfolding and communicating this link, the text of the guidelines provides the repertoire of process, and attempts to understand the making of PRISMA as a reliable methodology to negotiate and consent on a proper set of rules.<sup>72</sup> Therefore, the social configuration of the expert

group as well as its communicative processes become an abstract recipe that contains mechanisms that build trust and acceptance by the biomedical community.

Turning the construction of PRISMA into an abstract procedure, its techniques were related to other agreed upon methods or standards. This increases the transparency and acceptability of the PRISMA standard, since authors can understand the standard's connections to their local practices.<sup>73</sup> For example, the guidelines and the interview respondents both mentioned the prominent role of the Delphi methodology to achieve formal and reliable consensus. Promoted by the United States' National Institutes of Health (NIH) during the 1970s and 1980s, it has become an established procedure to organize expert consensus and mitigate individual biases.<sup>74</sup> In another example, the PRISMA authors had to comply with the authorship standards of the International Committee of Medical Journal Editors, by omitting "the PRISMA group" as an author in the 2020 version.

Unsurprisingly, guideline construction procedures became standardized themselves. Influential guideline experts have formalized this procedure into "guidance for developers of health research reporting guidelines,"<sup>75</sup> in essence a guideline for creating guidelines, or a practice that constructs evidence practices. As interview participants noted, the PRISMA group was eager to standardize their own communication procedures and contribute to such a guideline. Recalling efforts by one of the leading experts, one interviewee mentioned:

I mean there is standardization at the root of the guideline, but then it's the process and getting to that guideline, that also is its own standardized process that I think he's trying to standardize because there are many different approaches.<sup>76</sup>

In turn, the latest update of the PRISMA guideline was based on this now standardized procedure and also reports its compliance with it. Such "network-building" provides a mutual legitimization of both standards—the guidelines for reporting reviews, and the guidelines for creating guidelines—and makes them more authoritative.<sup>77</sup> Turning its own construction even further into a procedurally regulated endeavor, PRISMA benefits from the same valuations as systematic reviews that comply with PRISMA. Since PRISMA turns practices into evidence-practices by the procedural inscription of values, guideline making has also been transformed into an evidence-practice. In other words, after redefining how knowledge turns into authoritative evidence, the guideline can become evidence by the very same definition.

Beyond the construction and interaction with guideline objects, developers further professionalized the role and authority of guidelines by systematically evaluating their effectiveness. Titles such as "Epidemiology of systematic reviews,"<sup>78</sup> witness how epidemiological methods and concepts were turned into a new professional narrative, coming from "meta-epidemiology,"<sup>79</sup> into

more interdisciplinary conceptions of “meta-research.”<sup>80</sup> Leaving the boundaries of epidemiology aside, interdisciplinary researchers, institutes, journals, and educational programs focused on providing the “the repertoire of ‘science’” in guideline development.<sup>81</sup> Aligning these tasks with the overall goal of moving toward higher quality science and evidence-based medicine, the network became a constituency that not only benefits from various expertise, but also from the representation of different groups.<sup>82</sup>

As we have shown in this section, the steering group attempted to manage what has been called the “second tension” throughout this book. Although the definition and evaluation of guidelines is heavily influenced by scientific practices, the formed constituency provides a cross-professional space where review authors, journal editors, and guideline researchers are invited to contribute. This helped to make the issues of PRISMA visible and valuable to those various contexts. At the same time, the possibility to equally influence the logic of the guidelines avoids the impression that one group or field authoritatively translates its knowledge to another. Thus, potential frictions between the diverse groups were actively minimized throughout the process.

### ***Applicability by Simplicity***

In order to influence writing practices, a guideline needs to formulate concise rules which authors can follow. In this section, we deal with how these items are formulated and—based on the interview results—what motivated the guideline authors to do so.

PRISMA complies with the typical form of a journal publication. As such, it not only provides a structure consisting of a narrative and methodology section but also presents its regulatory items like research results. First, in a sample flow chart, it displays how authors of systematic reviews can properly report the stages of including and excluding primary studies. Second, the item list displays the various aspects and rules of proper reporting, which may be used as a checklist by authors. It grew from six overarching categories that roughly address the stages of reviewing,<sup>83</sup> to 27 separate and rather detailed items in PRISMA’s 2009 version.<sup>84</sup> With the latest update, some of the items were given additional subitems so that the overall number did not change in the 2020 version. As interviewees have noted, much of the efforts during item formulation negotiations were related to stripping down the number of items and rules so that the guidelines would not only be publishable, but also easy to use. Not surprisingly, some respondents have explained that PRISMA represents only the minimum or mandatory reporting, rather than what could be considered as recommended or optimum.

Because things were discussed (that) we couldn’t possibly put everything in. So we had sort of an outline about which would be the required items in the checklists. And that’s what the majority of the time the in-person meeting was involved with, then we all went away.<sup>85</sup>

In its focus on PRISMA's applicability, the group took a different approach to other attempts in standardizing the methodological quality of reporting or conduct. Especially in the case of systematic reviewing, potential guidelines compete against the epistemic and social authority of the Cochrane Collaboration. By providing extensive and strict methodological guidance for conduct and reporting, software infrastructures, detailed editorial supervision, and publication in its own database, the Cochrane Collaboration defines the overall process of systematic reviewing on a much more comprehensive level.<sup>86</sup> For this reason, interviewed participants not only mentioned the greater quality of Cochrane reviews in conducting and reporting but also the much higher efforts to perform and write them. Thus, the group also implicitly focused on applicability by juxtaposing their goals and efforts to those of Cochrane.

Cochrane is very detailed, and there's Cochrane for every kind of thing that you want to do. It was clear from the get go, that we were not going to be a Cochrane group, we were not going to hang together for the rest of our careers doing this.<sup>87</sup>

Limiting the size and scope of guidelines is a common phenomenon in the construction of clinical treatment guidelines. Since the guideline has to fit into its applicatory context, the group tries to envision the "repertoire of 'practice,' which refers to the usefulness of the guideline."<sup>88</sup> Developers weigh the guidelines' knowledge claims against the circumstances of different contexts and usage cases in order to judge whether the guidelines will be useful and improve the overall outcome. In contrast, extraordinary situations may demand improvisation and are not covered by the guidelines' knowledge claims, rendering it inapplicable or useless. Envisioning such cases enables developers to configure the standard's complexity and scope of application.

A careful consideration of complexity and scope is particularly important for the dissemination of multidisciplinary guidelines, such as PRISMA.<sup>89</sup> Highly applicable guidelines provide substantial support in most situations and practitioners perceive them to be useful, so that they willingly accept the guideline. In addition, translations into different languages increased its applicability among nonacademics, especially medical practitioners, as one interviewee noted.<sup>90</sup> Therefore, what some interviewees perceived to be "the minimum," may be better interpreted as the most cost-effective level of reporting, in which the effectiveness of each rule is weighed against the necessary efforts to comply with it.<sup>91</sup>

Seen in this light, PRISMA's particularly restricted focus on reporting makes it applicable as a standard for systematic reviews of various study types and research topics. In contrast to Cochrane's standard, which provides guidance for the design and conduct of reviews, PRISMA explicitly regulates only the writing of reviews, and tells authors what details have to

be included in their manuscript. Although the distinction between conduct and reporting is fuzzier in the case of reviews than in clinical trials, the focus on reporting avoids conflicts with methodological plurality, as participants explained. In that sense, the guideline limits its own scope and controls the number and size of targeted groups, which makes potential conflicts manageable.<sup>92</sup> However, the restriction to reporting also mobilizes the regulatory capabilities of academic journals, as we will explain in the next sections.

## **Dissemination by Journals**

The guidelines were published in biomedical journals in order to effectively reach potential authors of systematic reviews. In this section, we discuss some of the unique characteristics of its publications, found during the document analysis and the interviews.

The PRISMA documents were published in multiple scientific periodicals. While QUOROM was published only once,<sup>93</sup> the 2009 version was published in seven different journals,<sup>94</sup> and was officially translated three times,<sup>95</sup> in order to quickly approach multiple biomedical sub-communities. Likewise, the explanation and elaboration document—an additional paper that offers a more detailed look into the guideline's items and also provides some examples—was published in five different journals in 2009 and translated once.<sup>96</sup> The latest update has been published as a pre-print, and in five different journals.<sup>97</sup> In addition, there was one additional explanatory document.<sup>98</sup> Since cross-publication is usually considered unethical for researchers, interviewees noted how it was suggested and discussed by the team's publication experts.

Beside the potential for faster communication, cross-publication also promised wider access, since researchers and their respective institutions may have different journal subscriptions. But it also means the involvement of multiple editorial offices and peer review processes, which demands huge efforts from the guideline developers. In addition, different editorial standards or peer reviews can lead to huge variations in the final documents, although all are intended to represent the same standard.<sup>99</sup> More strikingly, since the guidelines already incorporate the intellectual contributions of many experts, peer reviews may undermine the sophisticated consensus practices. As one participant noted:

What I would call the aftermath of that ... was a general sense of, "we're not going to do this again." Why are we publishing in so many journals the same thing? And it is one of the challenges with publishing. That means what are the journal(s) supposed to do about peer review, given that so many dozens of people have been involved in reaching this consensus? How can any of that be changed by one or two peer reviewers?<sup>100</sup>



The guidelines were placed among some of the “big five,”<sup>101</sup> which are the most impactful journals in biomedicine. While QUOROM was the only document in *The Lancet*, PRISMA of 2009 and its 2020 update were published in the *British Medical Journal* and *Annals of Internal Medicine*. Other journals were *PloS Medicine*, the *Journal of Clinical Epidemiology*, the *International Journal of Surgery*, *Systematic Reviews*, *Open Medicine* (discontinued), *Physical Therapy*, and the *Italian Journal of Public Health*. In addition, four official translations are listed on the PRISMA website, of which three were also published in national journals.

In the interviews, participants argued that the group targeted high impact journals, as these have more resources for methodological quality assurance, and the necessary awareness for improving reporting. But more importantly, such journals improve the dissemination, since they are more central and authoritative within their respective communities. High impact can be achieved by specialized journals that have become local authorities within usually smaller sub-disciplines. On the other hand, generalized journals often reach high citation impacts too. Since such generalized journals target various audiences or even link many sub-disciplines, their published methods and standards are subject to intense criticism and academic competition.<sup>102</sup> Therefore, the successful enrollment of more generalized journals into PRISMA’s narrative provides the guidelines with cross-field legitimization and authority.

In publishing and implementing PRISMA, a journal can make an individual commitment toward reporting quality in its domain. The journal employs the professional story of the guidelines, and aligns itself with the experts and networks that developed the guideline; whether they are from the same domain as the journal or not. But similar to the guideline developers that contributed mainly in order to boost their academic recognition, journals benefit from PRISMA’s high impact too. Not surprisingly, interview participants noted that cross-publication was brought up by journal editors, and some of them might have been motivated by improving the impact metrics of their periodicals. Similar to scholars who can shape their epistemic practices in accordance with such metrics,<sup>103</sup> journal editors try to influence their metrics by inviting authors or to solicit review articles.<sup>104</sup> Likewise, journal editors can participate in the development and dissemination of highly cited guidelines and standards.

### ***Enforcement by Gatekeeping***

In contrast to other standard innovations, PRISMA would also be implemented into editorial processes, so that authors of systematic reviews would have to comply with PRISMA in order to get their manuscript accepted. In this section, we discuss the extent and role of this practice. Usually, new standards or methods for “doing science” become established by orchestrating and demonstrating their epistemic superiority, so as to

finally persuade individual researchers. Whereas evaluation and demonstration of effectiveness ordinarily requires time and additional resources, as explained above, PRISMA was legitimized with the help of the participation of prolific researchers and, as will be shown, academic journals.

Traditionally, individual researchers demand more evidence for a standard's effectiveness before they comply with, and this can hinder quick acceptance and dissemination.<sup>105</sup> Many methods or standards become pervasive only due to traditional modes of academic quality assurance; largely, peer review. Since, in a peer review system, experienced and prolific scientists evaluate the intellectual contributions of other researchers, they can utilize whatever standard or guideline they find appropriate. Although this system generally ensures a certain level of academic quality control, it notably did not prevent the decrease in reporting quality in the first place.

However, peer reviewers may now consider PRISMA when they appraise the reporting quality of systematic reviews, or when editors ask them to do so. But this still means that the dissemination and application of guidelines is dependent on the awareness, and application by many individuals. So, varying expertise in relation to reporting does not only result in authors submitting incompletely reported manuscripts, but also peer reviewers not detecting the flaws.

“Unfortunately, you’re assuming everybody is at (a) certain level. You are assuming people would know how to write a paper, but that’s not the case.”<sup>106</sup>

In addition to the role of peer reviewers in the evaluation of manuscripts, editorial offices also have substantial influence on deciding whether a submission will be published or not. Usually, editors decide which submission will be sent for review, and select appropriate peers, which is why they are called the “the gatekeepers of science.”<sup>107</sup> They determine the intellectual contexts of a submitted manuscript and also heavily influence formal characteristics of the texts, such as writing styles or references.<sup>108</sup> In fact, interviewees have mentioned that editorial offices may even have aggravated the reporting crisis by putting limitations on word or reference counts. Nevertheless, guideline developers hoped that PRISMA would be implemented into journal processes and overseen by editorial offices or method editors.

Ideally, authors would fill out the checklist and submit it as additional material together with their manuscript. The editorial office or specifically trained methods experts would then appraise the manuscript and the checklist in order to judge the level of compliance. Due to the procedural nature of PRISMA, compliance can be checked on a per-rule basis, which turns the overall handling into a more formalized process that can be performed without proficiency in either the content or method of the review. Such a process could even be automated, similar to the checking of statistical reporting.<sup>109</sup> Utilizing editorial capacities in advance of the peer

review system would provide the necessary centrality to ensure that every systematic review is judged by the same criteria. This increases the authority of PRISMA by extending its intellectual authority with a more formalized type of regulation enacted by the gatekeepers of science.

Beyond the publication in high impact journals, several journals officially endorsed the guideline. As the 2020 version concludes, PRISMA was endorsed by almost 200 journals or organizations publishing systematic reviews, which provide the guidelines with the necessary outreach to achieve a wide dissemination. However, the mere endorsement does not clarify the actual level of implementation which can vary a lot. So, while engaged editors verify the submitted checklists and occasionally ask authors for further clarifications, other endorsers may just publish them together with the manuscript.<sup>110</sup>

As our interviews have shown, the goal of making PRISMA implementable by academic journals played a crucial role in the making of the guidelines. As Tiago Moreira suggests, guideline makers discuss the acceptability of the guidelines by assessing the “repertoire of ‘politics.’”<sup>111</sup> In doing so, they envision the guidelines’ recommendations through the lenses of the various groups and identify potential lines of conflict. In interpreting the relations between authors and journals, the PRISMA group imagined the latter’s regulatory capacity and decided what editors can demand from authors, before they withdraw their submissions and turn to a competitor. As already indicated above, the often emphasized boundary between conduct, as performing the review, and reporting, as writing down the results, reflects the careful appraisal and utilization of these regulatory capacities. In other words, PRISMA was tailor-made to be implemented on the journal level, as participants explained:

Journals are able to implement a guideline by way of telling authors who must adhere to this guideline, it’s a lot easier to get to authors and researchers that way. I think that’s one of the key reasons from my understanding as to why reporting guidelines have been the focus over conduct guidelines.<sup>112</sup>

Reducing the guidelines to a very specific set of values and requirements enables the journal to establish it as a required standard. Although academic journals have achieved some level of authority independent of individual experts or the overall referee system, they are subject to various epistemic and social constraints.<sup>113</sup> As such they must navigate between the economic expectations of the publishers, and authors who might submit to a different periodical if the imposed formal requirements become too burdensome or not applicable to their research.<sup>114</sup> Similar to when clinical guidelines are neglected whenever anomalies occur during medical treatments, authors can turn to a different journal when their systematic reviews are of such a type that PRISMA is not applicable. In this respect, the spread of PRISMA

is more like standardization in the industry, in which standards are issued by a variety of competing organizations that develop and market their standards as a form of decentralized regulation or soft law.<sup>115</sup>

### **Templating Evidence in Biomedicine**

In this study, we tried to understand how biomedicine's most appraised evidence practice, the writing of systematic reviews, is shaped and defined by formal standards, most notably the "preferred reporting items for meta-analyses and systematic reviews,"<sup>116</sup> or PRISMA. Understanding this reporting guideline as an attempt to standardize evidence practices, we investigated how texts, researchers, methodologists, and journal editors got engaged in social configurations and practices to create a guideline that is applicable, and acceptable. To do so, we performed a document analysis of the PRISMA reporting guideline, and interviews with its developers. By using the "multiple worlds" framework suggested by Tiago Moreira,<sup>117</sup> we identified several similarities and differences between the construction of PRISMA and clinical treatment guidelines.

The emergence of PRISMA exemplifies the interaction of medical practice and biomedical research, described as the "second tension" throughout this book. In telling a coherent story about the problems of systematic reviewing and how those can be solved, PRISMA focuses on the practices of reviewing and how those can be improved procedurally. Conceived as a regulatory tool, PRISMA represents an intervention aimed at improving reports of systematic reviews so that they can be considered as biomedical evidence. This originates from what is often understood as the core of evidence-based medicine, in which doctors are provided checklists and standards to increase treatment uniformity and reduce errors.<sup>118</sup> Likewise, PRISMA tries to guide authors through the writing of systematic reviews to ensure that all reviews contain the necessary information and nothing is left out. So, the basic principles behind the improvements of medical practices were used to improve evidence practices such as systematic reviewing.

In becoming a new standard, PRISMA interferes with already established practices and local authorities that have defined the characteristics of systematic reviews. In our analyses, we found that some efforts were taken to make PRISMA applicable, as well as acceptable. Besides keeping the guidelines rather simple for easy application, it was designed with respect to the regulatory capabilities of academic journals. Since PRISMA focuses only on reporting, compliance can be enforced or supervised by editorial offices. This turned the guideline not only into a regulatory tool for journal editors, but also fostered a wider dissemination and application. In addition, its developers formed a professional community that evaluates endorsements and compliance with PRISMA. This community also provides

updates and extensions in order to keep PRISMA relevant to contemporary trends in biomedical research.

Our analysis has shed some light on the configurations and decisions that enabled the wide dissemination and application of the PRISMA guideline in a diverse and global endeavor that lacks in central authorities. As such, this study provides insights into standardizations and the very mechanisms that shape evidence practices in science. Since disciplines such as the social sciences, psychology or climate science also proclaimed crises, our results can be used to inform similar efforts in those fields, or at least, explain if and when such forms of overarching standardizations are inapplicable.<sup>119</sup> However, more research is needed to better understand some factors affecting the dissemination and application of PRISMA, as well as the reflexive discourse that follows its implementation.

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