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Evaluation of the development process and impact of the S3-guideline for the prevention and control of SARS-CoV-2 transmission in schools

Dissertation

zum Erwerb des Doktorgrades der Medizin an der Medizinischen Fakultät der Ludwig-Maximilians-Universität zu München

vorgelegt von

Katharina-Jaqueline Pascale Wabnitz

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Erstes Gutachten: Prof. Dr. Eva Rehfuess

Zweites Gutachten: Prof. Dr. Georg Marckmann

Drittes Gutachten: Prof. Dr. Tobias Dreischulte

Dekan: Prof. Dr. med. Thomas Gudermann

Tag der mündlichen Prüfung: 10.01.2025

Affidavit



LUDWIG-MAXIMILIANS-UNIVERSITÄT MÜNCHEN

Promotionsbüro Medizinische Fakultät





Affidavit

Wabnitz, Katharina-Jaqueline Pascale	
Surname, first name	
Street	
	_
Zip code, town, country	
hereby declare, that the submitted thesis entitled:	
Evaluation of the development process and impact of the S3 control of SARS-CoV-2 transmission in schools	-guideline for the prevention and
(Evaluation des Erstellungsprozesses und der Nutzung der S3 trolle der SARS-CoV-2 Übertragung in Schulen)	-Leitlinie zur Prävention und Kon-

is my own work. I have only used the sources indicated and have not made unauthorised use of services of a third party. Where the work of others has been quoted or reproduced, the source is always given.

I further declare that the dissertation presented here has not been submitted in the same or similar form to any other institution for the purpose of obtaining an academic degree.

Gräfelfing, 12.06.2025 place, date

Katharina Wabnitz Signature doctoral candidate

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List of abbreviations

AWMF Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachge-

sellschaften (Association of the Scientific Medical Societies)

COVID-19 coronavirus disease 2019

EBM evidence-based medicine

EBPH evidence-based public health

EIPH evidence-informed public health

EtD framework Evidence-to-Decision framework

FolA Freedom of Information Act

LMU Ludwig-Maximilians-Universität

NICE National Institute for Health and Care Excellence

PHSM public health and social measures

SARS-CoV-2 severe acute respiratory syndrome coronavirus 2

WHO World Health Organization

List of tables and figures

Table 1: Methods overview of sub-studies I and II

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List of publications

Paper I for this dissertation

Wabnitz, K., Rueb, M., Pfadenhauer, L.M., Strahwald, B., Rehfuess, E.A. Rapid development of an evidence- and consensus-based guideline for controlling transmission of SARS-CoV-2 in schools during a public health emergency – A process evaluation. Frontiers in Public Health 11:1075210 (2023)

Paper II for this dissertation

Wabnitz, K., Rueb, M., Rehfuess, E.A., Strahwald, B., Pfadenhauer, L.M. Assessing the impact of an evidence- and consensus-based guideline for controlling SARS-CoV-2 transmission in German schools on decision-making processes: a multi-component qualitative analysis. Health Res Policy Sys 21, 138 (2023).

1. Your contribution to the publications

1.1 Contribution to paper I and journal impact factor

Title Rapid development of an evidence- and consensus-based guideline

for controlling transmission of SARS-CoV-2 in schools during a pub-

lic health emergency – A process evaluation

Authors Wabnitz, K.*, Rueb, M.*, Pfadenhauer, L.M., Strahwald, B., Re-

hfuess E.A.

Journal Frontiers in Public Health

Impact Factor 5,2 (2022)

Journal ranking (2022)

Category 1: Public, environmental & occupational health (Social Sciences Cita-

tion Index (SSCI)) Rank: 25/180

Percentile in Category: 86,4

Category 2: Public, environmental & occupational health (Science Citation Index

Expanded (SCIE))

Rank: 43/207

Percentile in category: 79,5

Contribution

The doctoral candidate, LMP and MR jointly developed the protocol for this research with substantial input from EAR and BS. Recruitment, data collection and analysis were carried out jointly by the doctoral candidate and MR: The doctoral candidate and MR alternately assumed the interviewing and observing roles in an equal number of interviews. The doctoral candidate and MR independently wrote memos after each interview. The doctoral candidate developed a first version of the deductive coding framework and carried out the first round of deductive coding of all interviews. The doctoral candidate carried out the first round of inductive coding of all interviews, developing further codes and sub-codes. The doctoral candidate and MR discussed the deductively and inductively developed codes and MR reviewed all coded interviews. The doctoral candidate and MR resolved any disagreements during the coding process through discussion. All authors discussed the results and their implications. The doctoral candidate wrote the first draft of the manuscript and led the subsequent process of incorpo-

^{*}These authors share first authorship for this paper.

rating co-authors' comments before first submission as well as the process of responding to peer reviewers' comments during the publication process.

1.2 Contribution to paper II and journal impact factor

Title Assessing the impact of an evidence- and consensus-based guide-

line for controlling SARS-CoV-2 transmission in German schools on decision-making processes – a multi-component qualitative analysis

Authors Wabnitz, K., Rueb, M., Strahwald, B., Rehfuess, E.A., Pfadenhauer,

L.M.

Journal Health Research Systems and Policy

Impact Factor 4,0 (2022)

Journal ranking (2022)

Category Health policy & services (Social Sciences Citation Index (SSCI)

Rank: 16/87

Percentile in category: 82,2

Contribution

The doctoral candidate, LMP and MR jointly developed the protocol for this research with substantial input from EAR and BS. Recruitment and data collection were carried out jointly by the doctoral candidate and MR: The doctoral candidate and MR alternately assumed the interviewing and observing roles in an equal number of interviews. Data analysis was carried out mainly by the doctoral candidate: The doctoral candidate developed the deductive coding framework and carried out the deductive coding of all interviews as well as the first round of inductive coding of all interviews, developing further codes and sub-codes. The doctoral candidate and MR discussed the deductively and inductively developed codes and MR reviewed a subset of all coded interviews. The doctoral candidate and MR resolved any disagreements during the coding process through discussion. The doctoral candidate carried out further reviews of the coded data. All authors discussed the results and their implications. The doctoral candidate wrote the first draft of the manuscript and led the subsequent process of incorporating co-authors' comments before first submission as well as the process of responding to peer reviewers' comments during the publication process.

2. Introduction

2.1 Evidence-informed decision-making in public health

2.1.1 Tracing the origins of evidence-informed public health decisionmaking

Since the Second World War, scientific evidence has increasingly been embraced as a foundation for political and practical decision-making across sectors (1). The health sector, particularly clinical practice, can be seen as very influential in shaping and adopting the ideas and tenets of what came to be known as evidence-based decisionmaking. By the end of the 20th century, the term "evidence-based medicine" (EBM) was coined and defined by Canadian clinical epidemiologists as "...the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients" (2). Concomitantly, "evidence-based public health" (EBPH) was described as the "conscientious, explicit, and judicious use of current best evidence in making decisions about the care of communities and populations in the domain of health protection, disease prevention, health maintenance and improvement (health promotion)" (3). It is noteworthy that both definitions do not further explicate the concept of evidence. In the realm of public health, three types of evidence have been proposed: evidence highlighting the strength and direction of associations between risk factors and diseases; evidence describing the impact of specific interventions to improve population health (4) and evidence that provides information on successful implementation of those interventions (5). Making evidence-based decisions in public health requires the systematic identification, assessment and synthesis of the best available scientific evidence, being transparent about uncertainty and conflicts of interest and a structured process to reach decisions (6). The inclusion of community perspectives and preferences was posited as integral to EBPH as early as 2004 (7), analogous to the understanding of EBM as being the integration of the best available scientific evidence with clinical expertise and patient values (8). The term "evidenceinformed public health" (EIPH) explicitly acknowledges that beyond scientific evidence and community preferences, further factors such as financial, material, and human resources, contextual factors and the political climate are important and need to be considered in decision-making processes (9).

2.1.2 Challenges arising at the science-policy interface in public health

There are two main sources for those challenges that typically characterise the interface between public health science and policy.

The first source is complexity in the interventions and how they interact with society: Public health interventions are often complex in that they contain multiple interacting components (10). Further, these interventions are increasingly conceptualised as "events in [complex] systems" (11). This means that public health interventions do not take an effect independently from the context into which they are introduced but are shaped by and shape this context. As a result, the relationships between interventions and outcomes of public health measures are often non-linear and emergent from the interaction between different parts of the system's context, its constituent agents and the intervention (12). For evaluation of effectiveness, this stipulates a "focus on the dynamic properties of the context into which the intervention is introduced" (13), rendering public health intervention evaluation studies more complicated and resourceintense. Additionally, public health measures can have unintended effects beyond health outcomes which ought to be anticipated and considered. Therefore, reliable and high-quality evidence of intervention effectiveness and of the extent and type of unintended consequences is often lacking or cannot be readily transferred from one context to another. Settings such as workplaces, communities and schools have been described as complex systems (11).

The second source is political and practical decision-making and underlying values and worldviews: While an intervention might have been proven to be effective in addressing a particular population health issue, this does not readily translate into social desirability or acceptance by relevant stakeholders and with that, into a political or practical priority (1). Put differently, public health decision-making, by virtue of affecting and being affected by a range of factors beyond evidence of intervention effectiveness, is usually about negotiating societal preferences and values alongside scientific, technical and financial considerations (14). It is therefore also inherently complex.

2.1.3 Public health guidelines to facilitate evidence-informed decisionmaking

To aid EIPH decision-making, recommendations in the form of public health guidelines are being developed by the World Health Organization (WHO) (15) and national level institutions such as the National Institute for Health and Care Excellence (NICE) in the UK (16). Evidence-to-decision (EtD) frameworks compile substantive criteria (i.e., those aspects that are relevant for the guideline development process as they influence or are influenced by implementation of the guideline) and/or procedural criteria (i.e., how the guideline should be developed, e.g., systematically or transparently) (17). These frameworks can be used to ascertain that all relevant factors and outcomes are considered in the development of recommendations and to enable transparent reporting (18). This is particularly relevant for the development of rapid guidelines in the face of emergencies.

Not only do such criteria need to be considered but they also need to be weighed up in the process of developing recommendations given that it is usually impossible to fully avoid trade-offs between intended and unintended outcomes of measures. Including stakeholders, i.e., those affected by implementation of recommendations and considering their values and preferences, is considered good practice for public health guidelines (15), as it is for clinical guidelines.

As a result, public health guideline development is not only about compiling and assessing the available evidence of intervention effectiveness and further (unintended) outcomes. It is also about negotiating the values which are to guide the process of developing recommendations as well as the resultant weighting of decision criteria and degree of acceptability of trade-offs between intended and unintended outcomes.

Evidence on the implementation or impact (in the sense of their role in decision-making processes) of public health guidelines was found to be scarce (19).

2.2 Public health decision-making under uncertainty during the COVID-19 pandemic – the case of schools in Germany

The following section highlights how the above-described challenges and characteristics of EIPH decision-making were present in the case of implementing public health and social measures (PHSM) in schools as part of the COVID-19 response in Germany.

Especially in the context of an air-borne, highly contagious virus such as severe acute respiratory syndrome corona virus 2 (SARS-CoV-2), PHSM such as mask mandates and social distancing can be important tools to ease the strain on health care systems and society (20). Decision-making by politicians and practitioners regarding the choice and implementation of these measures was subject to immense time pressure as well as "complex, intersecting social, economic, and political pressures" (21). Scientific evidence for effectiveness as well as unintended consequences of PHSM implemented during the COVID-19 pandemic, let alone unintended effects of these, was patchy at first, sometimes conflicting but also rapidly evolving and therefore partly unscrutinised (22-26).

Hence, making evidence-informed decisions regarding PHSM in specific settings such as schools was very challenging. In many countries, including Germany, schools were closed entirely at the beginning of the pandemic although most evidence on the effectiveness of closing schools stemmed from seasonal influenza control (27) and evidence for a range of negative effects of school closures, such as impaired child mental health or loss of income of caregivers was available from previous outbreaks (28-30) and being gathered for COVID-19 (23). With growing evidence supporting the relatively minor role of school-based outbreaks in community transmission and the less severe impacts of COVID-19 on young people (31), keeping schools open became more of a political priority in Germany and internationally (32, 33). Interventions aiming to keep schools open safely (ff. school measures, excl. school closures) include measures which decrease the likelihood of contacts; measures which render any contacts safer; and surveillance and response measures (26).

Political decision-making regarding the design and implementation of school measures in Germany led to heterogenous levels of restriction across Federal States (34). Relatedly, diverse sources of scientific policy advice were consulted, ranging from individual experts over existing institutions, such as the Robert Koch Institute and the German National Academy of Sciences Leopoldina, to ad hoc established expert committees (35). The latter were shown to often be dominated by biomedical expertise and to be intransparent in their activities (36).

To provide decision-makers across Federal States with a scientifically robust and legit-imate tool to aid decision-making regarding PSHM in schools, a multi-disciplinary and multi-stakeholder panel including scientists, public health practitioners, students, parents, and teachers was convened. They aimed to rapidly develop an evidence- and consensus-based guideline (ff. S3-guideline) for PSHM in schools. The Association of the Scientific Medical Societies (Arbeitsgemeinschaft der Wissenschaftlich Medizinischen Fachgesellschaften, AWMF) oversees the development of guidelines for clinical practice in Germany. Guidelines by the AWMF are categorised based on the extent to which "elements of systematic development" (37) are applied with S3 denoting a guideline to be both evidence- and consensus-based.

2.2.1 A rapid guideline for decision-making regarding PSHM in German schools during the COVID-19 pandemic – rationale for evaluation

The rapid development of an S3-guideline for decision-making in the political instead of the clinical realm was unprecedented in Germany. The inclusion of stakeholders who were not representative of patient groups but of those groups affected by PHSM in schools (i.e. students, parents and teachers, ff. school family) resulted in a very diverse panel. Procedures for clinical guidelines established by the AWMF, notably systematic evidence searches and formal consensus-building processes for recommendations were adopted for this guideline development process (38). To enable the systematic and transparent consideration of unintended consequences, the novel WHO-INTEGRATE Evidence-to-Decision (EtD) framework was applied during the process (14). This framework was developed to support decision-making "about complex interventions in complex systems" (14). To the knowledge of the doctoral candidate, this EtD framework had not been formally applied in Germany before. The framework posits that six criteria and quality of evidence are to be considered when developing recommendations. These criteria are "balance of health benefits and harms, human rights and sociocultural acceptability, health equity, equality and non-discrimination, societal implications, financial and economic considerations and feasibility and health system considerations" (14). Consideration and weighing up of these criteria ought to be enabled by including appropriate types of evidence and expertise for each in the development of recommendations.

In light of these novel aspects which characterised this guideline development process as well as the substantial resources it required and the need to understand the usefulness and usability of different tools to support EIPH decision-making – particularly dur-

ing emergencies – an evaluation of this guideline was deemed important. A multipronged approach was conceived to evaluate the strengths and weaknesses of the guideline development process and to assess whether this guideline had an impact on decision-making regarding PSHM in schools, i.e., whether it was known and/or used by political and practical decision-makers.

2.3 Research questions

The overarching research question for the evaluation of the S3-guideline for the prevention and control of SARS-CoV-2 transmission in schools (ff. S3-guideline) was: What can be learned from the guideline development process as well as from its reception in the media and in politics?

Two sub-questions were developed to be answered in two separate studies:

- 1. How did guideline panel members perceive the guideline development process and what were its strengths and weaknesses? (Sub-study I)
- 2. What was the impact of the guideline on decision-making processes at the Federal and Federal State level? (Sub-study II)

Results of sub-studies I and II were published in peer-reviewed journals (paper I and paper II, respectively) and are hereby submitted as a cumulative dissertation and further described below.

2.4 Overview of the dissertation

The methodological steps for each study are summarised in table 1.

Ethical approval for the whole project was obtained prior to recruitment of participants in both sub-studies from the Ethics Committee of the Medical Faculty, Ludwig-Maximilians-Universität München (No. 21-0944). All interview participants received study information sheets and gave written informed consent prior to inclusion.

Table 1: Methods overview of sub-studies I and II (tabular overview of sub-study II adopted from table 1 in (39))

	Sub-study I		Sub-study II	
		Component 1	Component 2	Component 3
Sampling frame	Guideline panel mem- bers	16 Federal State ministries of education, family and health	Individuals involved in decision-making regarding school measures in Bavaria and	Guideline panel mem- bers

			Bremen	
Data coll- ection	Semi- structured interviews	Inquiries via e- mail according to Freedom of Information Acts (FoIA) of each Federal State	Semi-structured	l interviews
Data ana- lysis	Thematic qualitative content analysis according to Kuckartz (40)	Categorisation of responses	Thematic qualitative content analysis according to Kuckartz (40)	
Integration	Not applicable	Narrative integration of results		

2.4.1 Sub-study I: Process evaluation of the guideline development

2.4.1.1 Methods

To assess the strengths and weaknesses of the guideline development process, we used a qualitative retrospective design. A qualitative approach was deemed appropriate given that we wanted to assess how individuals who were part of the guideline development process experienced it (41). Because of severe time and resource constraints, concomitant research was not feasible. We carried out virtual semi-structured interviews with guideline panel members who we recruited purposively with a view to including at least two individuals per stakeholder group (scientists, practitioners (at local health or school authorities), school family, observers) and the guideline secretariat. To select among those in all stakeholder groups who expressed their willingness to participate in the study, we used a virtual random order generator to eliminate researcher selection bias. Interview topics were a) participants' perception of the guideline development process, b) their understanding of evidence and expertise and of the role of evidence and expertise in the process and c) their views on the consideration of further implications and unintended consequences of PHSM in the guideline development process (42). We applied Kuckartz' deductive-inductive thematic qualitative text analysis to analyse the data (40). As interviews were carried out in German, the final category system as well as quotes used in the peer-reviewed article were translated into English by the doctoral candidate and reviewed by a second author.

2.4.1.2 Results

Findings were structured in a category system consisting of four deductively developed main categories all of which include two to three inductively developed sub-categories (Table 2).

Table 2: Category system for sub-study I (process evaluation), adopted from Annex 2 in (42)

Main categories	Sub-categories
Perception of the guideline development process	Methods and implementation of the guideline development process
	Guideline development under time pressure
Evidence and its role in the process	Understanding of scientific evidence
	Role of evidence in the process
Expertise and its role in the process	Understanding of expertise
	Role of expertise in the process
	Hierarchies in relation to expertise and degree of involvement
Consideration of societal implica- tions and unintended conse- quences	Experience with applying the WHO-INTEGRATE framework
	Lack of evidence and expertise regarding unintended consequences and societal implications
	Usefulness of applying an Evidence-to-Decision framework

Owing to time constraints, the guideline secretariat (scientists based at the Chair of Public Health and Health Services Research at the Ludwig-Maximilians Universität Munich who oversaw the process scientifically and convened the guideline panel in cooperation with the AWMF) played a steering role not only in identifying and assessing the evidence but also in formulating recommendations. Some methodological decisions concerning e.g., prioritization of endpoints, panel member selection and the involvement of the school family in recommendation development were reflected upon critically. In principle, there was consensus regarding the critical role of evidence in the development of recommendations. However, given guideline panel members' diverse scholarly and non-scholarly backgrounds, their understanding of scientific evidence, quality criteria thereof as well as opinions regarding the relative importance of certain types of evidence, was rather divergent. This could not be sufficiently addressed in the short process of guideline development and presented a challenge in addition to the

inherent limitations of the available evidence base. These included lack of availability of empirical studies, a time lag between collection of data included in available studies and the pandemic status quo at the moment of guideline development and limited transferability of evidence from settings other than the school setting to the school setting. Three sources of expertise characterised the guideline panel: expertise grounded in scientific studies and disciplinary knowledge, expertise as lived experience of being affected by school measures and expertise as practical experience with implementing school measures (42). Generally, expertise was deemed very important given the limitations of the published literature and the need to weigh up and interpret it as well as to include practical considerations. However, hierarchies based on possessing certain academic credentials, experience with guideline development and an academic background to begin with were perceived within the panel. Both evidence and expertise in relation to some decision criteria (namely legal issues and macroeconomic consequences of measures) stipulated by the WHO-INTEGRATE framework were missing and some criteria received more attention than others. Panel members who were not part of the smaller working groups where it was explicitly applied, recalled that weighing up of criteria happened mostly in discussion during full panel meetings. Decisions regarding the application of this framework, particularly in the context of a rapid guideline, were questioned. Its full potential might not have been utilised.

2.4.2 Sub-study II: Evaluation of the guideline's impact on political and practical decision-making

2.4.2.1 Methods

A multi-component design was applied to assess the guideline's impact, as outlined in Table 1 above. Impact was defined as "knowledge about and use of the S3-guideline by political and practical decision-makers" (39).

For component 1 of this sub-study, we sent inquiries via e-mail following the FoIAs of each Federal State to all Federal States' ministries of education, health, and family, respectively.

For components 2 and 3, we carried out semi-structured interviews with individuals involved in decision-making in Bavaria and Bremen and with guideline panel members, respectively.

Bavaria and Bremen were chosen for their very dissimilar settings with Bavaria being the second most densely inhabited and a rather wealthy Federal State in the South of Germany and Bremen being a smaller, comparatively less wealthy city-state in the North of Germany. Since a rather low response rate from individuals involved in decision-making was expected, we complemented component 2 (interviews with individuals involved in decision-making) with inquiries following the FoIA of each Federal State (component 1) and interview data with guideline panel members (component 3). We assumed these interviews to yield rich data to answer the research question for this

sub-study because of participants' special interest as well as involvement in decisionmaking processes concerning school measures.

Kuckartz' deductive-inductive thematic qualitative text analysis was applied for analysis of the interview data (40) and replies to the FoIA inquiries were categorised using the categories yes/no/unclear.

2.4.2.2 Results and interpretation

Analysis of responses to the FoIA inquiries showed that all nine Federal State ministries of education that provided a response, knew the guideline. The guideline was used to check existing directives in five of those and contributed to changes in directives for school measures in two Federal States.

Findings from the analysis of the interview data derived from guideline panel members and individuals involved in decision-making were structured in a category system consisting of two deductively developed main categories which include three and four inductively developed sub-categories, respectively (Table 3).

Table 3: Category system for sub-study II (impact evaluation), adopted from Appendix 3 in (39)

Processes of decision-making regarding school measures

Hierarchies in the development and implementation of decisions

Sources and channels of information and advice for decision-makers

Consideration of unintended consequences and further aspects when informing and making decisions

Impact of the S3-guideline on processes of decision-making regarding school measures

Perceived value of the S3-guideline for pandemic decision-making

The role of the S3-guideline in political decision-making

The role of the S3-guideline for decision-making in schools

Perceived limitations to the guideline's actual impact

Decision-makers sought advice from different groups and institutions such as health authorities, research institutes or emergency task forces whose representatives were asked to make suggestions for directives based on their assessment of the evidence. Societal implications beyond health outcomes as well as concerns regarding feasibility

and acceptability were said to have had an important influence on formulation of directives.

Overall, participants' views regarding the guideline's impact were mixed. On the one hand, its value in being based on systematic evidence searches and appraisals as well as a structured consensus-building process, was emphasised. On the other hand, participants' statements regarding the guideline's actual role in policymaking and in schools were ambiguous. Recognition of the guideline as a legitimate basis for pandemic decision-making in society and across all Federal States' governments was described as insufficient. Furthermore, lack of context-specific implementation features and its non-binding character limited the guideline's impact which was said to have been considered alongside other sources of information.

2.4.3 Strengths and limitations of this evaluation

2.4.3.1 Strengths and limitations across sub-studies I and II

An active process of reflecting on the possible biases arising from the limitations described below, ways to minimise them and on the doctoral candidate's positionality accompanied this project.

The main limitation of this evaluation is that it was not conducted by a group or institution that was fully external from the guideline secretariat as there was no dedicated funding available. EAR, LMP and BS were part of the guideline secretariat; hence eligible to be recruited for sub-study I. KW and MR were also employed at the Chair of Public Health and Health Services Research at the LMU while conducting this evaluation. To minimise any biases arising from this circumstance, KW and MR carried out recruitment, data collection and most of the data analysis for both sub-studies. Access to the primary data was also restricted to KW and MR who were not tasked with guideline development. Intellectual and procedural proximity to the subject matter of qualitative studies can be advantageous in that it can facilitate data interpretation that is relevant.

To minimise acquiescence or desirability bias, each interviewee was reassured that transcripts would be anonymized and that they would be able to read and check the manuscript prior to data analysis. We cannot exclude the presence of recall bias as we carried out the interviews almost a year after the first version of the guideline was conceived and published.

Only the doctoral candidate was involved in development of sub-categories; therefore, no inter-coder reliability could be established. She aimed to establish intra-coder reliability by critically reviewing the category systems a few times.

Translation of quotes was carried out by the doctoral candidate. All translated quotes were checked by a second co-author, however some loss or changes in meaning cannot be excluded.

2.4.3.2 Strengths and limitations in sub-study I

To minimise researcher selection bias, participants who expressed their interest to participate in the study were chosen following a random order in each stakeholder group.

Representation of perspectives from all stakeholder groups was achieved but no quantitative balance between stakeholder groups was pursued. Data saturation regarding included perspectives and content of each category was likely achieved and quotes were chosen with a view to demonstrating how the analysis was grounded in the primary data. Given that we emphasised at the beginning of each interview that results would be fully anonymised and that we offered participants to review the transcripts before analysis, we are relatively confident that they felt comfortable enough to share their honest views and to describe their experiences in enough depth to render the data rich.

2.4.3.3 Strengths and limitations in sub-study II

To maintain feasibility, we set out to recruit individuals involved in decision-making in two Federal States only. However, recruitment was very challenging as decision-makers were still tasked with making pandemic-related decisions so that attempts at recruitment in further Federal States and over a longer period would have been warranted. This was impeded by time and resource constraints. No individual with a political mandate could be recruited despite our strategy of approaching them through gate-keepers. Professional and institutional backgrounds represented in the sample were not very diverse as four participants representing two Bavarian institutions and just one participant representing a Bremen ministry could be recruited. Therefore, we likely did not achieve saturation in terms of the potential diversity of perspectives of those who informed or made decisions regarding school measures. Sending out inquiries following the FolA of each Federal State served to integrate the qualitatively elicited perspectives of individuals with a different, more objective way of assessing the guideline's impact.

Additionally, we reiterated here that transcripts would be entirely anonymised and no information that could be compromising would be published. However, the data yielded from interviews with individuals involved in decision-making was only moderately rich, both in terms of the included perspectives as well as the content. We assume the reason for this to be that participants were obliged to maintain confidentiality in regards to political decision-making processes or their lack of insight into these. Richer data might have been created through more comprehensive grounding of this study in systems thinking and political theory.

We could only integrate interview data from components 2 and 3 narratively with results from component 1, as ministries in Bavaria and Bremen sent no replies to FoIA inquiries.

2.5 Conclusions

The S3-guideline for the prevention and control of SARS-CoV-2 transmission in schools was an attempt to support EIPH decision-making regarding the COVID-19 response in the context of schools in Germany. The complexities that arise at the science-policy interface described above were recognizable in both sub-studies. Rapidly developing a guideline during a health crisis while also considering relevant implications and unintended consequences beyond health outcomes and including all stake-holders was ambitious and characterised by a number of challenges. While further methodological consideration on acceptable trade-offs between these objectives under time pressure is needed, the value of a such developed guideline was recognised in both sub-studies. The guideline was known in all of the Federal States' ministries for education that responded to the FoIA requests and it instigated changes in existing directives in two Federal States. Based on the results of this dissertation, some impact of the guideline can be presumed.

Scrutinizing and improving methods for rapid guidelines and their uptake in political and practical decision-making is needed. More scholarly work and deliberation on the usefulness and usability of guidelines for EIPH in Germany's federal governance system – both during emergencies and beyond – is warranted. The research carried out for this dissertation provides important insights which can inform future guideline development and dissemination processes nationally and internationally, as well as their evaluation.

Given that guideline impact is not usually comprehensively assessed, this project constitutes a valuable effort in broadening the evidence base for EIPH.

2.6 Reflections on the doctoral candidate's positionality

The doctoral candidate trained as a medical doctor in Germany and as a public health professional in the United Kingdom. Therefore, the context of clinical practice in which an understanding of trustworthy evidence to result from controlled experiments prevailed, presents the foundation of her epistemological perspective. This was broadened by the study and application of social science and qualitative methods and related epistemological viewpoints, such as critical realism and constructivism, during the master's programme in public health. Appreciation of the importance of context, values, and worldviews as well as power hierarchies and political priorities in both evidenceinformed medicine and public health policy, practice and research characterised the doctoral candidate's perspective when carrying out this research project. This was complemented with experience in systematic reviews and the conduct of scientific projects with diverse groups. This epistemological perspective and scientific socialisation will likely have influenced data collection, analysis, and interpretation. Reflecting on the influence of the doctoral candidate's own positionality and scrutinizing findings and their interpretation, including by discussing them with her co-authors, was therefore an of dissertation. integral part this

3. Summary (in English)

Background

Background

In Germany, public health and social measures (PHSM) for infection prevention and control have been implemented in a range of settings during the COVID-19 pandemic, including in schools. While PHSM in schools such as cohorting, mask mandates and surveillance measures can contribute to reducing SARS-CoV-2 transmission, their implementation can also have unintended and negative consequences beyond intended health outcomes. Therefore, a multi-disciplinary and multi-stakeholder panel was brought together to develop an evidence- and consensus-based guideline for PHSM in schools, aiming to provide policymakers and practitioners with a scientific foundation for their decisions. This specifically included consideration of unintended consequences, facilitated by the use of the WHO-INTEGRATE Evidence-to-Decision framework. We sought to understand strengths and weaknesses of the guideline development process as well as the impact of this guideline as a tool for evidence-informed policymaking during a public health emergency. We aimed to not only contribute to the knowledge base around the evidence-to-policy interface but also to identify good practices for future public health emergencies.

Methods

We took a multi-pronged approach to evaluating the S3-guideline for the prevention and control of SARS-CoV-2 transmission in schools (ff. S3-guideline) in terms of strengths and weaknesses of its development process (sub-study I) and its impact on political and practical decision-making processes (sub-study II). We defined impact as knowledge about and use of the S3-guideline by political and practical decision-makers. We chose a qualitative, retrospective design for both sub-studies. In sub-study I, we carried out semi-structured interviews with guideline panel members who we recruited purposively, aiming to include all disciplinary perspectives and stakeholder groups represented in the panel plus the guideline secretariat. In sub-study II, we sent Freedom of Information Act (FoIA) inquiries to ministries of education, family, and health in all 16 Federal States. Additionally, we conducted semi-structured interviews with individuals involved in decision-making regarding PSHM in schools in two Federal States and with members of the guideline panel. To analyse the interview data, we applied deductive-inductive thematic qualitative content analysis according to Kuckartz in both sub-studies.

Results

The guideline development process was characterised by heterogeneity in terms of the quality and scope of the available evidence as well as the types of expertise that participants represented, notably scientific expertise and expertise grounded in lived experi-

ences. The full potential of the WHO-INTEGRATE framework might not have been harnessed and certain methods-related decisions taken in light of the considerable time pressure were reflected upon critically by participants. Overall, participants' perceptions regarding the impact of the guideline were heterogeneous. Its evidence- and consensus-based development process was perceived to render the guideline a valuable source of information but limitations in its usability were noted such as lack of context-specificity. Analysis of responses to the FoIA inquiries showed that the guideline was known in nine out of 16 Federal State ministries of education and considered to check existing directives for school measures in five Federal States; two of which instigated changes in their directives according to the guideline.

Conclusions

The guideline development process was subject to a range of challenges, yet its output was relatively well recognised by decision-makers in Federal States' ministries for education and considered alongside other sources of evidence. To have an impact on decision-making during public health emergencies while meeting ambitious objectives such as effective stakeholder engagement, further reflection on methods for rapid guidelines and their integration into political and practical decision-making is warranted. More research on the usability and usefulness of public health guidelines for decisionmaking German Federal in the State system is needed.

4. Zusammenfassung (deutsch)

Hintergrund

In Deutschland wurden während der COVID-19-Pandemie Maßnahmen zur Infektionsprävention und -kontrolle in verschiedenen Settings, darunter auch Schulen, umgesetzt. Während Kohortierung, Maskenpflicht und Surveillancemaßnahmen in Schulen (ff. Schulmaßnahmen) zu einer Reduktion der SARS-CoV-2-Übertragung beitragen können, können sie auch über die angestrebten gesundheitlichen Effekte hinaus unbeabsichtigte und negative Folgen haben. Daher wurde ein Gremium einberufen, in dem diverse wissenschaftliche Disziplinen und Perspektiven von Praktiker:innen sowie Betroffenen vertreten waren. Dieses Gremium sollte eine evidenz- und konsensbasierte Leitlinie für Entscheidungstragende in Politik und Praxis entwickeln, mit dem Ziel, die Wissenschaftlichkeit ihrer Entscheidungsgrundlage zu erhöhen. Diese Leitlinie sollte auch unbeabsichtigte und negative Folgen von Maßnahmen berücksichtigen. Zu diesem Zweck wurde das WHO-INTEGRATE Evidence-to-Decision framework angewandt. Unser Ziel war es, die Stärken und Schwächen ihres Entwicklungsprozesses sowie den Nutzen dieser Leitlinie als Instrument für evidenzinformierte Politikgestaltung in einer Gesundheitskrise zu verstehen. Wir wollten damit nicht nur einen Beitrag zum Wissen rund um die Schnittstelle zwischen Evidenz und Politik leisten, sondern auch gute Praktiken für künftige Gesundheitskrisen identifizieren.

Methodik

Wir untersuchten die S3-Leitlinie zur Prävention und Kontrolle der SARS-CoV-2-Übertragung in Schulen (ff. S3-Leitlinie) im Hinblick auf Stärken und Schwächen ihres Entwicklungsprozesses (Teilstudie I) und ihres impacts auf Entscheidungsfindungsprozesse (Teilstudie II). Wir definierten impact als Wissen von und Nutzen der S3-Leitlinie durch Entscheidungstragende in Politik und Praxis. Für beide Teilstudien wählten wir ein qualitatives, retrospektives Design. In Teilstudie I führten wir semistrukturierte Interviews mit Mitgliedern des Leitliniengremiums durch. Diese wurden gezielt rekrutiert, um die Perspektiven aller im Gremium vertretenen Disziplinen und Interessengruppen sowie des Leitliniensekretariats zu berücksichtigen. In Teilstudie II richteten wir Anfragen nach dem Informationsfreiheitsgesetz an die Bildungs-, Familien- und Gesundheitsministerien in allen 16 Bundesländern. Zusätzlich führten wir semistrukturierte Interviews mit Personen, die an der Entscheidungsfindung zu Schulmaßnahmen in zwei Bundesländern beteiligt waren, sowie mit Mitgliedern des Leitliniengremiums. Zur Auswertung der Interviewdaten wurde in beiden Teilstudien die inhaltlich strukturierende, qualitative Inhaltsanalyse nach Kuckartz angewandt.

Ergebnisse

Der Prozess der Leitlinienentwicklung war heterogen in Bezug auf die Qualität und den Umfang der verfügbaren Evidenz sowie die Art der Expertise, die die Leitliniengruppe hatte; nämlich einerseits wissenschaftliche Expertise und andererseits Expertise, die auf gelebter Erfahrung beruhte. Das volle Potenzial des WHO-INTEGRATE Rahmenwerks wurde möglicherweise nicht ausgeschöpft, und bestimmte methodische Entscheidungen, die angesichts des erheblichen Zeitdrucks getroffen wurden, wurden von den Teilnehmenden kritisch reflektiert. Insgesamt nahmen die Teilnehmenden den impact der Leitlinie unterschiedlich wahr. Der evidenz- und konsensbasierte Entwicklungsprozess machte die Leitlinie aus ihrer Sicht zu einer wertvollen Informationsquelle, aber es wurden auch Einschränkungen in ihrer Anwendbarkeit festgestellt, wie z.B. fehlende Kontextspezifität. Die Analyse der Antworten auf die Anfragen nach den Informationsfreiheitsgesetzen zeigte, dass die S3-Leitlinie in neun von 16 Bildungsministerien auf Bundeslandebene bekannt war. In fünf Bundesländern wurde sie genutzt, um existierende Regelungen zu überprüfen, von denen zwei ihre Vorgaben daraufhin veränderten.

Schlussfolgerungen

Der Prozess der Leitlinienentwicklung war mit einer Reihe von Herausforderungen verbunden, dennoch war die Leitlinie in den Bildungsministerien der neun Bundesländer, die antworteten, bekannt und wurde neben anderen Informationsquellen berücksichtigt. Um die Entscheidungsfindung während Gesundheitskrisen zu beeinflussen und gleichzeitig ehrgeizige Ziele, wie die wirksame Einbeziehung von Interessengruppen zu erreichen, sind weitere methodische Überlegungen für schnelle Leitlinien und deren Integration in Politik und Praxis notwendig. Die Nutzbarkeit und der Nutzen von Public Health-Leitlinien in Entscheidungsfindungsprozessen im deutschen föderalen System müssen weiter erforscht werden.

5. Paper I

Reference Wabnitz, K., Rueb, M., Pfadenhauer, L. M., Strahwald, B., & Rehfu-

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6. Paper II

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