

Method

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Author for correspondence:

Dawid Pieper, E-mail: dawid.pieper@uni-wh.de

Health Technology Assessment of Public Health Interventions Published 2012 to 2016: An Analysis of Characteristics and Comparison of Methods

Stephanie Polus¹ , Tim Mathes¹, Corinna Klingler², Melanie Messer³, Ansgar Gerhardus^{4,5}, Constance Stegbauer⁶, Gerald Willms⁶, Heidi Ehrenreich⁷, Georg Marckmann² and Dawid Pieper¹

¹Institute for Research in Operative Medicine (IFOM), Witten/Herdecke University, Germany; ²Institute of Ethics, History & Theory of Medicine, LMU Munich, Germany; ³Bielefeld University, Faculty of Health Science, Germany; ⁴Department for Health Services Research, Institute for Public Health and Nursing Research, University of Bremen, Germany; ⁵Health Sciences Bremen, University of Bremen; ⁶aQua Institute for Applied Quality Improvement and Research in Health Care, Germany and ⁷AOK-Bundesverband, Germany

Abstract

Objectives. The aim of this study was to provide an overview of the methodological characteristics and compare the assessment methods applied in health technology assessments (HTAs) of public health interventions (PHIs).

Methods. We defined a PHI as a population-based intervention on health promotion or for primary prevention of chronic or nonchronic diseases. HTAs on PHIs were identified by systematically searching the Web pages of members of international HTA networks. We included only full HTA reports published between 2012 and 2016. Two reviewers extracted data on the methods used to assess effectiveness/safety, as well as on economic, social, cultural, ethical, and legal aspects using *a-priori* standardized tables.

Results. We included ten HTAs provided by four different organizations. Of these, all reports assessed the effectiveness of the interventions and conducted economic evaluations, seven investigated social/cultural aspects, and four each considered legal and ethical aspects, respectively. Some reports addressed applicability, context/setting, and intervention fidelity issues in different ways. We found that most HTAs adapted their methods to some extent, for example, by including nonrandomized studies, expanding the search strategy, involving stakeholders, or applying a framework to guide the HTA process.

Conclusions. Our analysis provides a comprehensive overview of methods applied in HTAs on public health interventions. We found that a heterogeneous set of approaches is used to deal with the challenges of evaluating complex public health interventions.

Health policy decisions are increasingly based on health technology assessments (HTAs). HTA is a systematic approach to evaluate the properties, effects, and impacts of health technologies or interventions (1). However, while most HTAs focus on clinical medicine and pharmaceuticals, HTAs of public health interventions (PHIs) are still rare (2;3).

HTA methods to evaluate public health interventions may differ substantially from clinical/medical HTAs. Assessing complex interventions such as those in the field of public health is associated with a range of challenges, such as very heterogeneous evidence due to the variety of methodological characteristics, and the diversity of populations, interventions and intervention components, comparisons, and outcomes and outcome measurements (4). Due to their complexity, public health interventions are, for example, often evaluated using nonrandomized study designs (5–7). The typical methodological decisions made when carrying out HTAs, such as the choice of electronic databases or risk of bias assessment, are, therefore, not always applicable for HTAs on public health interventions (8–10), for example. Therefore, it is challenging to choose which methods to use for such HTAs.

There are only few HTA agencies that provide standardized, formalized methods specific for public health interventions and they exhibit surprising heterogeneity (9). Until now, the methods applied in HTAs on public health interventions have not been systematically assessed.

Objectives

The aim of this study was to provide an overview of the methodological characteristics and compare the assessment methods that have been used in HTAs of PHIs. More specifically,

our purpose was to cast some light on methodological approaches to address challenges in HTAs of PHIs.

Methods/Design

The detailed methods are presented in our protocol (11). As no outcome of direct patient or clinical relevance is assessed in this work, the protocol was not registered in PROSPERO.

Searches

We systematically searched the webpages of members of the International Network of Agencies for Health Technology Assessment (INAHTA), Health Technology Assessment International (HTAi), and the European Network for Health Technology Assessment (EUnetHTA), and screened the full lists of all published HTAs. Between June and July 2017, one reviewer performed the searches and preselected all potentially relevant titles. References were managed with EndNote X7.

Inclusion Criteria

Two reviewers independently screened potentially relevant full text reports according to the following inclusion criteria: (i) Full HTA report as defined by INAHTA (12); (ii) Assessment of a public health intervention; (iii) Publication date: 2012 to 2016; and (iv) Language: English, German, Spanish, French. We excluded all literature review-based HTAs using accelerated (e.g., rapid reviews) or abbreviated HTA/systematic review methods, overviews of reviews (or umbrella reviews), scoping reviews, mini-HTAs, etc., and protocols (12;13).

In this review, we considered only population-based interventions on health promotion and interventions for primary prevention of noncommunicable (e.g., cardiovascular diseases, diabetes, and injuries) or infectious diseases to ensure consistent study selection (14). We excluded HTAs on screening and vaccination because these require special evaluation methods (e.g., diagnostic accuracy studies or modeling) (15). Furthermore, we decided only to include HTA reports published from 2012 to 2016 to have a full coverage of 5 years. HTA reports of all countries were eligible for inclusion.

Data Extraction and Quality Assessment

Two reviewers independently extracted the data, except for ethical aspects, where the data were extracted by one reviewer and verified by a second reviewer. Data extraction included details on the methods applied for the domain's effectiveness/safety, as well as for economic, social, cultural, ethical, and legal aspects. In case of disagreement, the reviewers discussed the problematic cases and consulted with a third reviewer. We piloted the data extraction forms a priori using HTA reports published before 2012. We did not assess the quality of HTA reports because our focus lay on exploring methodological features of the HTAs.

Data Synthesis and Analysis

We tabulated the information retrieved from the reports for each domain using Microsoft Excel (2010). We planned to describe dichotomous and nominal variables using absolute numbers and percentages, and to show means and standard deviations for metric variables. Due to the small sample size, however, we

did not perform statistical analyses but instead report only absolute numbers. We also planned to perform subgroup analyses according to public health intervention focus, healthcare system, target audience, and evaluation level. This was, however, not feasible due to the small study sample.

Postprotocol Changes

Data extraction was performed independently as reported in the protocol, except for the ethical aspects as detailed above.

Results

We screened the websites of 127 different HTA organizations and found 125 potentially relevant HTA reports published by thirty-four institutions (see Supplementary File 1). We excluded the majority of HTAs because they did not comply with our definition of an HTA (see Supplementary File 2 for a list of excluded HTA-reports). We included ten HTAs from four countries/organizations (16–25), including five HTAs from the National Institute of Health Research in the United Kingdom, three HTAs from the German Institute of Medical Documentation and Information, and one HTA each from the Health Information and Quality Authority in Ireland and the Institute for Clinical and Economic Review in the United States. The selection process is depicted in Figure 1. The included HTA reports and their main characteristics are listed in Tables 1 and 2. More detailed characteristics can be found in Supplemental File 3. In the following, the study IDs detailed in Table 1 are used to refer to the HTA reports.

All ten HTA reports assessed the health effectiveness and cost effectiveness of the interventions. Seven documents also investigated social/cultural aspects (16–21;23), four considered legal aspects (16;17;19;20), and four reports also discussed ethical aspects (16–19).

The scope and specificity of HTA objectives differed across reports. Whereas some narrowed their objectives to for example, assessing effectiveness (and cost-effectiveness) of the intervention (e.g., Balzer et al., 2012; Karczszak et al., 2012) (16;17), others provided an extensive list of detailed objectives extending to specific aspects such as acceptability of the intervention (e.g., HIQA, 2014; Tappenden et al., 2012) (19;22).

Bee et al.; 2014 (21); and O'Mara-Eves et al.; 2013 (24); involved stakeholders to aid the review process. Five reports used, modified, or developed a framework to assist in conducting the review, for example, to conceptualize how the intervention may work or may be modified (18;24), to scope or organize possible intervention types (23;25), or to assess possible health-related quality-of-life outcomes (21). It was, however, not always feasible to identify to what extent and in what way the framework was finally used in the actual conduct of the review. O'Mara-Eves et al., 2003 (24), additionally conducted a process evaluation using a previously developed data extraction tool for public health interventions.

Health Effectiveness/Safety

The reports searched a range of 3–32 databases. Two reports included only randomized controlled trials (RCTs) to assess effectiveness/safety in their systematic reviews (16;22), whereas the rest additionally included nonrandomized study designs, for example, cohort studies, nonrandomized trials, controlled before–after and

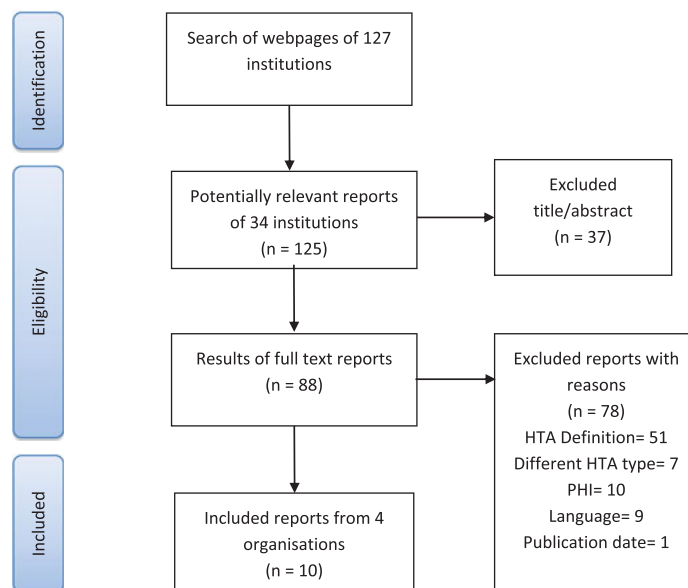


Fig. 1. Flow chart.

interrupted time series studies. Five reports used additional sources, such as grey literature or contacting experts/key contacts to complement their search strategy (20;21;23;24;25).

The risk of bias tool most often used was the Cochrane risk of bias tool, but some reports (additionally) used other tools or a combination of tools to meet their needs. These included, for example, the Effective Public Health Practice Project Quality Assessment Tool for Quantitative Studies (EPHPP) (19;23), the EPPI Centre tool for quality assessment (24), or Oxford Centre for Evidence-based Medicine Levels of Medicine (18). Froeschl et al.; 2013 (17); developed their own tool, and O'Mara-Eves et al.; 2013 (24); modified the Cochrane risk of bias tool for their purposes. One report integrated the risk of bias assessment in the data extraction, but did not report the tool being used (25).

Four publications (20;22;23;25) considered context/setting in their assessments. Brown et al.; 2016 (23); and Bamba et al.; 2015 (25); used the “methodological tool for the assessment of the implementation of complex public health interventions in systematic reviews” (26) for their assessment, adapted for obesity interventions in the case of Bamba et al.; 2015 (25). Two reports narrowed down the scope of their review to the national context (20;22), and Tice et al.; 2016 (20); also applied a value assessment framework and a stakeholder panel to generate contextual information. Bamba et al.; 2015 (25); also separated results according to the international or the UK context.

We also assessed whether the reports considered the applicability or generalizability of the results. One report (19) discussed applicability aspects but did not use a specific methodological tool to systematically assess these aspects. In a separate section, they discussed the “applicability of the results in an Irish context” and “applicability of other studies,” which are also elaborated on in the discussion section of the HTA report. One other HTA, Bamba et al., 2015 (25), partly considered applicability of the evidence in their discussion.

Three reports from the United Kingdom (21;23;25) assessed intervention integrity. Bee et al., 2014 (21), detailed as explicit objectives “to explore all available data relating to the acceptability of community-based interventions [...]” and “to assess key factors influencing the acceptability of and barriers to the delivery and implementation of community-based interventions.” They

conducted one large search, which incorporated all objectives of the HTA, and included acceptability studies that were either quantitative/qualitative or mixed-method approach studies. Bamba et al., 2015 (25), and Brown et al., 2016 (23), assessed delivery fidelity as well as sustainability of the interventions with the same tool used for their context/setting assessment (26). None of the other reports assessed sustainability of the intervention.

Seven reports that (at least partly) conducted meta-analyses assessed statistical heterogeneity by means of the I^2 statistics or other statistical methods. One did not pool data due to high heterogeneity (20). One report combined quantitative and qualitative studies in a mixed-method approach (21), and four reports explicitly conducted subgroup analyses, for example, for different populations or settings (19;21;24;25).

Economic Aspects

Of the ten included HTA reports, the majority conducted systematic reviews of economic evaluations. Only one conducted a primary economic evaluation in addition to a systematic review of economic evaluations with the purpose to inform the primary economic evaluation (19). One report conducted a nonsystematic review of economic evaluations (20).

HIQA 2014 (19) conducted a cost-utility analysis as a primary economic evaluation and, additionally, a *post-hoc* budget-impact analysis. The comparator was routine care, which reflects the societal analysis perspective. HIQA 2014 (19) considered only direct medical costs. They did not report the valuation of outcomes. They used a Markov modeling approach and performed a probabilistic sensitivity analysis. They presented the results narratively as well as with graphic aids, such as tables, a cost-effectiveness plan, and an acceptability curve.

All reports except Tice et al. 2016 (20) conducted systematic reviews of economic evaluations and included full economic evaluation types (cost-effectiveness analyses, cost-utility analyses, and cost-benefit analyses). Other included economic evaluation types were cost-consequences analyses (16;18;22), and cost-minimization studies (25). Four publications did not specify which studies they included (21;23–25).

Table 1. Main Characteristics

Study ID	Organization, country	Title	Objective	Intervention description	Population
Balzer et al., 2012 (16)	DIMDI, Germany	Fall prevention for elderly people in their personal living environment [orig. title: Sturzprophylaxe bei älteren Menschen in ihrer persönlichen Wohnumgebung].	To assess the effectiveness of prevention interventions to reduce falls or fall-related injuries in home or institutional environments.	Individually tailored preventive measures that are medical or non-medical and multimodal or multifactorial prevention programs.	People over 60 years who live in their own houses or in any form of care institutions.
Fröschl et al., 2013 (17)	DIMDI, Germany	Prevention of fetal alcohol syndrome [orig. title: Prävention des fetalen Alkoholsyndroms].	To assess the effectiveness, cost-effectiveness and ethical, social and legal aspects of preventive interventions for pregnant women and women at childbearing age with risky alcohol consumption patterns to prevent fetal alcohol syndrome (FAS).	Any form of prevention intervention directed at women at childbearing age (e.g., short intervention by gynecologist or midwife, motivational discussion, self-help group).	Women at childbearing age and pregnant women.
Korczak et al., 2012 (18)	DIMDI, Germany	Effectiveness and efficiency of psycho-, logic, psychiatric, social-medical-, and complementary medicinal interventions for babies that suffer from excessive crying in special ambulatory “crying units” [orig. title: Effektivität und Effizienz von psycho- logischen, psychiatrischen, sozial-medizinischen und komplementär-medizinischen Interventionen bei Schreibabys (z. B. regulative Störung) in Schreieambulanzen].	To assess the effectiveness and efficacy of interventions to reduce colic (excessive crying) in babies.	Different psychological, psychotherapeutic, socio-medical, and complementary medicine interventions.	No information, only babies with colic, with a minimum of 30 cases per study.
HIQA, 2014 (19)	The Health Information and Quality Authority (HIQA), Ireland	Health technology assessment (HTA) of public access defibrillation.	<ul style="list-style-type: none"> - To review the clinical evidence on the effectiveness and safety of public access defibrillation programs for out-of-hospital cardiac arrest and identify the main factors associated with effective implementation of such programs. - To review and summarize Irish data on the epidemiology of out-of-hospital cardiac arrest, the existing availability of automatic external defibrillators, and relevant initiatives in the management of sudden cardiac arrest and the configuration of emergency medical services. - To review the international cost-effectiveness literature on public access defibrillation. 	Public access defibrillation interventions that include the provision of static automated external defibrillators (AEDs) in a range of publicly- accessible locations, that are designed to be used opportunistically by trained or untrained volunteers or bystanders who witness a cardiac arrest are eligible for inclusion. Also eligible are studies that involve community groups of trained lay-volunteers or lay responders such as police and firefighters who would not ordinarily have access to AEDs. Interventions that focus on the provision of AEDs in the homes of individuals who are at high risk of cardiac arrest or in hospital or other high dependency care facilities are ineligible.	All adults and children who experience a sudden cardiac arrest in any location except for hospitals or other high dependency care facilities that monitor patients and routinely provide emergency medical care. This includes sporting and entertainment venues, public areas, commercial premises, long-term care facilities and public transportation services and facilities.

(Continued)

Table 1. (Continued.)

Study ID	Organization, country	Title	Objective	Intervention description	Population
			<ul style="list-style-type: none"> - To estimate the clinical benefits, cost-effectiveness, resource implications, and budget impact of potential public access defibrillation program configurations in Ireland. - To consider any wider implications that the technology may have for patients, the general public or the healthcare system. - Based on this assessment, to advise on the optimal configuration of an Irish public access defibrillation program. 		
Tice et al., 2016 (20)	Institute for Clinical and Economic Review (ICER), USA	Diabetes Prevention Programs (DPPs): Effectiveness and Value.	This report addresses several key issues related to DPPs for patients, provider organizations, payers, and other policymakers and includes: (1) a landscape analysis of available DPP approaches, (2) a comparative effectiveness evaluation of DPPs, and (3) an assessment of the costs, cost-effectiveness, and potential budget impact of DPPs.	The interventions of interest included lifestyle interventions to prevent or delay the development of type 2 diabetes mellitus (DM) that have full or pending recognition from the CDC Diabetes Prevention Recognition Program (DPRP), including programs incorporating smartphone and Web-assisted delivery methods. Medical and surgical therapies were not considered.	The population of focus for the review was adults ages 18 and older with prediabetes. We attempted to examine the impact of different definitions of prediabetes on the outcomes of interest, but there was insufficient data to perform this analysis.
Bee et al., 2014 (21)	NHS/National Institute of Health Research (NIHR), UK	The clinical effectiveness, cost-effectiveness and acceptability of community-based interventions aimed at improving or maintaining quality of life in children of parents with serious mental illness: a systematic review.	To assess the clinical effectiveness, cost-effectiveness and acceptability of community-based interventions aimed at increasing or maintaining quality of life (QoL) in children of parents with serious mental illness (SMI).	Any community-based (i.e., non-residential) psychological or psychosocial intervention that involved professionals or paraprofessionals and parents or children, for the purposes of changing knowledge, attitudes, beliefs, emotions, skills or behaviors concerning health and well-being. This included any health, social care, or educational intervention aimed at the young person, their parent or their family unit. Interventions that targeted children in the community were eligible for inclusion irrespective of their parents' inpatient or outpatient status.	Children aged 0 to < 18 years or their parents, one or more parents with SMI with or without substance misuse/other mental health comorbidity, > 50 percent sample participants experiencing parental SMI.

(Continued)

Table 1. (Continued.)

Study ID	Organization, country	Title	Objective	Intervention description	Population
Tappenden et al., 2012 (22)	NHS/National Institute of Health Research (NIHR), UK	The clinical effectiveness and cost-effectiveness of home-based, nurse-led health promotion for older people: A systematic review.	<ul style="list-style-type: none"> - To assess the clinical effectiveness and cost-effectiveness of home-based, nurse-led health promotion intervention for older people in the UK - Review existing health economic evaluations of home-based, nurse-led health promotion programs from the perspective of the NHS and Personal Social Services (PSS) - Explore, as far as existing evidence allows, those elements of this form of complex intervention that may contribute to its clinical effectiveness, and - Identify key gaps in current evidence and to identify areas in which future research may be warranted. 	<ul style="list-style-type: none"> - Structured home-based, nurse-led health promotion - Complex intervention, in that it that may comprise multiple, potentially interacting components. The focus within this assessment is principally on nurse-led health promotion activities undertaken within the subject's home. 	Older people (> 75 years or > 70 years when considered a vulnerable population on the basis of age) with long-term medical or social needs at risk of admission to hospital, residential or nursing care.
Brown et al., 2016 (23)	NHS/National Institute of Health Research (NIHR), UK	Community pharmacy interventions for public health priorities: a systematic review of community pharmacy-delivered smoking, alcohol and weight management interventions.	<ul style="list-style-type: none"> - To systematically review the effectiveness of community pharmacy interventions to manage alcohol misuse, smoking cessation, and weight loss; - To explore if and how age, sex, ethnicity, and socioeconomic status moderate effectiveness; and - To describe how the interventions have been organized, implemented, and delivered. 	Any type of community pharmacy intervention to manage alcohol misuse, smoking cessation and weight loss of any duration based in any country and in people of any age was included.	People of any age.
O'Mara-Eves et al., 2013 (24)	NHS/National Institute of Health Research (NIHR), UK	Community engagement to reduce inequalities in health: a systematic review, meta-analysis and economic analysis.	The overarching aims of this project were to identify community engagement approaches that are effective in improving the health of disadvantaged populations and/or reducing inequalities in health; and to describe the approaches in terms of the circumstances in which they work and the costs associated with their implementation.	Community engagement approaches to reduce inequalities of health.	Group of people defined as a "community".

(Continued)

Table 1. (Continued.)

Study ID	Organization, country	Title	Objective	Intervention description	Population
Bambra et al., 2015 (25)	NHS/National Institute of Health Research (NIHR), UK	How effective are interventions at reducing socioeconomic inequalities in obesity among children and adults? Two systematic reviews.	To systematically review the effectiveness of interventions (individual, community, and societal) in reducing socioeconomic inequalities in obesity among (1) children aged 0–18 years (including prenatal) and (2) adults aged ≥ 18 years, in any setting, in any country, and (3) to establish how such interventions are organized, implemented, and delivered.	Intervention on individual, community, and societal levels that might reduce existing inequalities in the prevalence of obesity (i.e., effective targeted interventions or universal interventions that work more effectively in low-socioeconomic status [SES] groups), as well as those interventions that might prevent the development of inequalities in obesity (i.e., universal interventions that work equally along the SES gradient).	Children aged 1–18 yrs (including prenatal) and adults >18 (i.e., two separate reviews per population) Targeted at disadvantaged individuals, communities or society or aimed at reducing childhood obesity universally but analyzed and presented the effects of the intervention by SES.

Table 2. Assessed Aspects

Study ID	Effectiveness/safety	Economic aspects	Social/cultural aspects	Ethical aspects	Legal aspects	Context/setting	Applicability/generalizability	Intervention integrity	Sustainability	Heterogeneity
Balzer et al., 2012 (16)	✓	✓	✓	✓	✓	✗	✗	✗	✗	✓
Fröschl et al., 2013 (17)	✓	✓	✓	✓	✓	✗	✗	✗	✗	✗
Korczak et al., 2012 (18)	✓	✓	✓	✓	✗	✗	✗	✗	✗	✗
HIQA, 2014 (19)	✓	✓	✓	✓	✓	✗	✓	✗	✗	✓
Tice, et al., 2016 (20)	✓	✓	✓	✗	✓	✓	✗	✗	✗	✓
Bee et al., 2014 (21)	✓	✓	✓	✗	✗	✗	✗	✓	✗	✓
Tappenden et al., 2012 (22)	✓	✓	✗	✗	✗	✓	✗	✗	✗	✓
Brown et al., 2016 (23)	✓	✓	✓	✗	✗	✓	✗	✓	✓	✓
O'Mara-Eves et al., 2013 (24)	✓	✓	✗	✗	✗	✗	✗	✗	✗	✓
Bambra et al., 2015 (25)	✓	✓	✗	✗	✗	✓	(✓)	✓	✓	✓

Reports differed on whether the search strategy for economic evaluations was integrated into the overall generic search or whether they conducted a separate search in addition to the generic search. Korczak et al. 2012, Balzer et al. 2012, Froeschl et al. 2013, Brown et al. 2016, O'Mara-Eves et al. 2013, and Bambra et al. 2015 (16–18;23–25) integrated the economic search in the overall search strategy on effectiveness, and in addition to the generic databases, searched one economic database (i.e., NHS Economic Evaluation Database). HIQA 2014 (19) and Bee et al. 2014 (21) conducted separate searches for the economic evaluations; in one report this was not clearly specified (22). In four reports, both the title-abstract screening and the full-text screening were conducted by two persons independently (title-abstract: 16;18;21;23; full text: 16;17;21;23). Three and four reports, respectively, did not provide clear information regarding the title-abstract screening or the full text screening (title-abstract: 17;19;24; full-text: 18;19;22;24).

Of the ten reports, four presented cost data as reported, two converted the currency (inflated and in Euro). In one case, this was not clear, and three reports did not include any economic evaluation studies. All presented the results exclusively narratively. All HTAs that identified studies in their searches assessed the quality of the included studies. It was only possible in one case to determine an explicit effect of the economic evaluation on the HTA overall results/decision (19); for most, this remained unclear or was not applicable due to missing studies.

Social and Cultural Aspects

Seven HTAs addressed social and/or cultural aspects to a different extent (16–21;23). Three reports used a theoretical framework to conceptualize the social/cultural aspects. HIQA 2014 (19) used the EUnetHTA Core Model, which addresses eight different issues of patients and social aspects. Tice et al. 2016 (20) used the “care value framework” that addresses significant benefits or disadvantages to the patients, their caregivers, the delivery system, other patients, or the public next to benefits or disadvantages in relation to health effectiveness. In a first step, Bee et al. 2014 (21) conceptualized health-related quality of life outcomes through stakeholder consultations, the main outcome of the HTA. The other four HTAs did not report a framework.

All seven HTAs used a systematic literature search and hand searches to identify studies that assess social and cultural aspects. Except for HIQA 2014 (19), all reports integrated their search strategy into the overall search for the HTA. HIQA 2014 (19) did not report their methods in detail but referred to the EUnetHTA Core Model, which suggests a separate systematic search for patient-related issues and social aspects. Brown et al. 2016 (23) limited their search to controlled studies. HIQA 2014 (19) and Bee et al. 2014 (21) combined review methods (systematic literature searches) with qualitative methods, for example, semi-structured interviews, expert interviews, and policy roundtables. Quality assessment of the included studies was performed in five HTAs (18–21;23) applying different assessment tools. All results on social and cultural aspects were reported narratively. The findings on social and cultural aspects had implications for the HTA, as the reports integrated the results in the discussion and recommendations.

Legal Aspects

Four reports addressed legal aspects (16;17;19;20). Each of these used a different method. Balzer et al. 2012 (16) conducted an

additional hand search of the literature to retrieve information on legal aspects, Froeschl et al. 2013 (17) summarized information that was found in the studies identified through the overall systematic literature search for the HTA. In HIQA 2014 (19), a legal analysis of the technology was performed by an additional team from the faculty of law at a higher-education institution. Tice et al. 2016 (20) included legal aspects from the perspectives of the government, payers, purchasers, patients, and vendors combining a literature review, semi-structured interviews, and policy roundtable discussions. All results were reported narratively.

Ethical Aspects

Four reports self-identified as addressing ethical aspects (16–19). Ethical issues were sometimes addressed along with other aspects, legal (17) or social and legal (18), without clear differentiation between the different issues. Two reports dedicated several paragraphs solely to ethical aspects, although they discuss and analyze ethics in close association with social (16) or legal (19) aspects. Three reports (16–18) used a systematic literature search to identify relevant information, with only two specifically searching for literature addressing ethical aspects (16;17). Findings were narratively synthesized, with one report pointing out that only those points from the literature were described that were perceived as relevant by the authors (17). One report applied a theoretical framework, principlism (27), to identify and discuss ethical issues without conducting an additional literature search (19). In all reports, the outcomes of the analyses were considered in the conclusion at least to a certain extent.

Discussion

Effectiveness, Safety and Economic Aspects

The HTAs used a range of approaches to deal with the challenges of evaluating the effectiveness/safety of public health interventions. Most reports adapted their methods to a certain extent, for example, by applying a different risk of bias assessment or by including a variety of nonrandomized study designs. While some merely searched in several databases, others also used alternative sources to search for studies, such as grey literature or expert and stakeholder consultations. A recent methodological case study confirms the effectiveness and better value of supplementary searches compared with mere database searching in public health (28). Others broadened their scope, included different research objectives, and addressed more than just (economic) effectiveness aspects by considering the context/setting of the HTA results, applicability and/or aspects such as implementation and acceptability of the intervention. However, few HTAs assessed these aspects systematically. It is indeed interesting that despite the heterogeneity of methods chosen, most reports considered nonrandomized study designs as recommended by HTA guidance on public health interventions (9). This confirms that RCTs are often not feasible or unethical for the assessment of public health interventions (29).

Overall, due to the increasing awareness of the costs of health services, it seems important that HTA reports in the context of public health give higher priority to economic analyses. This should be reflected above all in the reporting quality and methods used in the economic evaluation. Taking into account that costs of public health interventions are quite high because population-based target groups are typically large, one could expect that

HTA authors had estimated the financial consequences of the interventions, for example, by budget impact analysis. However, only one HTA performed a primary economic evaluation and budget impact analysis (19).

Furthermore, in most cases, the economic evaluation was not discussed in the context of other domains of the HTA such as effectiveness/safety, and its influence on final recommendations was not explicitly clarified. In addition, it seems appropriate to recommend considering a more accurate application of existing guidance for conducting systematic reviews of economic evaluations (30). Approaches for systematically reviewing the economic literature were very heterogeneous, and standards were often not fulfilled. In four of the nine HTA reports conducting systematic reviews of economic evaluations, clear information about full-text screening (e.g., reviewers involved) was missing; four reports did not specify which study types were included. This is remarkable, because this procedure is crucial to ensure the quality of the review process.

Social, Cultural, and Legal Aspects

Social and cultural norms influence how people perceive a health issue, as well as their acceptance of an intervention and its implementation (31). This can modify the effectiveness of an intervention between different groups. Especially in public health interventions, social, cultural, and often legal aspects play a crucial role. Despite this, we found only seven reports that addressed social or cultural aspects, and even fewer that addressed legal aspects.

Within these reports, we found wide variation regarding the frameworks and methods used. In all HTAs, a systematic literature search was the basis for assessing social and cultural aspects. Most HTAs used a second or even third method in addition. For assessing legal aspects, each HTA used a different method. A consensus or codification of methods is still missing in these areas. This might at least partly explain why only few HTAs assess those aspects, despite their relevance for public health interventions. Whenever social, cultural, and legal aspects were assessed, the results had explicit implications on the HTA overall results, which further underlines their relevance.

Ethical Aspects

The majority of HTA reports addressing public health interventions did not discuss ethics. In that respect, our findings are similar to studies within other contexts (32). What is discussed under the label of ethics is quite heterogeneous. Korczak *et al.* 2012 (23), for example, only describes empirical data such as risk factors, while Balzer *et al.* 2012 (16) discusses the implications of relevant legal cases, and the authors of HIQA 2014 (19) elaborate on duties and moral conflicts arising from certain bioethical principles relevant to their context of interest. The methods used to gather relevant information also vary from systematic searches to the application of theory (principlism). This heterogeneity does not come as a surprise as there is an impressive variety of methods (and implied conceptualizations of what an ethical issue is) proposed for ethics assessments (33;34).

It has been argued that this methodological heterogeneity is not necessarily problematic as various approaches to ethical analysis arrive at similar results (35). However, some of the reports included here arguably do not even address ethical aspects, at least when ethics is understood as an endeavor to move beyond what is to what should be, rather than as equivalent to a legal

analysis. Furthermore, certain methodological choices, for example not specifically searching for ethics literature but using effectiveness or safety studies to identify ethical issues, were questionable (36). Accordingly, it seems to be of importance for institutions commissioning HTAs also in public health contexts to provide clearer guidance on how ethics assessments should be conducted, and possibly also on the question under what circumstances these assessments are necessary in the first place (37). This is particularly true insofar as outcomes of ethics analyses affected the final conclusions of the HTA reports.

Addressing Complexity

Very few used, modified, or developed theoretical frameworks to aid their HTA development process, despite the need for sound theoretical understanding of how a complex intervention causes change (38). It often remained unclear how much the framework guided the process. Others simply discussed the different aspects in separate sections or chapters. This result is not surprising, as detailed descriptions of most process steps are missing even in existing guidance (9). None of the reports explicitly mentioned having followed guidance for HTAs on public health interventions as identified by Mathes *et al.* (9). Brown *et al.* 2016 (23), however, stated to have used the EPHPP tool as “recommended by the Cochrane Public Health Review Group”. Two recent HTAs conducted by the Public Health Research (PHR) program of the National Institute for Health Research (NIHR) in the UK explicitly mention the complexity of public health interventions in the context of their research (23;25). Both have used the “methodological tool for the assessment of the implementation of complex public health interventions in systematic reviews” (26) to extract data on different aspects guided by the tool to assess intervention effectiveness.

Despite having applied a heterogeneous set of methods and approaches, most HTAs differed from traditional medical/clinical HTAs in that they introduced new methods and addressed additional aspects, trying to tackle the complexity of the intervention. While the German HTAs tend to use a single standardized, inflexible approach to assess effectiveness/safety of the intervention, the UK HTAs more often applied different methods to approach effectiveness and related aspects, such as context/setting or applicability. However, there seems to be no systematic, standardized approach and the methods are heterogeneously applied. Surprisingly, HTAs from one organization did not necessarily use the same methods although we could see an overall tendency, for example, for assessing ethical or social/legal aspects within an organization (Germany), or for assessing further aspects and processes, such as context or implementation/acceptability issues (United Kingdom). Due to the small sample included we were unable to identify patient or PHI characteristics that would explain the heterogeneity of methods. Complex public health interventions differ from one another in many ways, leading to various problems and research questions/aspects to be addressed, which may lead to the need to adapt approaches dealing with the different individual challenges. A consistent overall methodology would, however, be an advantage for decision makers and other consumers of HTAs in terms of understanding as well as in increasing credibility and facilitating the conduct of HTAs of public health interventions.

A recent European Union (EU)-funded project developed guidance specifically to address the challenge of evaluating complex intervention in HTAs (10). In future research, it would be

interesting to see whether approaches to conducting and integrating systematic assessments of the different aspects important in HTAs evaluating public health interventions will become visible.

Limitations

We found few HTAs assessing public health interventions, and the majority of these were conducted by only two organizations, one each from Germany and the United Kingdom. We did not include a broader scope of public health interventions to allow us to distinguish included HTAs from medical/clinical HTAs, which may have partly led to such a small study sample. Furthermore, the decision as to what constitutes a public health intervention is not straightforward. Our strict inclusion criteria, which have served to comply with a higher quality standard, may also have contributed to this. We excluded further HTA reports due for language reasons, including reports from Lithuania, Norway, and Sweden that were only published in the respective national language. In addition, the list of HTA agencies might be incomplete. This work may, therefore, not encompass a representative sample of all HTAs on public health interventions. Furthermore, our search was limited to the years 2012–16.

In conclusion, despite the limitations listed above, the results show that very few HTAs have yet been conducted in the field of public health. One reason may be that economic analyses of public health interventions tend to be more difficult due to the necessary long study periods. This may have prevented organizations from conducting economic evaluations in the first place. We found that some HTA organizations flexibly adapted the methods according to the specific complexity of the public health intervention assessed. Such need for flexibility may pose a further barrier for some organizations to conduct HTAs in this field. This may also partly explain why we found so few HTAs.

Health policy all over the world, however, continues to implement public health legislation and programs, seemingly without using systematic, evidence-based approaches similar to those commonly used in the traditional fields covered by HTAs, that is, clinical medicine and pharmaceuticals. Considering the importance, scope, and long-term benefits (or harms) as well as the potentially high budget impact of public health interventions in the context of limited resources, these findings should motivate the further research and development as well as international exchange of HTA methodology for public health interventions.

Supplementary material. The supplementary material for this article can be found at <https://doi.org/10.1017/S0266462319000515>

Conflicts of interest. The authors declare that there are no conflicts of interest.

References

1. **World Health Organization (WHO)** (2015) *2015 Global survey on health technology assessment by national authorities*. Geneva: WHO.
2. **Draborg E, Gyrð-Hansen D, Poulsen PB, Horder M** (2005) International comparison of the definition and the practical application of health technology assessment. *Int J Technol Assess Health Care* **21**, 89–95.
3. **Lavis JN, Wilson MG, Grimshaw JM, et al.** (2010) Supporting the use of health technology assessments in policy making about health systems. *Int J Technol Assess Health Care* **26**, 405–414.
4. **Burford B, Lewin S, Welch V, Rehfuss E, Waters E** (2013) Assessing the applicability of findings in systematic reviews of complex interventions can enhance the utility of reviews for decision making. *J Clin Epidemiol* **66**, 1251–1261.
5. **Petticrew M, Anderson L, Elder R, et al.** (2013) Complex interventions and their implications for systematic reviews: A pragmatic approach. *J Clin Epidemiol* **66**, 1209–1214.
6. **Petticrew M, Chalabi Z, Jones DR** (2012) To RCT or not to RCT: Deciding when ‘more evidence is needed’ for public health policy and practice. *J Epidemiol Community Health* **66**, 391–396.
7. **Hartling L, Bond K, Santaguida PL, Viswanathan M, Dryden DM** (2011) Testing a tool for the classification of study designs in systematic reviews of interventions and exposures showed moderate reliability and low accuracy. *J Clin Epidemiol* **64**, 861–871.
8. **Akers J, Aguiar-Ibáñez R, Baba-Akbari A** (2009) *Systematic Reviews: CRD's Guidance for Undertaking Reviews in Health Care*. York: Centre for Reviews and Dissemination (CRD).
9. **Mathes T, Antoine SL, Prengel P, et al.** (2017) Health technology assessment of public health interventions: A synthesis of methodological guidance. *Int J Technol Assess Health Care* **33**, 135–146.
10. **Gerhardus A, Oortwijn W, van der Wilt GJ** (2017) How to avoid giving the right answers to the wrong questions: The need for integrated assessments of complex health technologies. *Int J Technol Assess Health Care* **33**, 541–543.
11. **Mathes T, Willms G, Polus S, et al.** (2018) Health technology assessment of public health interventions: an analysis of characteristics and comparison of methods - Study protocol. *Syst Rev* **7**, 79.
12. **Merlin T, Tamblyn D, Ellery B; INAHTA Quality Assurance Group** (2015) What's in a name? Developing definitions for common health technology assessment product types of the International Network of Agencies for Health Technology Assessment (inahta). *Int J Technol Assess Health Care* **30**, 430–457.
13. **Page MJ, Shamseer L, Altman DG, et al.** (2016) Epidemiology and reporting characteristics of systematic reviews of biomedical research: A cross-sectional study. *PLoS Med* **13**, e1002028.
14. **EuroHealthNet** (2015) *European Joint Action on Chronic Diseases and Healthy Ageing Across the Life Cycle, Health Promotion and Primary Prevention in 14 European Countries: A Comparative Overview of Key Policies, Approaches, Gaps and Needs*. Brussels: EuroHealthNet.
15. **U.S. Preventive Services Task Force** (2015) *Procedure Manual*. Rockville, MD: USPSTF.
16. **Balzer K, Bremer M, Schramm S, Lüthmann D, Raspe H** (2012) *Sturzprophylaxe bei älteren Menschen in ihrer persönlichen Wohnumgebung*. Deutsche Agentur für Health Technology Assessment (DAHTA): Cologne, Germany.
17. **Fröschl B, Brunner-Ziegler S, Wirl C** (2013) *Prävention des fetalen Alkoholsyndroms*. Deutschen Institut für Medizinische Dokumentation und Information (DIMDI): Cologne, Germany.
18. **Korcak D, Kister C, Krause-Girth C** (2012) Effektivität und Effizienz von psychologischen, psychiatrischen, sozialmedizinischen und komplementärmedizinischen Interventionen bei Schreibabys (z. B. regulative Störung) in Schreieambulanz, in Schriftenreihe Health Technology Assessment (HTA) In der Bundesrepublik Deutschland. 2012, Deutschen Instituts für Medizinische Dokumentation und Information (DIMDI): Cologne.
19. **HIQA** (2014) *Health Technology Assessment (HTA) of Public Access Defibrillation*. Health Information and Quality Authority (HIQA): Dublin: HIQA.
20. **Tice JA, Chapman R, Shore KK, et al.** (2016) *Diabetes Prevention Programs: Effectiveness and Value*. Boston: Institute for Clinical and Economic Review.
21. **Bee P, Bower P, Byford S, et al.** (2014) The clinical effectiveness, cost-effectiveness and acceptability of community-based interventions aimed at improving or maintaining quality of life in children of parents with serious mental illness: A systematic review. *Health Technol Assess* **18**, 1–250.
22. **Tappenden P, Campbell F, Rawdin A, Wong R, Kalita N** (2012) The clinical effectiveness and cost-effectiveness of home-based, nurse-led health promotion for older people: A systematic review. *Health Technol Assess* **16**, 1–72.
23. **Brown TJ, Todd A, O'Malley C, et al.** (2016) Community pharmacy-delivered interventions for public health priorities: A systematic review of interventions for alcohol reduction, smoking cessation and weight management, including meta-analysis for smoking cessation. *BMJ Open* **6**, e009828.

24. O'Mara-Eves A, Brunton G, McDaid D, *et al.* (2013) Community engagement to reduce inequalities in health: A systematic review, meta-analysis and economic analysis. Southampton, UK: NIHR Journals Library.
25. Bambra CL, Hillier FC, Cairns J-M, *et al.* (2015) How Effective Are Interventions at Reducing Socioeconomic Inequalities in Obesity Among Children and Adults? Two Systematic Reviews. Southampton, UK: NIHR Journals Library.
26. Egan M, Bambra C, Petticrew M, Whitehead M (2009) Reviewing evidence on complex social interventions: Appraising implementation in systematic reviews of the health effects of organisational-level workplace interventions. *J Epidemiol Community Health* **63**, 4–11.
27. Beauchamp TL, Childress JF (2013) *Principles of Biomedical Ethics*. 7th ed. Oxford: Oxford University Press.
28. Cooper C, Lovell R, Husk K, Booth A, Garside R (2018) Supplementary search methods were more effective and offered better value than bibliographic database searching: A case study from public health and environmental enhancement. *Res Synth Methods* **9**, 195–223.
29. Polus S, Pieper D, Burns J, *et al.* (2017) Heterogeneity in application, design, and analysis characteristics was found for controlled before-after and interrupted time series studies included in Cochrane reviews. *J Clin Epidemiol* **91**, 56–69.
30. Mathes T, Walgenbach M, Antoine SL, Pieper D, Eikermann M (2014) Methods for systematic reviews of health economic evaluations: A systematic review, comparison, and synthesis of method literature. *Med Decis Making* **34**, 826–840.
31. Lysdahl KB, Mozygemba K, Burns J, *et al.* (2016) Guidance for assessing effectiveness, economic aspects, ethical aspects, socio-cultural aspects and legal aspects in complex technologies. https://www.integrate-hta.eu/wp-content/uploads/2016/08/IPP_Guidance-INTEGRATE-HTA_Nr.3_FINAL.pdf.
32. DeJean D, Giacomini M, Schwartz L, Miller FA (2009) Ethics in Canadian health technology assessment: A descriptive review. *Int J Technol Assess Health Care* **25**, 463–469.
33. Hofmann B (2014) Why not integrate ethics in HTA: Identification and assessment of the reasons. *GMS Health Technol Assess* **10**, p. Doc04.
34. Assasi N, Schwartz L, Tarride JE, Campbell K, Goeree R (2014) Methodological guidance documents for evaluation of ethical considerations in health technology assessment: A systematic review. *Expert Rev Pharmacoecon Outcomes Res* **14**, 203–220.
35. Saarni SI, Braunack-Mayer A, Hofmann B, van der Wilt GJ (2011) Different methods for ethical analysis in health technology assessment: An empirical study. *Int J Technol Assess Health Care* **27**, 305–312.
36. Droste S (2008) [Systematic search for information on ethical issues in HTA reports on medical technologies or interventions]. *Z Evid Fortbild Qual Gesundheitswes* **102**, 329–341.
37. Grunwald A (2004) The normative basis of (health) technology assessment and the role of ethical expertise. *Poiesis Prax* **2**, 175–193.
38. Craig P, Dieppe P, Macintyre S, *et al.* (2008) Developing and evaluating complex interventions: The new Medical Research Council guidance. *BMJ* **337**, a1655.