BMJ Public Health

Development of an overarching framework for anticipating and assessing adverse and other unintended consequences of public health interventions (CONSEQUENT): a best-fit framework synthesis

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To cite: Stratil JM, Biallas RL, Movsisyan A, *et al*. Development of an overarching framework for anticipating and assessing adverse and other unintended consequences of public health interventions (CONSEQUENT): a best-fit framework synthesis. *BMJ Public Health* 2024;**2**:e000209. doi:10.1136/bmjph-2023-000209

► Additional supplemental material is published online only. To view, please visit the journal online (https://doi.org/10.1136/bmjph-2023-000209).

Received 14 May 2023
Accepted 25 January 2024

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ABSTRACT

Introduction Despite the best intentions and intended beneficial outcomes, public health (PH) interventions can have adverse effects and other unintended consequences (AUCs). AUCs are rarely systematically examined when developing, evaluating or implementing PH interventions. We, therefore, used a multipronged, evidence-based approach to develop a framework to support researchers and decision-makers in anticipating and assessing AUCs of PH interventions.

Methods We employed the 'best-fit' synthesis approach, starting with an a priori framework and iteratively revising this based on systematically identified evidence. The a priori framework was designed using key elements of the WHO-INTEGRATE framework and the Behaviour Change Wheel, to root it in global health norms and values, established mechanisms of PH interventions and a complexity perspective. The a priori framework was advanced based on theoretical and conceptual publications and systematic reviews on the topic of AUCs in PH. Thematic analysis was used to revise the framework and identify new themes. To test the framework, it was coded against four systematic reviews of AUCs of PH interventions.

Results The Cosequences of Public Health Interventions (CONSEQUENT) framework includes two components: the first focuses on AUCs and serves to categorise them; the second (supplementary) component highlights the mechanisms through which AUCs may arise. The first component comprises eight domains of consequences: health, health system, human rights, acceptability and adherence, equality, and equity, social and institutional, economic and resources, and the environment.

Conclusion The CONSEQUENT framework is intended to facilitate classification and conceptualisation of AUCs of PH interventions during their development or evaluation to support evidence-informed decision-making.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Adverse and other unintended Consequences of Public Health Interventions (CONSEQUENT) exist and should be balanced against benefits in public health and health policy decision-making.
⇒ While there is an increasing interest among public health researchers in describing and identifying harms of public health interventions, the existing typologies and classifications have not been developed systematically and largely focus on health rather than broader societal consequences.

WHAT THIS STUDY ADDS

⇒ The CONSEQUENT framework was developed using a systematic, multicomponent approach integrating existing conceptual and empirical knowledge.
⇒ The framework is rooted in global health norms and values and embraces a complexity perspective highlighting a range of social, ecological and economic consequences in addition to health outcomes.
⇒ The framework offers structured definitions and examples for each of eight domains of CONSEQUENT, as well as potential mechanisms leading to these.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The CONSEQUENT framework can serve as a tool for researchers to assess and classify the adverse and other unintended CONSEQUENT and to explore underlying mechanisms. The framework may facilitate structured reflections on the adverse and other unintended consequences while developing, evaluating and implementing public health interventions.

INTRODUCTION

Promoting and improving the physical and mental health of populations is the central goal of public health (PH) interventions all over the globe. However, despite the best intentions, these interventions can have adverse effects, such as effects in the opposite direction of that intended or expected

(paradoxical effects) or effects on unrelated outcomes (unintended externalities).[1] For example, providing pre-exposure prophylaxis against HIV may lead to an increase in risky sexual behaviour and in sexually transmitted infections other than HIV.[2] The drilling of groundwater wells, which successfully reduced diarrhoeal disease mortality due to polluted surface water, has exposed an estimated 40 million Bangladeshis to harmful concentrations of arsenic contained in the groundwater.[3] It has also been shown how obesity-focused PH interventions have led to an increase in stigmatisation and social exclusion of those living with obesity.[4 5]

To truly promote PH, it is essential not only to evaluate intended beneficial outcomes of PH interventions, but also to anticipate and assess their possible adverse and other unintended consequences (AUCs). Unlike the scrutiny used for evaluating adverse drug reactions—which still remain susceptible to underestimating harm[6 7]—assessing the AUCs of PH interventions presents unique challenges: while adverse drug reactions primarily result directly from the drugs themselves and affect those taking them, PH interventions often function as 'events in systems',[8] where effects of the intervention arise as a result of the interaction between the intervention and the social, economic or political context in which it is implemented.[8–10] Individuals and populations not targeted by the intervention may even be those (most severely) affected by AUCs.[11 12] While adverse drug reactions are mostly health related, PH interventions usually have social, economic, ecological or political ramifications (eg, large-scale usage of the insecticide dichlorodiphenyltrichloroethane (DDT) in malaria prevention leading to adverse effects on the ecosystem).[13–16] Furthermore, consideration of an unintended effect of an intervention as adverse, beneficial or neutral is not always clear, as it depends on the perspective of the observer, as well as underlying sociocultural norms; both of these may change over time. For example, whether increased meat consumption is considered an adverse effect (beyond the effect of this on human health) is likely to depend on whether the evaluating person works in the meat industry or is an animal rights activist, whether the assessment takes place in Argentina or Nepal, and whether this is assessed the 1980s compared with the 2020s.

Anticipating and understanding AUCs should be a priority for those deciding on or implementing PH interventions—as there are moral, ethical, political and practical reasons for avoiding health and societal harms.[1 17 18] However, these are often not thoroughly examined in PH research, practice and policy, especially AUCs not directly related to health.[19–21] While unintended consequences of social action have been discussed in the broader scientific literature,[22–30] they constitute a largely neglected topic in empirical PH research,[17 31] except for specific areas, such as cancer screening[32] or illicit drug use.[33]

In recent years, PH researchers have begun to identify and describe harms and to suggest typologies or classifications of harms.[17 31] However, these have primarily focused on health rather than broader societal consequences and/or have not been developed in a systematic manner.[17 31] Important questions remain on how to identify the unintended and potentially harmful effects of PH interventions,[21] how best to evaluate them,[20 27] and how to incorporate the consideration of harms into the process of evidence-informed decision-making.[16 21 34 35] Being able to identify PH interventions and policies with substantive harmful effects and to subsequently adapt or deimplement these interventions is essential for programme implementers, service providers and policy-makers.

The primary objective of the research project was to develop a framework which supports PH researchers, practitioners and decision-makers in anticipating and assessing foreseeable AUCs of PH interventions (the *consequences* component of framework). The secondary objective was to map and conceptualise the mechanisms through which AUCs may arise (as a supplementary *mechanisms* component of framework).

MATERIALS AND METHODS

Overview of framework development process

The framework development process is rooted in an understanding that interventions have both intended and unintended consequences, depending on whether these consequences are the outcomes the intervention is supposed to produce[30] from the perspective of those conceptualising and implementing the intervention. A specification of further terms used in this manuscript can be found in online supplemental file 1.

We developed the final framework using the 'best-fit' framework synthesis approach.[36 37] This approach involves generating an initial framework based on existing frameworks, conceptual models or theories, followed by coding evidence identified through systematic literature searches against the initial framework, and revising it in an iterative process considering further evidence. Within the 'best-fit' framework synthesis approach,[36 37] this initial framework is referred to as an 'a priori' framework.

We used key elements from the WHO-INTEGRATE framework[35] and the Behaviour Change Wheel (BCW)[38] to create an a priori framework of AUCs and the possible mechanisms leading to these.[36 37] We then advanced and refined the framework based on theoretical and conceptual papers describing frameworks or systems of AUCs of PH interventions and/or their mechanisms, as well as empirical research on the AUCs of PH interventions implemented in policy and practice. These papers were identified using systematic searches in health databases and reference searches (online supplemental files 2–4). Thematic analysis was used to identify new themes and topics and thereby to revise the framework. In the final step, the findings in systematic reviews of the AUCs of four specific PH interventions were coded against the empirically advanced framework components,[39–42] which were conducted by or in cooperation with the members of the research team. This served to test the framework

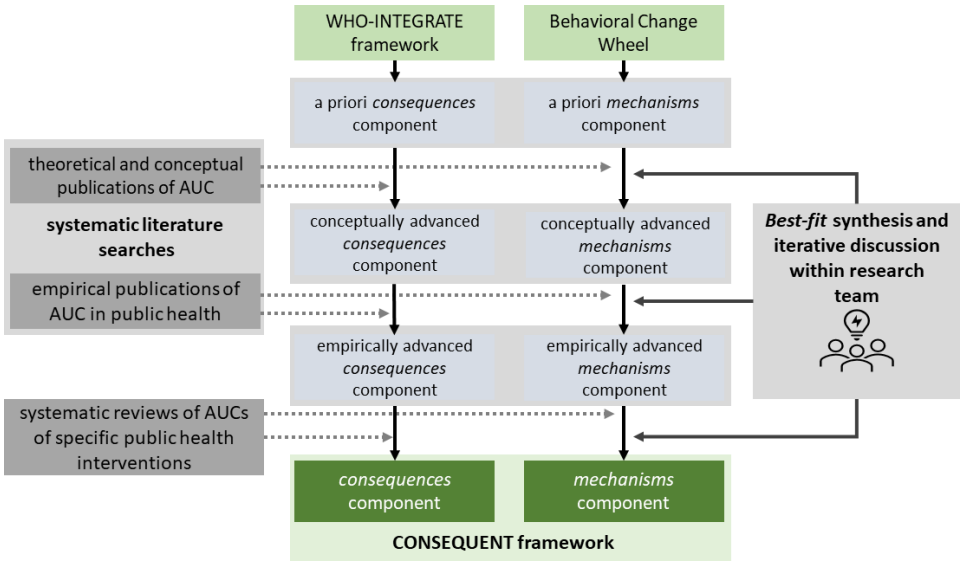

Figure 1 Framework development process. AUC, adverse and other unintended consequences; CONSEQUENT framework, Consequences of Public Health Interventions framework.

using examples from practice. The framework revisions across all steps were guided by discussions within the study team. The entire framework development process is visualised in figure 1. We used the Standards for Reporting Qualitative Research reporting guideline.[43]

Development of the a priori framework

For the categorisation of consequences, we used the criteria and subcriteria of the WHO-INTEGRATE framework version 1.0.[35 44 45] The WHO-INTEGRATE framework is an Evidence-to-Decision (EtD) framework which was developed in a research project commissioned by the WHO, to support evidence-informed decision-making, in particular in the context of guideline development. It consists of six substantive criteria, 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, as well as the meta-criterion quality of evidence. We chose this EtD framework, as (1) it provides a reference frame that is firmly rooted in global health norms and values, as well as key PH ethics frameworks; (2) it is embedded in a complexity perspective, viewing PH interventions as events in (complex) systems[8 9 46] and (3) it considers outcomes of PH interventions beyond health, including social, ecological and economic consequences.

For the categorisation of mechanisms, we used the BCW.[38] The BCW is a framework for describing, designing and evaluating behaviour change interventions. At its core, the 'COM-B system' emphasises three factors - physical and psychological capability (C), social and physical opportunity (O), and automatic and reflective motivation (M) - affecting behaviour change (B). Surrounding these core factors are nine intervention functions (eg, enablement, incentivisation or coercion) and seven policy categories (eg, environmental/social planning, service provision or regulation). We chose BCW as (1) it is the most widely used approach for examining behaviour change and (2) it considers impacts at both individual and societal levels. We focused on the nine intervention functions in BCW and derived a priori mechanisms based on these, including restriction, education, persuasion, incentivisation, coercion, training, enablement, modelling and environmental restructuring.

Through brainstorming and discussions within the research team, these two frameworks were iteratively revised and advanced, resulting in the two components of the a priori framework (online supplemental files 5 and 6).

Identification of eligible publications for 'best-fit' framework synthesis

To retrieve the publications of relevance to advance the a priori framework, we conducted comprehensive literature searches in Medline (Ovid), Embase (Ovid) and the Cochrane library for systematic reviews up until November 2020. The search strategy was developed by expanding the search strategy of the 2014 scoping review by Allen-Scott *et al*[31] and by following a guidance document by the Cochrane Adverse Effects Methods Group.[47–49] In brief, the search strategy combined terms related to unintended consequences with those related to PH. The search strategy for Embase (Ovid) is provided as an example in online supplemental file 2. Additionally, we conducted forward and backward citation searches of all included studies. We conducted these searches in Scopus, Google Scholar and Microsoft Academic.

First, to incorporate existing concepts of AUCs of PH interventions, we examined theoretical or conceptual papers which categorised, explored or explained AUCs in-depth, grounded in or alluding to empirical findings. These included papers (1) providing typologies or taxonomies of AUCs of PH interventions, such

as those by Allen-Scott *et al*[31] or Lorenc and Oliver,[17] (2) describing, discussing or exploring mechanisms of how PH interventions may lead to unintended consequences, such as those by Allen-Scott *et al*[31] and Bonell *et al*[1] and (3) offering guidance for identifying unintended consequences of PH interventions, such as those by Bonell *et al*[1] and Mittelmark.[50]

Second, to incorporate empirical insights to date, we retrieved and assessed systematic reviews with the primary objective to assess AUCs of PH interventions. Reviews with a primary focus on the effectiveness of interventions (ie, the intended beneficial effects of PH interventions) were excluded.

After removal of duplicate studies, the eligibility of studies was assessed independently by two researchers (JMS and RLB). Disagreements were resolved by discussion, and where necessary, by consulting with the full research team.

In selecting papers for inclusion, we adopted a broad approach to PH interventions. These encompass a variety of measures aimed at health promotion, disease prevention, health protection and overall improvements in population health and quality of life.[51] We deliberately excluded studies focusing solely on the iatrogenic effects of medical preventive measures like vaccines, medications, medical procedures and screening or counselling services designed for individual patients. This exclusion covered medical primary prevention (eg, drug prophylaxis for malaria), as well as secondary (eg, prostate or breast cancer screenings) and tertiary preventive measures.

While studies examining the iatrogenic effects of individual-level prevention were excluded, we did include research evaluating the AUCs of population-level prevention programmes. For example, we incorporated studies that assessed the impact of vaccination programmes on broader health behaviour or vaccine acceptance,[52 53] while omitting those focused solely on adverse reactions related to vaccines. Detailed inclusion and exclusion criteria are provided in online supplemental additional file 2.

Conceptual advancement of the a priori framework

As outlined above, we used the identified literature to revise the two components of the a priori framework. For this, we applied thematic analysis using a mix of inductive and deductive coding.[36 37] Specifically, the included papers were coded deductively against the categories and themes of the a priori framework, while the new themes not covered in the a priori framework were derived inductively.[36 37] The coding was done by two authors (JMS and RLB) using the software MAXQDA V.20 (Verbi, Berlin). The thematic analysis and the framework revisions were implemented in an iterative manner (see figure 1). The coding was conducted simultaneously for the consequences component and the mechanisms component of the framework.

First, the two components were revised and expanded based on the coding of the included theoretical and conceptual papers and the resulting new themes. The revisions were discussed in-depth within the research team, yielding conceptually advanced components. Next, the two components were further revised based on the coding of the systematic reviews of AUCs of PH interventions and discussions in the research team, yielding empirically advanced components.

Evaluating the empirically advanced framework through case studies

To assess the comprehensiveness of our empirically advanced framework, we applied it to four systematic reviews examining the unintended consequences of diverse PH interventions. These test case studies spanned various topics: setting-based drug prevention,[42] prevention of SARS-CoV-2 transmission in schools,[39] international travel-related control measures to control COVID-19[40] and measures to reduce the consumption of sugar-sweetened beverages.[41]

We intentionally chose these case studies to represent a wide and heterogeneous array of PH interventions.[54] Our selection criteria aimed to encompass different aspects, such as addressing communicable and non-communicable diseases; encompassing setting-based versus policy-level interventions; and covering interventions from providing information to creating incentives to restricting and eliminating choice—while still falling within the research team's areas of expertise. The systematic reviews of the AUCs of these PH interventions had been conducted by or in cooperation with research team members. After a final review and discussion within the research team, the two-component framework was finalised as the adverse and other unintended Consequences of Public Health Interventions (CONSEQUENT) framework.

Patient and public involvement

The primary target group of the framework are PH and healthy policy decision makers. In a next step of the project, we aim to conduct workshops with members of the primary target group in order to disseminate the findings as well as to receive feedback on the framework itself as well as the practical application guidance. Based on this feedback, the framework and/or guidance will be revised accordingly.

RESULTS

After the removal of duplicates, the literature searches identified 2998 records. The full texts of 150 records were screened for eligibility, and 15 records met the criteria for inclusion as theoretical or conceptual publications.[1 17 21 31 50 51 55–61] By screening the reference lists of the included records, as well as of the identified reviews, we included another three records.[62–64] We also identified 15 systematic reviews[11 33 65–76] reporting on AUCs of different PH interventions through the database searches. No

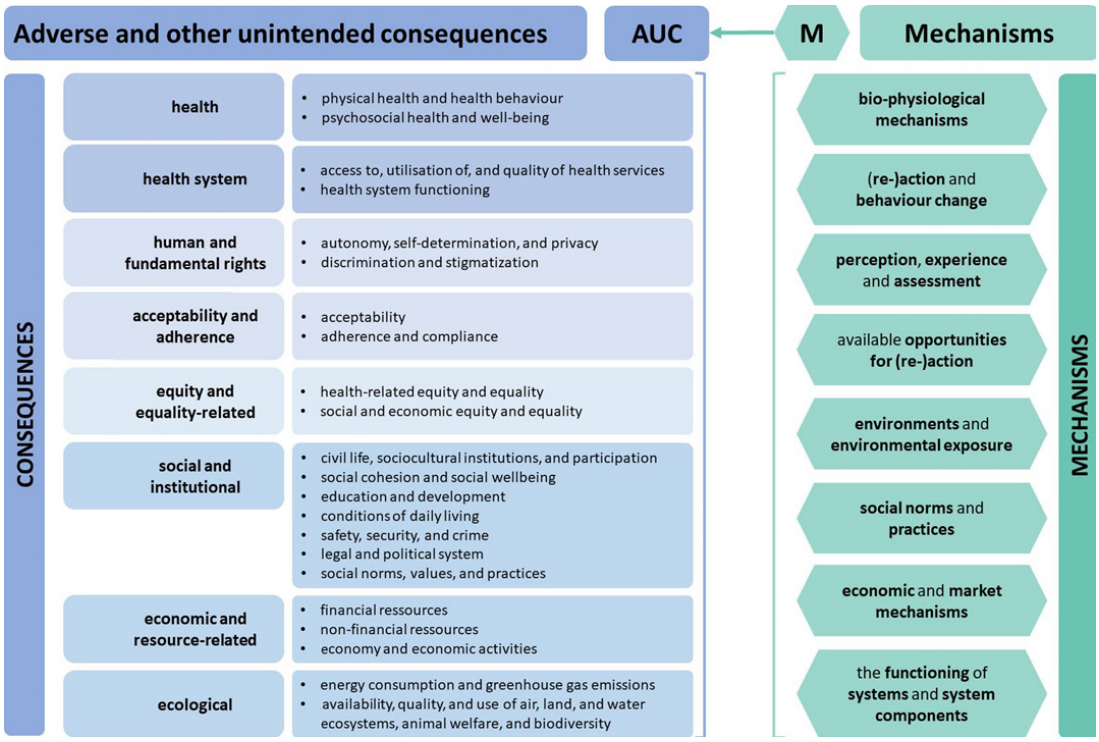

Figure 2 CONSEQUENT framework comprising consequences and mechanisms. AUC, adverse or other unintended consequences; CONSEQUENT framework, Consequences of Public Health Interventions framework; M, mechanisms.

additional records yielding systematic reviews were identified through searches of the reference lists. Eventually, 18 unique records of theoretical or conceptual publications and 15 unique systematic reviews were included for thematic analysis and coding. The Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) flow chart visualising this process is presented in online supplemental file 4.[77]

The two-component CONSEQUENT framework is presented in figure 2.

The consequences component of the CONSEQUENT framework comprises eight first-order domains: (1) health, (2) health system, (3) human rights, (4) acceptability and adherence, (5) equality and equity, (6) social and institutional, (7) economic and resource related and (8) ecological. Each first-order domain also comprises several specific second-order domains. For example, the first-order domain health includes consequences for physical health and health behaviour, as well as psychosocial health and well-being as second-order domains. Depending on the purpose and context of framework application, either the more generic first-order domains and/or the more granular second-order domains may be considered; second-order domains may also be adapted as needed (eg, differentiating the first order domain consequence health in COVID-19-related and non-COVID-19-related health consequences for the assessment of PH and social measures during the COVID-19 pandemic). Descriptions of first-order and second-order domains are provided in table 1, some examples are provided in table 2 and further examples—in online supplemental additional file 6.

The mechanisms component of the CONSEQUENT framework, which may be treated as a supplementary component, consists of eight mechanisms (figure 2). AUCs may arise through: (1) biophysiological mechanisms, (2) (re)action or behaviour change, (3) perception, experience and assessment, (4) available opportunities for (re)action, (5) environments and environmental exposures, (6) social norms and practices, (7) economic and market mechanisms and (8) the functioning of systems and system components. Each mechanism also includes a non-exhaustive list of more specific processes. For example, the mechanism of (re)action or behaviour change includes the following processes: affecting behavioural practice(s), evasive, resistant or counteractive (re)actions or practices, supplementing practices or products, human error or misuse, triggering automated behaviours and lack of action or (behaviour) change. In contrast to the second-order domains of consequences, these specific processes are not intended as standalone 'submechanisms', but rather illustrate how the mechanisms may operate and are likely to vary for different PH interventions. Descriptions of the mechanisms and specific processes are presented in table 3; further details and examples are provided in online supplemental additional file 7. The relationship between the final framework and the a priori and interim versions of the framework is depicted in online supplemental additional files 4 and 5.

Table 1 Consequences in the CONSEQUENT framework: first-order domains, second-order domains, definition

First order domain	Second order domain	Definition
Health	Physical health and health behaviour	This domain captures consequences for the physical health of individuals and populations, including related behavioural, environmental or metabolic risk factors, as well as the risk of accidents and being affected by violence. These consequences may affect those directly targeted by the intervention and/or those not targeted (ie, herd immunity as a type of spill-over effect).
	Psychosocial health and well-being	This domain includes consequences for mental health, including risk and protective factors and practices, quality of life and psychosocial well-being.
Health system	Access to, utilisation of and quality of health services	This domain captures consequences regarding the availability, accessibility, acceptability and quality of local health services and institutions. This includes the underutilisation or overutilisation of health services.
	Health system functioning	This domain addresses how the intervention interacts synergistically or adversely with other interventions in the same setting or population (eg, local health services) and broader aspects of the health system.
Human rights	Autonomy, self-determination and privacy	This domain covers consequences for all human rights and other fundamental rights, including the right to physical integrity, autonomy, self-determination or privacy.
	Discrimination and stigmatisation	This domain captures consequences regarding the discrimination and stigmatisation of individuals or groups, as well as consequences which lead to a shift in the balance of power between individuals and groups. Both are likely to lead to additional health-related or socioeconomic consequences.
Acceptability and adherence	Acceptability	This domain captures consequences regarding the acceptability of the intervention as well as the acceptability of other measures, goods or services in the target population and other affected populations.
	Adherence and compliance	Describes the degree to which a population targeted by an intervention adheres to or refuses to comply with the intervention.
Equality and equity	Health-related equality and equity	This domain covers the consequences regarding relative and absolute inequalities—whether assessed neutrally or judged with respect to their fairness—in health-related outcomes, as well as the relative capabilities of individuals to achieve health.
	Social and economic equality and equity	This domain covers consequences regarding relative and absolute inequalities—both assessed neutrally or judged with respect to fairness—in social and economic outcomes, as well as regarding fairness in opportunities to achieve those outcomes.
Social and institutional	Civil life, sociocultural institutions and participation	This domain captures consequences on the availability and accessibility of sociocultural institutions, ability to engage in civil life and the opportunity for social participation. On a macrolevel, it refers to the availability and quality of social services, civil life and culture within a society. On a mesolevel, it refers to the ability of actors and institutions of civil society, social life and culture to provide these services. On a microlevel, this domain refers to the availability and accessibility of social or cultural institutions and services to individuals, as well as the individual's ability to take part in the social life of a society.
	Social cohesion and social well-being	This domain captures consequences for the functioning of communities and the ability of individuals to be part of them. On a macrolevel or mesolevel, this includes social cohesion, solidarity or the risk of social and political division within communities, which can affect society as a whole (eg, the population of a nation state, macrolevel) or smaller communities (eg, families, cultural communities; mesolevel). On a microlevel, this includes the ability of individuals to be part of communities and experiences integration in them.
	Education and development	This domain captures consequences for educational and developmental opportunities and attainment along the life course from a population (macro) and individual level (micro) perspective, as well as for the institutions contributing to this (mesolevel).
	Conditions of daily living	This domain captures consequences for the conditions of daily living. On the microlevel, this involves, for example, housing and working conditions, on mesolevel consequences for stakeholders and institutions providing or contributing to them, and on macrolevel this includes the consequences regarding the broader physical environment.
	Safety, security and crime	This domain captures consequences for the safety and security of populations and individuals (eg, regarding crime, accidents or natural disasters), as well as those stakeholders and institutions contributing to this (eg, police, fire brigade). Regarding crime, it captures the consequences for victims, perpetrators and society at large.
	Legal and political system	This domain describes consequences for the legal and political system (macrolevel), its institutions (mesolevel), as well as the relationships of individuals within these systems or institutions (microlevel).
	Social norms, values and practices	This domain covers consequences regarding social norms and values, as well as associated practices, including the social roles and role expectations of individuals in a given society or community.

Continued

Table 1 Continued

First order domain	Second order domain	Definition
Economic and resource related	Financial resources	This domain captures consequences beyond the health system regarding financial costs, available financial resources and budgetary implications regarding the intervention itself, as well as individuals (microlevel), stakeholder groups or institutions affected by the intervention (mesolevel), or society at large (macrolevel). The financial consequences can lead to economic consequences (eg, bankruptcy of businesses).
	Non-financial resources	This domain addresses consequences beyond the health system regarding the availability, accessibility, affordability and quality of non-financial resources, such as devices and products, human resources and infrastructure among individuals (microlevel), stakeholder groups or institutions (mesolevel) and society at large (macrolevel).
	Economy and economic activities	This domain captures consequences for economic activities (eg, producing, distributing and consuming goods and services), for the economic situation (eg, poverty, bankruptcy), as well as the stability, resilience, and sustainability of economic activities and the economic situation. This includes individuals (microlevel) and stakeholder groups or institutions (mesolevel) in their role as economic actors (eg, employees or businesses), as well as the local, regional, national or supranational economy (macrolevel).
Ecological	Energy consumption and greenhouse gas emissions	This domain addresses consequences for energy consumption and energy efficiency, as well as consequences regarding changes in the discharge or absorption of carbon dioxide, methane and other greenhouse gases.
	Availability, quality and use of air, land and water	This domain captures different consequences regarding the quality (including risk of contamination) and availability or use of surface and groundwater, land, soil, air and atmosphere (beyond greenhouse gases).
	Ecosystems, animal welfare and biodiversity	This domain captures the consequences regarding, integrity and functioning of ecosystems, health and well-being of non-human animals (beyond their direct implications for human health and their economic value and function) and (natural) biodiversity.

CONSEQUENT framework, Consequences of Public Health Interventions framework.

DISCUSSION

The CONSEQUENT framework represents a novel comprehensive system to anticipate and assess AUCs of PH interventions, as well as the potential mechanisms leading to these. The framework is rooted in global health norms and values as it was developed drawing on the WHO-INTEGRATE framework[35]; it also reflects current best insights regarding behavioural science, given its roots in the BCW.[38] Furthermore, it explicitly embraces a complexity perspective,[46] and thus emphasises unintended consequences of PH interventions beyond the health of individuals and populations.

Conceptualisation of the relation of consequences and mechanisms in the CONSEQUENT framework

AUCs may arise through relatively simple or long and complex processes (this is displayed in online supplemental file 9, figure A1). AUCs may arise directly from the intervention (pathway A in online supplemental figure A1). For example, the taxation of sugar-sweetened beverages may lead to reduced revenue of vendors (the consequence) through an increase in prices a subsequently a reduction in demand (the mechanisms). AUCs may also arise indirectly, when a mediator on the intended pathway leads to an unintended consequence (pathway B). For example, a PH campaign promoting physical activity may lead to an increase in road traffic injuries (consequence) due to uptake of cycling and increased exposure of cyclists to accident-prone environments (mechanism). Intended consequences may also lead to unintended consequences (pathway C). For example, skin cancer prevention programmes via a successful reduction of sun exposure (intended consequence) may further lead to vitamin D deficiencies and related health consequences (unintended consequence).[17] Furthermore, AUCs can arise through one mechanism (pathway A) or through a combination of multiple mechanisms interacting with each other (pathway D).

Finally, an unintended consequence may lead to additional 'secondary' unintended consequences: an unintended consequence may lead to further unintended consequences in a chain (pathway E). For example, a PH media campaign promoting healthy eating patterns may interact with and reinforce social norms and attitudes regarding obesity and obese individuals more broadly, ultimately leading to an increase in weight-based discrimination and adversely affecting the mental health of obese individuals (eg, depression). It may also lead to lower levels of physical activity among obese individuals due to behaviours that aim to avoid further stigmatisation.[4 5]

The length and complexity of the causal pathways leading to AUCs depend on the perspective of the users conceptualising these: this entails the degree to which one 'zooms in' on a particular pathway. Consider the example of conceptualising the unintended consequences of a PH nutrition guideline to reduce the consumption of cholesterol. This may lead to an increase in the consumption of trans fats in margarine (change in health behaviour)

Table 2 Consequences in the CONSEQUENT framework: examples

First order domain	Second order domain	Examples
Health	Physical health and health behaviour	A taxation intervention to increase healthy eating behaviours may lead to an increase in alcohol consumption.[84]
	Psychosocial health and well-being	A school-based obesity prevention intervention may lead to body dissatisfaction.[85 86]
Health system	Access to, utilisation of and quality of health services	An intervention to increase birth weight may lead to an increased utilisation of hospital maternity services and an increase in caesarean sections.[87]
	Health system functioning	Capacity for surgery has been reduced as requisiting theatre space and ventilators to provide additional critical care capacity for patients with COVID-19 in the context of the SARS-CoV-2 pandemic reduced surgery capacity and led to delays in cancer surgery.[88]
Human rights	Autonomy, self-determination and privacy	Quarantine and lockdown of long-term care facilities to protect the elderly in a pandemic may lead to an infringement on freedom of movement, autonomy and self-determination among this population, as it was restricted to visit or leave the facility.[89]
	Discrimination and stigmatisation	A public health communication campaign aimed at increasing rates of HIV-testing in high-risk populations may lead to an increased stigmatisation of individuals or groups living with HIV/AIDS.[90 91]
Acceptability and adherence	Acceptability	A presumed consent legislation for organ donation may lead to a reduced willingness to become an organ donor.[92]
	Adherence and compliance	The implementation of rapid antigen tests to detect SARS-CoV-2 may reduce adherence to social distancing and hygiene practices.[93]
Equality and equity	Health-related equality and equity	A closure of businesses as an infection control measure during a pandemic may differentially affect the economic activities of white collar and blue-collar workers, thereby leading to differences in exposure to the virus in the workplace and during work-related mobility.[55]
	Social and economic equality and equity	The closure of schools during a pandemic may lead to worse educational outcomes for students from low-income households compared with students from high-income households.[14]
Social and institutional	Civil life, sociocultural institutions and participation	A lockdown measure to control the spread of an infectious disease limits the ability of an individual to take advantage of food assistance programmes and other social services.[94] This furthermore prevents theatres and other cultural institutions from opening and may lead to their closing, reducing the overall availability of such cultural services.[95]
	Social cohesion and social well-being	The introduction of vaccination mandates and vaccine passports may lead to political polarisation, societal fragmentation and social movements (eg, antivaccine movements) and divisions within families over this issue.[53]
	Education and development	Closure of schools as an infection control measure during a pandemic can decrease the quality of the education itself and the educational outcomes for children and youth.[14]
	Conditions of daily living	A traffic reduction measure to reduce outdoor air pollution may lead to a less harmful urban living environment for some population groups but increases commuting time for others.[96]
	Safety, security and crime	Criminalising recreational drug use may lead to an increase in crime rates in society and to increased incarceration of individuals, but may also lead to a strengthening of the police and other institutions fighting crime.[97]
	Legal and political system	Politicians or public health services providing changing or erroneous information regarding the severity of a pandemic or the effectiveness of protective measures may lead to an erosion of trust in governmental institutions.[98]
	Social norms, values and practices	A change in smoking legislation to reduce secondhand tobacco smoke may lead to changes in social norms regarding smoking behaviour in public.[99]

Continued

Table 2 Continued

First order domain	Second order domain	Examples
Economic and resource related	Financial resources	A taxation intervention to promote healthy eating patterns may increase cost to consumers (with the poorest groups most severely affected), reduce the revenue of elected shops or restaurants and increase tax revenue for local governments.[100–102]
	Non-financial resources	Providing households with access to piped drinking water reduces the time that women and children spend on water collection and frees time for other activities (eg, to generate income or go to school).[103]
	Economy and economic activities	Lockdown regulations as an infection control measure may lead to shops and restaurants going bankrupt, individuals not being able to work and the national economy shrinking.[104]
Ecological	Energy consumption and greenhouse gas emissions	Junk food and sugar-sweetened beverage taxes intended to improve population health may lead to changing consumption patterns, thereby also reducing greenhouse gas emissions.[105]
	Availability, quality and use of air, land and water	Public health measures reducing red meat consumption could lead to reduced pollution of terrestrial and aquatic ecosystems as well as local improvements in air quality through reducing industrial livestock farming.[106 107]
	Ecosystems, animal welfare and biodiversity	Spraying an insecticide as a vector control measure in the prevention and control of malaria may lead to toxic effects in insect and other animal populations not targeted by the measures with resulting negative effects on local ecosystems.[15]

CONSEQUENT framework, Consequences of Public Health Interventions framework.

and because of pathophysiological mechanisms to a further increase of cardiovascular mortality. The pathway leading to an increase in cardiovascular mortality can be adequately depicted as a long-interlinked chain of biophysiological processes in the human body. While this conceptualisation can be helpful from a biomedical perspective, a detailed understanding of the exact chain of biophysiological mechanisms may not be useful for PH decision-makers developing or wanting to use the PH nutrition guideline. In line with a complexity perspective,[46] we suggest that the degree to which the users 'zoom in' or 'zoom out' on the causal pathways and thereby the level of detail considered in theorising these pathways, should be guided by the principle of usefulness for the question at hand, rather than, by the principle of comprehensiveness.

Application of the framework

The framework was developed with two uses in mind:

The first intended use of the framework is to help PH researchers, practitioners and decision-makers conceptualise AUCs. That is, it can be used as a supporting tool to reflect on and anticipate AUCs of PH interventions when developing, evaluating or implementing an intervention. In this context, we refer to anticipating as the use of the framework as a tool to support stakeholders in systematically reflecting on (potential) AUCs of PH interventions when developing, evaluating or implementing PH interventions. In this application, the consequences listed in the first component of the framework are intended to guide deliberations on the potential AUCs of implementing the intervention in a given context, while the mechanisms listed in the second component of the framework are intended to support the identification of consequences through thinking about the pathways through which those consequences may arise. A comprehensive consideration of AUCs is important to appropriately judge the balance between benefits and harms of PH interventions, and anticipation of AUCs will inform their evaluation, as well as implementation of potential cointerventions or countermeasures. The CONSEQUENT framework is intended to organise these procedures and ensure that all relevant AUCs and mechanisms are considered. However, balancing the identified unintended consequences against each other and against the intended benefits involves value judgements and is part of the decision-making process, which falls beyond the scope of this framework. There are specialised tools available to aid decision-makers in this process.[16 44 45]

Box 1 offers an abbreviated guidance on how to apply the framework in this conceptual manner. The full guidance and an illustration of this application is provided in online supplemental file 10.

The second intended use of the framework is to provide researchers with a classification system of unintended consequences of PH interventions and the mechanisms leading to them. This can be the starting point for exploring and assessing unintended consequences in monitoring the implementation of PH interventions or in designing primary research to evaluate their effects, such a classification system can also reveal important gaps in the literature.[39–42] For example, a preliminary version of the framework was used in a systematic review of PH

Table 3 Mechanisms component of the CONSEQUENT framework: description and specific process

Mechanisms	Description	Specific process through which the mechanism may operate (not exhaustive)
Through biophysiological mechanisms	Unintended consequences may arise through the measure initiating or affecting (ie, stimulating, limiting or modulating) biophysiological or pathophysiologic mechanisms or processes, such as malignant transformations or immune system reactions and processes (includes maladaptive immune responses such as allergic reactions). This furthermore includes consequences resulting through causing, triggering, increasing or reducing addictions or dependencies, stress responses, as well as other pathophysiological mechanisms and processes. For example, a skin cancer prevention measure, namely the reduction of the exposure to sunlight may decrease the physiological sun induced Vitamin D production. This can result in an increased risk for other types of cancer.[17]	► Through (patho)physiological mechanisms. ► Through immune system reactions. ► Through addictions or dependencies. ► Through stress responses.
Through (re)action or behaviour change	Unintended consequences may arise through the measure initiating or affecting (ie, causing, triggering, increasing, decreasing or otherwise modulating) behavioural practices or actions of individuals, populations or institutions. This includes the initiation or modification of behaviours or actions such as avoidance or counteractive behaviours or actions, behaviour change focused on supplementing for goods or services and automated human reaction. Furthermore, consequences may arise through (human) errors and misuses (with the measure affecting the possibility and likelihood thereof), as well as through lack of action or lack of behaviour change in the face of a trigger or changing circumstances. For example, peer intervention to decrease substance use increases alcohol or drug use by affecting consumption behaviours. This can result in consequences for physical or mental health.[68 108]	► Through affecting behavioural practice(s). ► Through evasive, resistant or counteractive (re)action(s) or practices. ► Through supplementing practices or products. ► Through human error or misuse. ► Through triggering automated behaviours. ► Through a lack of action or (behaviour) change.
Through perception, experience and assessment	Unintended consequences may arise through the measure affecting or interacting with how individuals, populations, or institutions experience and perceive practices, environments, situations, disorders, themselves or other individuals, populations or institutions. Furthermore, this includes resulting changes in assessment, evaluation and judgement. This may include experiences or expectations of (non-financial) reward or gain or of harm, loss, punishment, judgement, injustice or infringing, as well as the emotional responses to these. This furthermore includes the experience or expectation of unmet needs, perceptions of risks or the experience or expectation of danger in (self-)labelling, stigmatisation and stereotyping. For example, an intervention to increase pre-exposure prophylaxis for HIV-prevention affects the perception of the risks associated with unprotected sexual intercourse. This can result in an increase of risky sexual contacts and associated sexually transmitted disease.[2 109–113]	► Through affecting experiences, perception or assessments. ► Through creating or fulfilling unmet needs ► Through emotional experiences. ► Through affecting the perception of risk. ► Through (self-)labelling, stigmatisation and stereotyping.
Through available opportunities for (re)action	The range of opportunities to act or react under existing or changing circumstances, which are perceived as available to individuals, populations or institutions, result from the interaction between the available and accessible resources, the characteristic of the setting (eg, rules and regulations), and characteristics or knowledge, skills and abilities of the individuals, populations or institutions. Thus, affecting one of these components can lead to an increase or decrease in the range of opportunities for (re)action perceived as available to the affected individual, population, or institutions and as a result can lead directly or indirectly (eg, through reactive behaviour change) to unintended consequences. Furthermore, can unintended consequences arise through changes in the situation or circumstances of individuals, populations or institutions when an adequate reaction to the change is (perceived as) not possible due to the lack of appropriate available opportunities. For example, infection control measures such as social distancing or curfews can constrain the option of meeting other individuals. This can lead to the experience of isolation and loneliness as a mental health consequence.	► Through rules and restrictions and their enforcement. ► Through (lack of) knowledge, skills and abilities. ► Trough (lack of) available and accessible resources, goods, or services. ► Through (self-)efficacy and empowerment.

Continued

Table 3 Continued

Mechanisms	Description	Specific process through which the mechanism may operate (not exhaustive)
Through environments and environmental exposure	Unintended consequences may arise when the measure leads to changes of the (natural, physical or social) environment individuals, populations or institutions are already exposed to. Furthermore, unintended consequences may arise when individuals, populations or institutions are more (or less) exposed to environments and environmental risks as a result of the measure. Environmental exposure is defined broadly and includes factors such as exposure to air, atmosphere, chemicals, physical agents, microbiological pathogens, noise, vibration, radiation, temperature, etc. It furthermore includes the exposure to goods and services (eg, types and quality of food and water), to accidents or to violence. For example, providing a financial incentive for physical active mobility to the workplace leads to an increase of individuals cycling to work. Due to an increased exposure to an accident-prone physical activity environment, this can result in an increase in road traffic accidents.	► Through changing characteristics of environments. ► Through changing exposure to environments. ► Through (affecting) quality and characteristics of goods and services. ► Through accidents and violence.
Through social norms and practices	Unintended consequences may arise through the measure affecting or interacting with social norms, practices or relationships. This includes the formation of new and the reformation of existing social norms, roles and identities, as well as social practices arising from them (eg, discriminatory practices or institutions). Furthermore, this includes the measures leading to unintended consequences through affecting social networks and relationships. For example, an anti-smoking campaign to reduce public tobacco smoking can promote changes in social norms and practices. This can result in smokers being perceived as deviant and face social judgement and exclusion.	► Through social roles, norms and practices. ► Through social networks and relationships. ► Through discriminatory practices or institutions.
Through economic and market mechanisms	Unintended consequences may arise through the measure affecting (ie, creating or restricting) or interacting with economic mechanisms and processes. This includes incentives or disincentives as well as price and market mechanisms resulting from the balance between the balance and supply of goods and services. For example, a public health programme which provides a bounty for a killed cobra to reduce the risk of snake bites, may lead to an increase due to the population incentivised to engage in the breeding of cobras (these are so-called perverse incentives).	► Through incentives or disincentives. ► Through demand, supply and their balance in markets.
Through the functioning of systems and system components	Unintended consequences may arise through the measure affecting or interacting with the functioning of systems (eg, health system), including single subsystems of bigger systems (eg, primary schools within the educational systems; or insect populations within an ecological system). In this context, systems can refer to social, economic, political, organisational or ecological systems. This includes the resilience, resistance, or sustainability of systems, the creation of synergies or antagonistic effects across systems, as well as the functioning of systems and its components. For example, a syringe exchange programme can serve as a delivery platform for other interventions or services (eg, vaccination services). This can result in an increased utilisation of other interventions or healthcare services.	► Through the functioning of system and system components. ► Through affecting resilience, resistance or sustainability of systems. ► Through creating synergies or antagonistic effects.

CONSEQUENT framework, Consequences of Public Health Interventions framework.

interventions to prevent illicit drug use. The application of the framework showed that most publications examined in the review did not follow a structured approach for the assessment of AUCs or solely focused on health-related consequences. Furthermore, potential mechanisms were rarely described or explored. This indicated a gap in the literature on illicit drug use specifically related to the societal and ecological consequences of PH interventions for prevention.[42]

Relationship with other frameworks of intervention harms

The proposed framework shares many features with other frameworks and classification systems of the harms of PH interventions.[17 31] We describe these below.

Allen-Scott *et al*[31] propose five underlying factors of AUCs of PH interventions, such as 'ignoring root causes', 'limited and/or poor quality evidence' and 'lack of community engagement'. These underlying factors deviate from what we refer to as mechanisms in the CONSEQUENT framework. We consider the underlying factors proposed by Allen-Scott *et al* to operate on a more

Box 1 Abbreviated guidance on the conceptual use of the Consequences of Public Health Interventions (CONSEQUENT) framework

Step 1: Develop an initial logic model: Begin by crafting a logic model or a complex system map to illustrate how the intended intervention will operate within its implementation context.[1 114]

Step 2: Extend the model using the CONSEQUENT framework: Enhance your preliminary logic model using the CONSEQUENT framework in two key areas:

⇒ 2 a. Identify the consequences: Use the framework's list of potential unintended consequences.

⇒ 2b. Examine the mechanisms: Use the framework's list of mechanisms to reflect on processes that might be triggered by the intervention, along with their potential consequences.

Step 3: Map affected populations: Conduct a mapping exercise to identify specific (sub)populations that could be uniquely affected by the intervention. Revise the extended logic model accordingly.

Step 4: Review the literature: Review publications on similar interventions, identified via systematic or non-systematic literature searches, to discern causal pathways and potential adverse unintended consequences. Update the logic model based on these insights.

Step 5: Engage stakeholders: Engage with affected stakeholder groups to incorporate unique insights into the specific contexts and operational dynamics of the intervention.[1] This should also include the viewpoints of those who oppose the intervention.[30]

Although the steps are outlined in a linear fashion, we recommend an iterative approach, revisiting and refining different steps to enhance the final logic model.

upstream level and rather align with what we refer to as root mechanisms. These are understood as mechanisms operating when planning or implementing a PH intervention. Based on the publications by Allen-Scott *et al*,[31 22 24 26] we discuss a range of relevant root mechanisms, notably: (1) not taking context into account, (2) insufficient buy-in and participation of relevant stakeholders, (3) (not) acting based on poor quality or insufficient information, (4) neglecting root causes and acting based on simple answers to complex problems and (5) (mis) allocating scarce resources. However, more work to explore these root mechanisms is needed.

While most categories of potential harms in the framework by Lorenc and Oliver[17] are also covered in our framework, the category of 'opportunity cost' is not. We did not include it in the current framework, as it requires numerous assumptions about a counterfactual reality in which the intervention would not have been implemented. However, we consider this aspect as part of the root mechanisms (ie, 'through (mis)allocating scarce resources').

Unintended consequences regarding equity and equality have been addressed in several publications, such as in the framework by Glover *et al* for identifying and mitigating the equity harms of COVID-19 policy interventions.[17 55 73] While these are covered in the framework component of consequences, they are not explicitly mentioned in the framework component on mechanisms as a standalone mechanism. This decision was made, as equity and inequality can arise through different mechanisms in different populations (eg, an increase in health inequality (the consequence) can arise through different populations acting within the constraints of different df (ie, opportunities).

Strengths and limitations of the framework development process

A significant strength of the CONSEQUENT framework is the systematic, multipronged and iterative development of the framework. The framework has a strong and explicit normative foundation as it was modelled based on the WHO-INTEGRATE framework,[35] and incorporates key insights from behavioural sciences.[38] It was advanced using theoretical/conceptual, as well as empirical literature on AUCs of PH interventions derived from systematic literature searches; new insights were integrated using a mix of inductive and deductive approaches of qualitative inquiry.

However, the project also has a few limitations. First, the literature searches regarding theoretical/conceptual papers and systematic reviews focusing on AUCs of PH interventions were likely not comprehensive. We conducted searches (primarily) in health-related databases, it is, therefore, likely that we missed insights on a broader range of consequences arising from PH interventions assessed and published by other disciplines (eg, economics literature, environmental sciences literature). Second, the identified empirical literature itself is likely not comprehensive regarding all unintended consequences that may have occurred; for example, unintended ecological consequences were rarely addressed. Third, while we achieved content saturation in the coding process (ie, themes were covered by multiple publications and those coded at a later stage did not provide new consequences or mechanisms), further publications may suggest additional consequences and mechanisms. For example, consideration of more publications on the AUCs of economic or market-based PH interventions derived from economic research may lead to additional insights. Fourth, we focused on the literature of AUCs of PH interventions. In some cases, the distinction between economic or social policy measures and PH interventions was challenging. We aimed to overcome this issue through extensive discussions in the team and a clear definition of inclusion and exclusion criteria. For example, we are aware of the extensive literature on unintended consequences of social action from outside the field of PH. Therefore, expanding the framework based on this body of literature may provide additional insights. Finally, our database searches for theoretical and conceptual papers were conducted in the early phase of the SARS-CoV-2 pandemic. The pandemic has since increased awareness about AUCs of PH interventions, leading to various publications on the topic.[13 53 55 78–82] However, to the best of our knowledge, none of these publications would necessitate a change in the structure of our framework.

Indeed, one such publication, co-led by coauthors of the CONSEQUENT framework, uses the CONSEQUENT first order domains in a conceptual framework of PH and social measures during health emergencies.[83]

We; therefore, suggest that further application and testing should take place by applying it to a more diverse set of PH interventions. Based on this, a systematic collation of the experiences may lead to a further advancement of the CONSEQUENT framework, extending it into areas that are currently insufficiently covered and/or adding further granularity, such as for the second-order domains of consequences or for specific mechanisms.

CONCLUSION

The CONSEQUENT framework is a two-component framework to anticipate and assess the AUCs of PH interventions, reflecting on both outcomes (ie, consequences), as well as the processes leading to these outcomes (ie, mechanisms). The framework may help PH researchers, practitioners and decision-makers in anticipating AUCs when developing, evaluating or implementing PH intervention. Furthermore, the framework can be used by researchers to assess AUCs of PH interventions, for example, to reveal gaps in the literature. Application and user-testing of the framework for practical utility may also inform further adaptations.

Acknowledgements We would like to thank Peter von Philipsborn for his support in finalising the application for the funding of this project. Without his contribution, this project would likely not have been possible.

Contributors The study was conceived by JMS and EAR in close collaboration with KO and with input and support from AM and Peter von Philipsborn (LMU Munich). The search strategy was developed by JMS in collaboration with EAR with input from AM. Literature screening and selection was conducted by JMS and RLB. A preliminary coding frame was conceived by JMS drawing on discussions among all members of the research team. Application of the preliminary framework to the documents included in the analysis and the development of the revised framework versions were conducted by JMS and RLB. EAR, AM and KO reviewed and provided in-depth feedback on intermediate versions of the framework, leading to further revisions by JMS in close collaboration with RLB. JMS drafted the manuscript with RLB contributing specific segments. Several versions of the manuscript were critically reviewed and revised by RLB, EAR, AM and KO. Guarantor: JMS.

Funding The authors received funding from the German Federal Ministry of Education and Research (Bundesministerium für Bildung und Forschung; BMBF) for this project. Grant number (001001EL2032).

Competing interests JMS and EAR are authors of the WHO-INTEGRATE framework. KO is the author of a different, widely used framework for classifying unintended consequences of public health interventions.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement All data relevant to the study are included in the article or uploaded as online supplemental information. This study is based on scientific articles which are referenced in the article and available in the public domain. Additional data are provided on request.

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REFERENCES

1 Bonell C, Jamal F, Melendez-Torres GJ, *et al*. "Dark logic": theorising the harmful consequences of public health interventions. *J Epidemiol Community Health* 2015;69:95–8.
2 Molina J-M, Charreau I, Spire B, *et al*. Efficacy, safety, and effect on sexual behaviour of on-demand pre-exposure prophylaxis for HIV in men who have sex with men: an observational cohort study. *Lancet HIV* 2017;4:e402–10.
3 Alam MGM, Allinson G, Stagnitti F, *et al*. Arsenic contamination in Bangladesh groundwater: a major environmental and social disaster. *Int J Environ Health Res* 2002;12:235–53.
4 Sikorski C, Luppa M, Kaiser M, *et al*. The stigma of obesity in the general public and its implications for public health - a systematic review. *BMC Public Health* 2011;11:661.
5 Ten Have M. Ethical aspects of obesity prevention. *Best Pract Res Clin Gastroenterol* 2014;28:303–14.
6 Osimani B. Hunting side effects and explaining them: should we reverse evidence hierarchies upside down? *Topoi* 2014;33:295–312.
7 Stegenga J. Hollow hunt for harms. *Perspectives on Science* 2016;24:481–504.
8 Hawe P, Shiell A, Riley T. Theorising interventions as events in systems. *Am J Community Psychol* 2009;43:267–76.
9 Rutter H, Savona N, Glonti K, *et al*. The need for a complex systems model of evidence for public health. *Lancet* 2017;390:2602–4.
10 Rhodes T, Lancaster K. Evidence-making interventions in health: a conceptual framing. *Soc Sci Med* 2019;238:112488.
11 Benjamin-Chung J, Abedin J, Berger D, *et al*. Spillover effects on health outcomes in low- and middle-income countries: a systematic review. *Int J Epidemiol* 2017;46:1251–76.
12 Fang D, Chen B, Hubacek K, *et al*. Clean air for some: unintended spillover effects of regional air pollution policies. *Sci Adv* 2019;5:eaav4707.
13 Turcotte-Tremblay A-M, Gali Gali IA, Ridde V. The unintended consequences of COVID-19 mitigation measures matter: practical guidance for investigating them. *BMC Med Res Methodol* 2021;21:28.
14 Viner RM, Russell SJ, Croker H, *et al*. School closure and management practices during coronavirus outbreaks including COVID-19: a rapid systematic review. *Lancet Child Adolesc Health* 2020;4:397–404.
15 Bouwman H, van den Berg H, Kylin H. DDT and malaria prevention: addressing the paradox. *Environ Health Perspect* 2011;119:744–7.
16 Stratil JM, Voss M, Arnold L. WICID framework version 1.0: criteria and considerations to guide evidence-informed decision-making on non-pharmacological interventions targeting COVID-19. *BMJ Glob Health* 2020;5:e003699.
17 Lorenc T, Oliver K. Adverse effects of public health interventions: a conceptual framework. *J Epidemiol Community Health* 2014;68:288–90.
18 Childress JF, Faden RR, Gaare RD, *et al*. Public health ethics: mapping the terrain. *J Law Med Ethics* 2002;30:170–8.
19 Oliver K. Can evidence-informed theory help us to avoid harmful public health polices? *Soc Sci Med* 2024.
20 Oliver K, Lorenc T, Tinkler J. Evaluating unintended consequences: New insights into solving practical, ethical and political challenges of evaluation. *Evaluation* 2020;26:61–75.
21 Oliver K, Lorenc T, Tinkler J, *et al*. Understanding the unintended consequences of public health policies: the views of policymakers and evaluators. *BMC Public Health* 2019;19:1057.
22 Merton RK. The unanticipated consequences of purposive social action. *American Sociological Review* 1936;1:894.

23 Morell JA. Systematic iteration between model and methodology: a proposed approach to evaluating unintended consequences. *Eval Program Plann* 2018;68:243–52.
24 Morell JA. Why are there unintended consequences of program action, and what are the implications for doing evaluation? *American Journal of Evaluation* 2005;26:444–63.
25 Morell JA. *Evaluation in the face of uncertainty: anticipating surprise and re- sponding to the inevitable*. New York: Guildford, 2010.
26 Vernon R. Unintended consequences. *Political Theory* 1979;7:57–73.
27 Jabeen S. Unintended outcomes evaluation approach: a plausible way to evaluate unintended outcomes of social development programmes. *Eval Program Plann* 2018;68:262–74.
28 Jabeen S. Do we really care about unintended outcomes? An analysis of evaluation theory and practice. *Eval Program Plann* 2016;55:144–54.
29 Koch D-J, Schulpen L. Introduction to the special issue "unintended effects of international cooperation." *Eval Program Plann* 2018;68:202–9.
30 Sherrill S. Identifying and measuring unintended outcomes. *Eval Program Plann* 1984;7:27–34.
31 Allen-Scott LK, Hatfield JM, McIntyre L. A scoping review of unintended harm associated with public health interventions: towards a typology and an understanding of underlying factors. *Int J Public Health* 2014;59:3–14.
32 Heleno B, Thomsen MF, Rodrigues DS, *et al*. Quantification of harms in cancer screening trials: literature review. *BMJ* 2013;347:f5334.
33 Longshore D, Reuter P, Derks J, *et al*. Drug policies and harms: a conceptual framework. *Eur Addict Res* 1998;4:172–82.
34 Allen-Scott LK, Hatfield JM, McIntyre L, *et al*. Operationalizing the 'population health' approach to permit consideration and minimization of unintended harms of public health interventions: a malaria control example. *Critical Public Health* 2016;26:244–57.
35 Rehfuess EA, Stratil JM, Scheel IB, *et al*. The WHO-INTEGRATE evidence to decision framework version 1.0: integrating WHO norms and values and a complexity perspective. *BMJ Glob Health* 2019;4:e000844.
36 Carroll C, Booth A, Cooper K. A worked example of "best fit" framework synthesis: a systematic review of views concerning the taking of some potential chemopreventive agents. *BMC Med Res Methodol* 2011;11:29.
37 Carroll C, Booth A, Leaviss J, *et al*. "Best fit" framework synthesis: refining the method. *BMC Med Res Methodol* 2013;13:37.
38 Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. *Implement Sci* 2011;6:42.
39 Kratzer S, Pfadenhauer LM, Biallas RL, *et al*. Unintended consequences of measures implemented in the school setting to contain the COVID-19 pandemic: A scoping review. *Cochrane Database Syst Rev* 2021;2022:CD015397.
40 Klinger C, Burns J, Movsisyan A, *et al*. Unintended health and societal consequences of international travel measures during the COVID-19 pandemic: a scoping review. *J Travel Med* 2021;28:taab123.
41 Bulubas M, Rehfuess E, von Philipsborn P, *et al*. Adverse and other unintended consequences of public health interventions to reduce sugar-sweetened beverage consumption: an overview of systematic reviews. 2024.
42 Biallas RL, Rehfuess E, Stratil JM. Adverse and other unintended consequences of setting-based interventions to prevent illicit drug use: a systematic review of reviews. *Journal of Public Health Research* 2022;11:2.
43 O'Brien BC, Harris IB, Beckman TJ, *et al*. Standards for reporting qualitative research: a synthesis of recommendations. *Acad Med* 2014;89:1245–51.
44 Stratil JM, Baltussen R, Scheel I, *et al*. Development of the WHO-INTEGRATE evidence-to-decision framework: an overview of systematic reviews of decision criteria for health decision-making. *Cost Eff Resour Alloc* 2020;18:8.
45 Stratil JM, Paudel D, Setty KE, *et al*. Advancing the WHO-INTEGRATE framework as a tool for evidence-informed, deliberative decision-making processes: exploring the views of developers and users of WHO guidelines. *Int J Health Policy Manag* October 2020.
46 Petticrew M, Knai C, Thomas J, *et al*. Implications of a complexity perspective for systematic reviews and guideline development in health decision making. *BMJ Glob Health* 2019;4:e000899.
47 Golder S, McIntosh HM, Loke Y. Identifying systematic reviews of the adverse effects of health care interventions. *BMC Med Res Methodol* 2006;6:22.
48 Loke Y, Price D, Herxheimer A. Chapter 14: adverse effects. In: Higgins J, Green S, eds. *Cochrane handbook for systematic reviews of interventions version 510*. The Cochrane Collaboration, 2011.
49 Loke YK, Price D, Herxheimer A, *et al*. Systematic reviews of adverse effects: framework for a structured approach. *BMC Med Res Methodol* 2007;7:32.
50 Mittelmark MB. Unintended effects in settings-based health promotion. *Scand J Public Health* 2014;42:17–24.
51 Wilson N, Thomson G. Tobacco taxation and public health: ethical problems, policy responses. *Soc Sci Med* 2005;61:649–59.
52 Hansen BT. No evidence that HPV vaccination leads to sexual risk compensation. *Hum Vaccin Immunother* 2016;12:1451–3.
53 Bardosh K, de Figueiredo A, Gur-Arie R, *et al*. The unintended consequences of COVID-19 vaccine policy: why mandates, passports and restrictions may cause more harm than good. *BMJ Glob Health* 2022;7:e008684:5.:.
54 Palinkas LA, Horwitz SM, Green CA, *et al*. Purposeful sampling for qualitative data collection and analysis in mixed method implementation research. *Adm Policy Ment Health* 2015;42:533–44.
55 Glover RE, van Schalkwyk MCI, Akl EA, *et al*. A framework for identifying and mitigating the equity harms of COVID-19 policy interventions. *J Clin Epidemiol* 2020;128:35–48.
56 Grummon AH, Hall MG, Block JP, *et al*. Ethical considerations for food and beverage warnings. *Physiol Behav* 2020;222:112930.
57 Guttman N, Salmon CT. Guilt, fear, stigma and knowledge gaps: ethical issues in public health communication interventions. *Bioethics* 2004;18:531–52.
58 Levy DT, Cummings KM, Villanti AC, *et al*. A framework for evaluating the public health impact of e-cigarettes and other vaporized nicotine products. *Addiction* 2017;112:8–17.
59 Loss J, Nagel E. Problems and ethical challenges in public health communication. *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz* 2009;52:502–11.
60 Quinn P. Crisis communication in public health emergencies: the limits of "Legal Control" and the risks for harmful outcomes in a digital age. *Life Sci Soc Policy* 2018;14:4.
61 Trudell B, Whatley MH. School sexual abuse prevention: unintended consequences and dilemmas. *Child Abuse Negl* 1988;12:103–13.
62 Cho H, Salmon CT. Unintended effects of health communication campaigns. *J Commun* 2007;57:293–317.
63 Dishion TJ, McCord J, Poulin F. When interventions harm. Peer groups and problem behavior. *Am Psychol* 1999;54:755–64.
64 MacLean L, Edwards N, Garrard M, *et al*. Obesity, stigma and public health planning. *Health Promot Int* 2009;24:88–93.
65 Brown AW, Allison DB. Unintended consequences of obesity-targeted health policy. *Virtual Mentor* 2013;15:339–46.
66 Burgess DJ, Fu SS, van Ryn M. Potential unintended consequences of tobacco-control policies on mothers who smoke: a review of the literature. *Am J Prev Med* 2009;37:S151–8.
67 Kuiper N, Goldston D, Godoy Garraza L, *et al*. Examining the unanticipated adverse consequences of youth suicide prevention strategies: a literature review with recommendations for prevention programs. *Suicide Life Threat Behav* 2019;49:952–65.
68 Werch CE, Owen DM. Iatrogenic effects of alcohol and drug prevention programs. *J Stud Alcohol* 2002;63:581–90.
69 Brooks SK, Webster RK, Smith LE, *et al*. The psychological impact of quarantine and how to reduce it: rapid review of the evidence. *Lancet* 2020;395:912–20.
70 Carter FA, Bulik CM. Childhood obesity prevention programs: how do they affect eating pathology and other psychological measures? *Psychosom Med* 2008;70:363–71.
71 Evans-Polce RJ, Castaldelli-Maia JM, Schomerus G, *et al*. The downside of tobacco control? Smoking and self-stigma: a systematic review. *Soc Sci Med* 2015;145:26–34.
72 Haignere CS, Gold R, McDanel HJ. Adolescent abstinence and condom use: are we sure we are really teaching what is safe? *Health Educ Behav* 1999;26:43–54.
73 Lorenc T, Petticrew M, Welch V, *et al*. What types of interventions generate inequalities? Evidence from systematic reviews. *J Epidemiol Community Health* 2013;67:190–3.
74 Ruiter RAC, Abraham C, Kok G. Scary warnings and rational precautions: a review of the psychology of fear appeals. *Psychology & Health* 2001;16:613–30.
75 Thomson K, Hillier-Brown F, Todd A, *et al*. The effects of public health policies on health inequalities in high-income countries: an umbrella review. *BMC Public Health* 2018;18:869.
76 C. Fong V, Iarocci G. Child and family outcomes following pandemics: a systematic review and recommendations on COVID-19 policies. *J Pediatr Psychol* 2020;45:1124–43.

77 Page MJ, McKenzie JE, Bossuyt PM, *et al*. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ* 2021;372:n71.
78 Diallo I, Ndejjo R, Leye MMM, *et al*. Unintended consequences of implementing non-pharmaceutical interventions for the COVID-19 response in Africa: experiences from DRC, Nigeria, Senegal, and Uganda. *Global Health* 2023;19:36.
79 Lippi G, Henry BM, Bovo C, *et al*. Health risks and potential remedies during prolonged lockdowns for coronavirus disease 2019 (COVID-19). *Diagnosis* 2020;7:85–90.
80 Muehlschlegel PA, Parkinson EA, Chan RY, *et al*. Learning from previous lockdown measures and minimising harmful biopsychosocial consequences as they end: a systematic review. *J Glob Health* 2021;11:05008.
81 ÓhAiseadha C, Quinn GA, Connolly R, *et al*. Unintended consequences of COVID-19 non-pharmaceutical interventions (NPIs) for population health and health inequalities. *Int J Environ Res Public Health* 2023;20:5223.
82 Zambrano-Monserrate MA, Ruano MA, Sanchez-Alcalde L. Indirect effects of COVID-19 on the environment. *Sci Total Environ* 2020;728:138813.
83 Rehfuess EA, Movsisyan A, Pfadenhauer LM, *et al*. Public health and social measures during health emergencies such as the COVID-19 pandemic: an initial framework to conceptualize and classify measures. *Influenza Other Respir Viruses* 2023;17:e13110.
84 Wansink B, Hanks A, Just DR. From coke to coors: a field study of a fat tax and its unintended consequences. 2017.
85 Puhl RM, Heuer CA. Obesity stigma: important considerations for public health. *Am J Public Health* 2010;100:1019–28.
86 ten Have M, de Beaufort ID, Teixeira PJ, *et al*. Ethics and prevention of overweight and obesity: an inventory. *Obes Rev* 2011;12:669–79.
87 Garner P, Kramer MS, Chalmers I. Might efforts to increase birthweight in undernourished women do more harm than good? *Lancet* 1992;340:1021–3.
88 Richards M, Anderson M, Carter P, *et al*. The impact of the COVID-19 pandemic on cancer care. *Nat Cancer* 2020;1:565–7.
89 Cousins E, de Vries K, Dening KH. Ethical care during COVID-19 for care home residents with dementia. *Nurs Ethics* 2021;28:46–57.
90 Courtwright A. Stigmatization and public health ethics. *Bioethics* 2013;27:74–80.
91 Thainiyom P, Elder K. Emotional appeals in HIV prevention campaigns: unintended stigma effects. *Am J Health Behav* 2017;41:390–400.
92 Domínguez J, Rojas JL. Presumed consent legislation failed to improve organ donation in Chile. *Transplantation Proceedings* 2013;45:1316–7.
93 Arnold L, Stratil JM. Strategie zum risikostratifizierten Einsatz von Antigen-Schnelltests. *Gesundheitswesen* 2021.
94 Warshawsky DN. Food insecurity and the covid pandemic: uneven impacts for food bank systems in Europe. *Agric Human Values* 2023;40:725–43.
95 Zhang R, Ji H, Pang Y, *et al*. The impact of COVID-19 on cultural industries: an empirical research based on stock market returns. *Front Public Health* 2022;10.
96 von Grafenstein L, Gao HO. Infrastructure policy and public health: evidence from OECD countries. *Science of The Total Environment* 2021;750:141157.
97 Hall W, Lynskey M. Assessing the public health impacts of legalizing recreational cannabis use: the US experience. *World Psychiatry* 2020;19:179–86.
98 Jennings W, Stoker G, Valgarðsson V, *et al*. How trust, mistrust and distrust shape the governance of the COVID-19 crisis. *Journal of European Public Policy* 2021;28:1174–96.
99 Bell K, Salmon A, Bowers M, *et al*. Smoking, stigma and tobacco "denormalization": further reflections on the use of stigma as a public health tool. A commentary on Social Science & Medicine's Stigma, Prejudice, Discrimination and Health Special Issue (67: 3). *Soc Sci Med* 2010;70:795–9.
100 Bíró A. The impact of sweet food tax on producers and household spending—evidence from Hungary. *Agricultural Economics* 2021;52:545–59.
101 Bødker M, Pisinger C, Toft U, *et al*. The rise and fall of the world's first fat tax. *Health Policy* 2015;119:737–42.
102 McColl K. "Fat taxes" and the financial crisis. *Lancet* 2009;373:797–8.
103 Cassivi A, Johnston R, Waygood EOD, *et al*. Access to drinking water: time matters. *J Water Health* 2018;16:661–6.
104 Nicola M, Alsafi Z, Sohrabi C, *et al*. The socio-economic implications of the coronavirus pandemic (COVID-19): a review. *Int J Surg* 2020;78:185–93.
105 Grout L, Mizdrak A, Nghiem N, *et al*. Potential effect of real-world junk food and sugar-sweetened beverage taxes on population health, health system costs and greenhouse gas emissions in New Zealand: a modelling study. *BMJNPH* 2022;5:19–35.
106 Godfray HCJ, Aveyard P, Garnett T, *et al*. Meat consumption, health, and the environment. *Science* 2018;361:eaam5324.
107 Parlasca MC, Qaim M. Meat consumption and sustainability. *Annu Rev Resour Econ* 2022;14:17–41.
108 Moos RH. Iatrogenic effects of psychosocial interventions for substance use disorders: prevalence, predictors, prevention. *Addiction* 2005;100:595–604.
109 Ayerdi Aguirrebengoa O, Vera García M, Arias Ramírez D, *et al*. Low use of condom and high STI incidence among men who have sex with men in PrEP programs. *PLoS One* 2021;16:e0245925.
110 Holt M, Lea T, Mao L, *et al*. Community-level changes in condom use and uptake of HIV pre-exposure prophylaxis by gay and bisexual men in Melbourne and Sydney, Australia: results of repeated behavioural surveillance in 2013-17. *Lancet HIV* 2018;5:e448–56.
111 Rojas Castro D, Delabre RM, Molina JM. Give PrEP a chance: moving on from the "risk compensation" concept. *J Int AIDS Soc* 2019;22 Suppl 6:e25351.
112 Traeger MW, Schroeder SE, Wright EJ, *et al*. Effects of pre-exposure prophylaxis for the prevention of human immunodeficiency virus infection on sexual risk behavior in men who have sex with men: a systematic review and meta-analysis. *Clin Infect Dis* 2018;67:676–86.
113 Vuylsteke B, Reyniers T, De Baetselier I, *et al*. Daily and event-driven pre-exposure prophylaxis for men who have sex with men in Belgium: results of a prospective cohort measuring adherence, sexual behaviour and STI incidence. *J Int AIDS Soc* 2019;22:e25407.
114 Rehfuess EA, Booth A, Brereton L, *et al*. Towards a taxonomy of logic models in systematic reviews and health technology assessments: a priori, staged, and iterative approaches. *Res Synth Methods* 2018;9:13–24.