

A scoping review of unintended harm associated with public health interventions: towards a typology and an understanding of underlying factors

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Abstract

Objectives Unintended harm theory as related to public health interventions (PHI) is under developed, with harm evaluation and reporting often absent or incomplete. This review presents a typology for, and underlying factors linked to, PHI-associated unintended harm.

Methods This scoping review was conducted electronically and includes articles from 1992 to June of 2013. Out of 2,490 originally identified titles, 26 full-text articles were included that discussed unintended harm associated with PHI. An iterative data analysis process was utilized to identify both a typology and underlying factors associated with unintended harm.

Results A typology of PHI-associated unintended harm was identified: (1) physical; (2) psychosocial; (3) economic; (4) cultural and (5) environmental. Five underlying factors associated with PHI unintended harm emerged: (1) limited and/or poor quality evidence; (2) prevention of one extreme leads to another (boomerang effects); (3) lack of community engagement; (4) ignoring root causes; and (5) higher-income country PHI implementation in a lower- or middle-income country.

Conclusions PHI planning and evaluation frameworks may benefit from the consideration and potential

incorporation of the unintended harm typology and underlying factors.

Keywords Public health interventions · Unintended harm · Unanticipated consequences · Typology · Underlying factors · Evaluation

Introduction

Public health interventions (PHI) aim to prevent injury and disease while protecting health in communities or populations. PHI are most likely to succeed when they take into account three factors in the target population: (1) the unique social determinants; (2) the needs and motivations; and (3) the implementation context (Davies and Macdowall 2006; Glanz and Bishop 2010). Historically, PHI have been deemed appropriate for implementation if they abide by ethical principles and are based on a synthesis of effectiveness evidence (Chalmers 2003; Upshur 2002).

A fundamental pitfall of effectiveness evidence is that harm evaluation and reporting are often absent or incomplete (Bernal-Delgado and Fisher 2008; Ioannidis and Lau 2001). To date, there exists no systematically derived typology for unintended harm associated with PHI that can be utilized for evaluation and reporting (Christakis 2009). Furthermore, research focusing on PHI-associated unintended harms in lower- or middle-income countries (LMICs) is nearly non-existent. This is a key issue, as vulnerable populations living in LMICs are often the subject of PHI that are not designed for their unique environmental, cultural, economic and health system contexts and as a result may be at an increased risk of experiencing unintended harms (Garner et al. 1992; McMichael et al. 2005).

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Here, we respond to these gaps by providing a scoping review of evidence on unintended harms associated with PHI. This review provides a foundation for future systematic or realist reviews and the timely incorporation of unintended harm theory into PHI development, implementation and evaluation frameworks.

Key concepts

What is Harm?

Harm is a deliberately inflicted actual or potential injury, ill effect, adverse event or danger (Oxford 2013). Our examination of unintended harm specifically includes well-meaning PHIs that do not intend to produce harmful consequences. For the purposes of this review we also differentiate between “public” versus “private” harms, where “public” harms are thought of collectively while still keeping consideration that the public is composed of private individuals standing in complex social and legal relation to one another (Feinberg 1984).

The Harm Principle

The Harm Principle proposed in 1859 by John Stuart Mill has historically been used to determine when PHI are ethically justifiable (Mill 1859). Evidence-based public health (EBPH) now suggests that decisions regarding the ethical validity of a PHI should be based not only on the Harm Principle, but also on a gold standard of evidence (an up-to-date systematic review of well-executed research) together with preferences of the community (Brownson et al. 2009; Chalmers 2003; Kohatsu et al. 2004).

The Precautionary Principle

While indeed a synthesis of best evidence is crucial, the reality is that immediate concern based not only on emerging evidence of potential harm, but also on existing paradigms and premises, leads public health policy and programs to be developed and implemented in the face of uncertainty. The attempt to minimize harm in the face of uncertainty is known as the Precautionary Principle (Tickner 2004). What is yet to be ascertained is how uncertainty, premises, immediate action and the goal to minimize harmful unanticipated consequences are related.

Unanticipated consequences (UC)

Robert Merton’s (1936) work provides a key definition of the consequences of purposive action, which are limited to “those elements in the resulting situation which are exclusively the outcome of the action, i.e., those elements

which would not have occurred had the action not taken place” (Merton 1936, 895) and result from an interplay of action and the conditions of action. The conditions of action, or underlying mechanisms associated with the generation of UC are ignorance, error, values, immediate interest and self-defeating prophecy (Merton 1936). Ignorance is the “limitation to a correct anticipation of consequences of action [that] is provided by the existing state of knowledge” (Merton 1936, 898), and there is an important distinction between knowledge in hand and the knowledge that can be conceivably obtained due to the complexity of interrelated forces and circumstances. Error is a “common fallacy frequently involved in the too-ready assumption that actions which have in the past led to desired outcomes will continue to do so” (Merton 1936, 901). Here, context of action becomes a pertinent aspect of decision-making. Basic values refer to “instances where there is no consideration of further consequences because of the felt necessity of a certain action enjoined by certain fundamental values” (Merton 1936, 903). Merton proposed that basic values are related to boomerang effects as activities oriented towards certain values release processes that react to change the very scale of values that precipitated them. The occurrence of PHI boomerang effects has been reported in current evaluations of anti-smoking ads, preventive health messaging and prevention of obesity (Henriksen et al. 2006; Lucas et al. 2009; Werle 2012). Immediate interest denotes “instances where the actor’s paramount concern with the foreseen immediate consequences excludes the consideration of further or other consequences of the same act” (Merton 1936, 901). This factor relates to the Precautionary Principle, as action motivated by interest should not be antithetical to an exhaustive investigation of context and evidence (Merton 1936; Tickner 2004). The Self-defeating prophecy holds that “the prediction has become a new element in a concrete situation, thus tending to change the initial course of developments” (Merton 1936, 903). All things will not be the same due to the fact that the scientist has introduced his predictions or actions.

UC theory in conjunction with the Harm Principle, the Precautionary Principle and EBPH are foundational constructs for our synthesis of PHI unintended harm literature, the development of a typology and the investigation of underlying factors.

Methods

The purpose of this scoping review was to gather evidence on typologies of unintended harm outcomes and potential underlying factors to inform further systematic synthesis, theory development and evaluation framework

refinement. The chosen scoping review methodology provided the required flexibility for synthesis of a variety of study designs and article types (Arksey 2005; Levac et al. 2010).

Identifying relevant studies

The initial literature search was completed in September 2010 and an update in June 2013. Manuscripts published between 1980 and 2013 were accessed via the electronic databases: Web of Science, PubMed and MEDLINE (OVID). The search terms used in combination included harm OR “unintended harm” OR “harm principle” AND “public health” OR “public health intervention” OR “public health policy” OR “population health intervention” OR “prevention program” OR “health promotion program” OR “health protection program” OR “community health program”. The World Health Organization (WHO), Canadian Public Health Agency of Canada (PHAC), Centers for Disease Control and Prevention (CDC) and the National Institute for Care and Health Excellence (NICE) were searched for gray literature using the same combinations of the search terms to reduce the possibility of publication bias (Cooper et al. 2009). Gray literature was used for background and framing purposes. Hand searching of sources cited in the retrieved manuscripts was also undertaken.

Study selection

Inclusion criteria

The article dealt with (1) the concept of unintended harm and PHI, (2) frameworks for evaluating unintended harm, (3) empirical evidence of PHI unintended harm or, (4) evaluation of evidence used to develop and implement PHI.

Exclusion criteria

The article dealt with (1) harm reduction (i.e., safe needle/injection drug use, alcohol and anti-smoking programs), (2) self-harm or, (3) genetic screening.

Charting the data

Key information included author, year, study design, PHI category, population at risk of unintended harm, reported unintended harm and external/underlying factors associated with unintended harm. A narrative review and a descriptive analytical method were used to extract data on unintended harm outcomes and underlying factors.

Analytic framework

The data analysis stage was adapted from the integrative review method and consisted of data reduction, data display and data comparison (Whittemore and Knafelz 2005).

Data reduction

Data reduction involved the division of primary sources into sub-groups based on PHI topic area and context of PHI implementation. Primary source data were then extracted and coded to simplify, focus and organize the data into a manageable framework. Pre-determined relevant data (descriptions of short- and long-term unintended harm and reason or factors related to the generation of unintended harm) for each primary source were compiled into a coding matrix using Microsoft Excel™.

Data display

The extracted data from the primary sources was converted into a display according to particular subgroups: emerging thematic areas associated with PHI unintended harm outcomes and underlying factors. To achieve this an adapted form of thematic analysis (Burnard 1992) was utilized and included the following stages: (1) notes were made about each article during the study selection phase; (2) an inclusive heading or category system was developed and refined; (3) the category system was discussed between researchers for congruence; (4) each article was examined using the category system as a guide for coding; and (5) relevant sections of article text were coded to the categories and organized into table format.

Data comparison

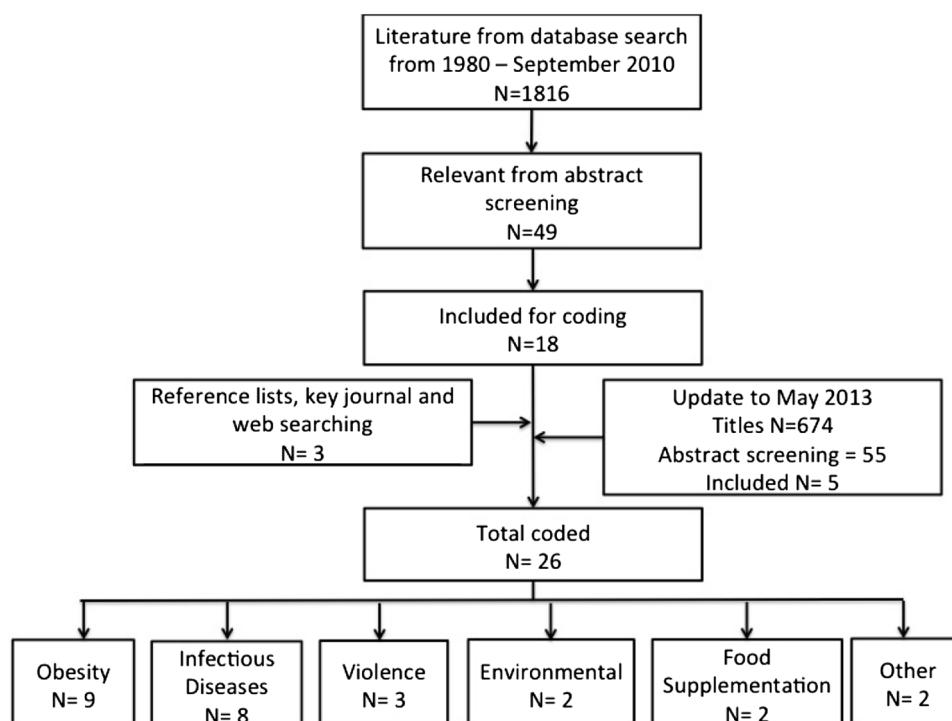
Through examination of data displays, a conceptual map was generated to display the relationship of the emerging outcome and underlying factor categories.

Results

Overview of the literature

Out of 2,490 identified titles, 26 theoretical and empirical full-text articles were included in the analysis phase of the scoping review (Fig. 1). The included articles' publication year ranged from 1992 to 2013 and described PHI targeted at a variety of populations and public health concerns (Table 1).

Fig. 1 Outlines the electronic database search strategy and resulting included studies according to the inclusion and exclusion criteria



A typology for unintended harm associated with PHI

Through data display and comparison we identified five categories of PHI-associated unintended harm outcomes: (1) physical; (2) psychosocial; (3) economic; (4) cultural and (5) environmental. These categories were not founded on a pre-determined conceptual framework, but were allowed to emerge from the data based on researchers' observations of recurrent themes (Burnard 1992).

Physical

Physical harm, meaning a harm occurring to the physical structure of a human who was associated with a PHI, was the most commonly occurring PHI associated harm in this study ($n = 20$). Infants and children had a disproportionately greater risk of experiencing physical harms associated with PHI in the areas of: birth weight, obesity, food supplementation, infectious diseases, and suicide as these PHI are most often targeted at this population (Table 1). Daniels et al. (1999) discusses the treatment of patients with cholera with oral rehydration salts that become infected with other bacterial isolates due to the unsanitary conditions the salt solution was prepared under. There is further evidence of obstructive labor due to efforts to increase birth weight in LMIC countries with weak health systems (Garner et al. 1992) and of increased cigarette smoking and growth failures in low socio-economic children exposed to certain obesity PHI (O'dea 2005).

Physical harms were found to be associated with limited and/or poor quality evidence (Table 2), especially the lack of long-term evidence of effectiveness (Carter et al. 1997; Striegel-Moore 2001), as well as the utilization of reductionist evaluation models that fail to examine outcomes beyond those that were intended (Carter and Bulik 2008; Lykkesfeldt and Poulsen 2010; Thomson et al. 2008). Moreover, physical boomerang effects, such as an increase in threats and attempts of suicide following a school suicide prevention program (Callahan 1996) and the development of eating disorders following childhood obesity prevention programs (Carter and Bulik 2008) are important considerations for those implementing PHI in a variety of areas (Table 2).

Psychosocial

A psychosocial harm involves injury or damage to both psychological and social aspects and may involve the connection between social conditions and mental health (Merriam-Webster 2013c). This review identified 16 studies that reported psychosocial harms associated with various PHI (Table 1). PHI focused on obesity were the most common to have psychosocial harms associated with their outcomes and children were the most likely population reported to experience psychosocial harm in a number of PHI areas (Table 1). Specifically, obesity interventions have been shown to lead to stigmatization, victimization, development of body dissatisfaction and lowered

Table 1 Characteristics of included studies

Article	Article type or study design	PHI category	PHI target population	Unintended harm typology
(Allison and Weber 2003)	Review	Obesity	Children	Physical Psychosocial
(Atkinson and Nitzke 2001)	Editorial	Obesity	Children	Physical Psychosocial
(Balog 2009)	Review and viewpoint	Infectious disease	Adolescent girls	Physical Psychosocial Economic
(Barr et al. 2011)	Review and viewpoint	Infectious disease	People living with HIV	Psychosocial Cultural
(Blake et al. 2003)	Multi-stage cluster	Infectious disease	Adolescents	Physical
(Callahan 1996)	Case study	Suicide	Children	Physical Psychosocial
(Carter et al. 1997)	Longitudinal	Obesity	Adolescent girls	Physical Psychosocial
(Carter and Bulik 2008)	Systematic review	Obesity	Children	Physical Psychosocial
(Clifford et al. 2009)	Systematic review	Indigenous health	Indigenous populations	Physical Psychosocial Cultural
(Daniels et al. 1999)	Longitudinal	Infectious disease	Cholera patients in Guinea	Physical
(Garner et al. 1992)	Viewpoint	Birth weight	Mothers and infants in LMICs	Physical
(Greer and Ryckley 2011)	Essay	Obesity	Population wide	Psychosocial Economic
(Jefferson et al. 2012)	Systematic review	Infectious disease	Children	Physical
(Johnston 2008)	Review	Food supplementation	Population wide	Physical
(Lykkesfeldt and Poulsen 2010)	Review	Food supplementation	Population wide	Physical
(Moreira et al. 2009)	Cross-sectional	Infectious disease	LMIC population wide	Physical Psychosocial Economic
(O'dea 2005)	Point of view	Obesity	Children	Physical Psychosocial
(Petrosino et al. 2000)	Systematic review	Delinquency	Adolescents	Psychosocial
(Qadir et al. 2010)	Review and viewpoint	Wastewater irrigation	LMIC population wide	Physical Economic Environmental
(Story et al. 2003)	Longitudinal	Obesity	Children	Physical Psychosocial
(Striegel-Moore 2001)	Editorial	Obesity	Children	Psychosocial
(Taal and Edelaar 1997)	Longitudinal	Abuse	Children	Psychosocial
(Thomson et al. 2008)	Systematic review	Road transport	Population wide	Physical Psychosocial Environmental
(Vartanian and Smyth 2013)	Symposium	Obesity	Obese individuals	Physical Psychosocial
(Wolitski et al. 2004)	Longitudinal	Infectious disease	HIV positive men	Physical Cultural
(Zimet et al. 2005)	Cross-sectional	Infectious disease	Adolescents	Psychosocial Cultural

self-esteem in children exposed to anti-obesity programs in schools (Atkinson and Nitzke 2001; Carter and Bulik 2008; O'dea 2005; Striegel-Moore 2001). Moreover, stigma, fear

and social discrimination are common unintended harms associated with PHI that do not address underlying paradigms or false premises and/or fail to engage the target

Table 2 The matrix of associations between the public health intervention (PHI) unintended harm typology (physical, psychosocial, economic, environmental, and cultural) and the emergent underlying factors of PHI unintended harm [ignoring root causes, implementation

of PHI in a low-or middle-income country (LMIC), limited and/or poor quality evidence, prevention of an extreme leads to another extreme (boomerang effect) and lack of community engagement]

Typology	Ignoring root causes (<i>N</i> = 5)	Implementation in a LMIC (<i>N</i> = 2)	Limited and/or poor quality evidence (<i>N</i> = 15)	Boomerang effect (<i>N</i> = 11)	Lack of community engagement (<i>N</i> = 6)
Physical (<i>N</i> = 20)	<i>N</i> = 3 ^a	<i>N</i> = 2 ^b	<i>N</i> = 11 ^c	<i>N</i> = 8 ^d	<i>N</i> = 2 ^e
Psychosocial (<i>N</i> = 16)	<i>N</i> = 2 ^f	<i>N</i> = 1 ^g	<i>N</i> = 9 ^h	<i>N</i> = 9 ⁱ	<i>N</i> = 3 ^j
Economic (<i>N</i> = 4)	<i>N</i> = 1 ^k	<i>N</i> = 1 ^l	<i>N</i> = 3 ^m	<i>N</i> = 0	<i>N</i> = 2 ⁿ
Environmental (<i>N</i> = 2)	<i>N</i> = 0	<i>N</i> = 0	<i>N</i> = 2 ^o	<i>N</i> = 0	<i>N</i> = 0
Cultural (<i>N</i> = 4)	<i>N</i> = 1 ^p	<i>N</i> = 0	<i>N</i> = 2 ^q	<i>N</i> = 0	<i>N</i> = 3 ^r

Articles may code to multiple typologies and underlying factors

^a Garner et al. (1992), Wolitski et al. (2004), Vartanian and Smyth (2013)

^b Garner et al. (1992), Moreira et al. (2009)

^c Carter et al. (1997), Johnston (2008), Lykkesfeldt and Poulsen (2010), Clifford et al. (2009), Wolitski et al. (2004), Balog (2009), Thomson et al. (2008), Allison and Weber (2003), Jefferson et al. (2012), Qadir et al. (2010), Vartanian and Smyth (2013)

^d Atkinson and Nitzke (2001), Allison and Weber (2003), Story et al. (2003), Carter and Bulik (2008), O'dea (2005), Daniels et al. (1999), Callahan (1996), Vartanian and Smyth (2013)

^e Clifford et al. (2009), Blake et al. (2003)

^f Greer and Ryckeley (2011), Vartanian and Smyth (2013)

^g Moreira et al. (2009)

^h Carter et al. (1997), Clifford et al. (2009), Balog (2009), Thomson et al. (2008), Striegel-Moore (2001), Allison and Weber (2003), Carter and Bulik (2008), Barr et al. (2011), Vartanian and Smyth (2013)

ⁱ Taal and Edelaar (1997), Petrosino et al. (2000), Striegel-Moore (2001), Allison and Weber (2003), Story et al. (2003), O'dea (2005), Carter and Bulik (2008), Callahan (1996), Vartanian and Smyth (2013)

^j Clifford et al. (2009), Zimet et al. (2005), Barr et al. (2011)

^k Qadir et al. (2010)

^l Moreira et al. (2009)

^m Balog (2009), Greer and Ryckeley (2011), Qadir et al. (2010)

ⁿ Greer and Ryckeley (2011), Qadir et al. (2010)

^o Thomson et al. (2008), Qadir et al. (2010)

^p Wolitski et al. (2004)

^q Clifford et al. (2009), Wolitski et al. (2004)

^r Clifford et al. (2009), Zimet et al. (2005), Barr et al. (2011)

population in a dialogue (Barr et al. 2011; Vartanian and Smyth 2013).

Psychosocial harm was also associated with the underlying factor, prevention of one extreme leads to another (boomerang effects), in both violence (Petrosino et al. 2000; Taal and Edelaar 1997) and obesity targeted PHIs (Allison and Weber 2003; Atkinson and Nitzke 2001; O'dea 2005; Story et al. 2003; Striegel-Moore 2001; Vartanian and Smyth 2013) (Table 2). As an example, the Scared Straight program has led to an increase in crime and delinquency in certain communities (Petrosino et al. 2000). In the area of infectious diseases, limited evidence on long-

term effects of the human papilloma virus vaccine may be linked with a false sense of security of protection from sexually transmitted infections (Balog 2009) and those seeking HIV prevention and treatment face the risk of stigma, discrimination and human rights abuses (Barr et al. 2011).

Economic

An economic harm, defined as damage that relates to production, distribution and consumption of goods and services, was identified in four of the included studies

(Merriam-Webster 2013a). Balog (2009) reported that if the long-term effects of a vaccine are unknown, individuals, governments and private companies might waste resources to rollout this vaccine with no long-term benefits for the population (Table 1). In addition, fear of economic repercussions may make governments less likely to implement required PHI in the area of wastewater irrigation, resulting in a variety of unintended harms for the population and their environment (Qadir et al. 2010).

PHI that are not based on a synthesis of evidence and have limited commitment from policy makers may result in wasted time and resources (Greer and Ryckley 2011). This is especially important in LMICs where resources are already extremely scarce (Moreira et al. 2009). Hence, limited evidence of effectiveness and lack of political will or community engagement may act as important mechanisms for potential unintended economic harm (Table 2).

Cultural

A cultural harm refers to any damage to a population's "way of life", which includes language, arts and sciences, spirituality, social activity and interactions (RCHI 2013). Our review identified four studies that discussed cultural harms associated with PHIs in the areas of indigenous health and infectious diseases (Table 1). Wolitski et al. (2004) reported that the disclosure of HIV status may lead to increased trust/intimacy between partners and, therefore, lead to more unprotected sex. Further, PHI of known effectiveness are often not being implemented in indigenous populations, and if they are, with little consideration of fundamental determinants of health that are unique to the population (Clifford et al. 2009).

The most common underlying factors found to be associated with cultural harms are limited availability and implementation of quality contextualized evidence (Clifford et al. 2009; Wolitski et al. 2004) as well as a lack of community engagement (Barr et al. 2011; Clifford et al. 2009; Zimet et al. 2005) (Table 2).

Environmental

An environmental harm is damage or injury to the circumstances, objects or conditions by which one is surrounded (Merriam-Webster 2013b). Our review identified two studies that discussed environmental unintended harms (Table 1). Both suggested that the availability of limited and/or quality evidence when developing and implementing PHI was the most common underlying factor (Table 2). Qadir et al. (2010) stressed the importance of reducing environmental and human health risks (waste water bacterial and heavy metal poisoning) through dialogue across the rural–urban and sector divide to increase

essential knowledge at various levels. Thomson et al.'s (2008) analysis indicated that there is sufficient evidence on the direct harms of road transport, but that we have limited evidence of indirect health impacts (such as air quality and climate change) that occur in the socio-ecological continuum.

The availability of good quality evidence during PHI planning and implementation was an important underlying factor associated with the generation of environmental unintended harm (Table 2) (Qadir et al. 2010; Thomson et al. 2008). This is especially salient in LMIC settings where the resources required to repair environmental damage are scarce, and the potential impact on the largely rural populations is significant (Qadir et al. 2010).

Underlying factors of PHI-associated unintended harm

Five themes emerged from our thematic content analysis (Burnard 1992) that describe underlying factors or mechanisms of PHI unintended harm.

Limited and/or poor quality evidence

Limited or poor quality of evidence was identified in 15 studies that discussed PHI in a variety of topic areas (Table 2) and was reported due to no systematic review on the PHI topic, and/or little to no empirical evidence on the effectiveness or harmfulness of the given PHI (Clifford et al. 2009; Jefferson et al. 2012; Johnston 2008; Lykkesfeldt and Poulsen 2010). This was especially true for long-term efficacy data, which are often lacking, and may lead to unevaluated harmful outcomes of a PHI (Balog 2009; Carter et al. 1997; Striegel-Moore 2001).

The PHI area of obesity frequently reported a lack of good quality evidence, by indicating that interventions need to be evaluated based on controlled research that aims to measure the effect on body weight, body image, self-esteem and eating behavior over the long term (Allison and Weber 2003; Burnard 1992; Carter and Bulik 2008; Carter et al. 1997; Striegel-Moore 2001). Currently, there is limited empirical evidence on the long-term physical and psychosocial effects (such as dietary restriction, growth failures, low self-esteem and development of body dissatisfaction) of certain obesity PHI (Carter et al. 1997; O'dea 2005; Striegel-Moore 2001). This lack of quality evidence may lead to unintended harms that could not be anticipated during the planning and implementation phases.

Prevention of one extreme leads to another extreme (boomerang effect)

In 11 studies examining PHI in the areas of: infectious diseases, obesity, suicide and violence the theme of

preventing one extreme leads to another often opposing extreme (a boomerang effect) emerged (Table 2). Boomerang effects are counterproductive results that are opposite to what was originally intended and can be associated with an individual's psychological reactance (an aversive affective reaction to regulations on one's autonomy or freedom) and/or justice beliefs (Henriksen et al. 2006; Lucas et al. 2009; Werle 2012).

The included obesity PHI studies reported that attempting to prevent obesity led to some participants experiencing an increase in dietary restraint, lowering of self-esteem, development of body image dissatisfaction and in some extreme cases, the development of anorexia (Allison and Weber 2003; Carter and Bulik 2008; O'dea 2005; Story et al. 2003; Striegel-Moore 2001). Infectious disease boomerang effects occurred when an oral rehydration solution intervention to treat those with cholera resulted in their subsequent infection with alternative bacterial isolates (Daniels et al. 1999).

Lack of community engagement

In six of the included studies, lack of direct community participation and knowledge translation (moving best practice evidence into action) emerged as an underlying factor associated with PHI unintended harm (Table 2). Studies reported that often engagement of target populations is minimal, conditional or even tokenistic (Barr et al. 2011) leading to interventions that fail to consider more complex underlying biological, societal and environmental factors (Greer and Ryckley 2011). Interventions lacking community engagement have been associated with an increased risk of sexually transmitted diseases and pregnancy (Blake et al. 2003), increased stigma, victimization and discrimination (Barr et al. 2011; Greer and Ryckley 2011) and environmental contamination (Qadir et al. 2010).

Ignoring root causes

A root cause are the underlying social or environmental circumstances that influence behavior and ultimately disease or injury risk (Marmot 2006). Root causes are often tackled through action on the social determinants of health (WHO 2010). Ignoring root causes was identified in five studies focusing on the PHI areas of birth weight, infectious diseases, obesity and clean water (Table 2). Garner et al. (1992) described the implementation of a PHI to increase the birth weight of newborns in LMICs, where an unintended harm of this PHI was the increase in obstructed labor frequency. This PHI was originally developed in high-income countries that have strong health systems and are able to perform caesarian births in a relatively safe and

timely manner. Unfortunately, in LMICs, the weak health system does not support this type of emergency surgery, putting both the mother and baby in danger of unintended harms (Garner et al. 1992).

Additionally, obesity interventions that aim to stigmatize obese individuals with underlying premise that obesity is a modifiable risk factor and, therefore, individuals can take responsibility for their health, are ignoring important evidence on root causes (Vartanian and Smyth 2013). Further consideration of alternate causative factors, especially the social and environmental determinants of obesity, are critical when designing obesity interventions, in order to minimize harmful unintended consequences (Greer and Ryckley 2011; O'dea 2005).

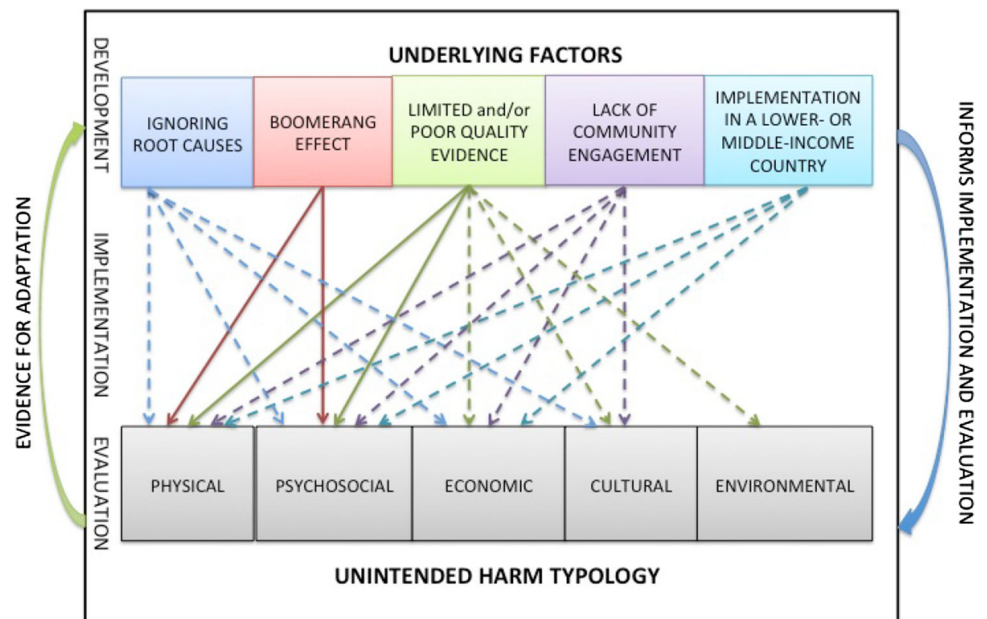
Higher-income country public health intervention implemented in a LMIC

Related to root causes, this theme represents well-meaning PHIs that were developed and tested in high-income countries being implemented in LMICs without adaptation to local context and often-limited health resources (ignoring context). Garner et al. (1992) discussed PHI that aimed to increase birth weight and resulted in the unintended harmful consequence of increased likelihood of difficulties resulting from labor and delivery. Moreira et al. (2009) reported on a PHI that aimed to diagnose patients who are suspected of having tuberculosis and the difficulties of unintended harms associated both with commission and omission of diagnosis. Hence, physical harms were most often associated with the implementation of a PHI in a LMIC (Table 2) and were linked to sub-optimal use of scarce resources (Moreira et al. 2009) and the presence of weak health systems in LMICs (Garner et al. 1992).

Relationships between PHI unintended harm typologies and underlying factors

Based on Table 2, a conceptual map was developed to illustrate the relationship between the unintended harm typology and the emergent underlying factors (Fig. 2). Certain underlying factors emerged as potential predictors of unintended harm typologies. Both physical and psychosocial harms were most often associated with the mechanisms of limited and/or poor quality evidence and the potential for prevention of one extreme to lead to another (boomerang effects). Evidence is limited for economic, cultural and environmental harms, yet both limited and/or poor quality evidence and a lack of community engagement emerge as important mechanisms in the generation of these unintended harms.

Fig. 2 A concept map illustrating the relationships between the unintended harm typology and emergent underlying factors. *Solid lines* indicate higher levels of evidence to support the underlying factor and typology relationship. *Dashed lines* indicate the presence, yet limited evidence on the underlying factor and typology relationship



This conceptual map is intended to provide guidance for public health professionals when developing, implementing and evaluating PHI in a variety of areas and illustrates that the existence of unintended harm is not a linear process. As such, we propose that PHI development and evaluation is a constant feedback loop that must take into consideration the complexities of evidence, context, potential boomerang effects and community engagement to minimize physical, psychosocial, economic, cultural and environmental unintended harms.

Discussion

This scoping review is intended to raise awareness of harmful unintended consequences of PHI to facilitate learning and creativity in the face of uncertainty (McDaniel et al. 2003). Our typology and underlying factors provide the initial groundwork for the development of a framework that will assist with the evaluation and reporting of PHI unintended harms. This framework will also assist Precautionary Principle thinking as public health professionals aim to prevent or limit harm in the face of uncertainty (Tickner 2004).

Utilization of the unintended harm typology

PHI should be constructed from a holistic perspective, with consideration given not only to the social determinants of health but also to ecological or environmental aspects of health (Qadir et al. 2010; Thomson et al. 2008). The presented typology is, therefore, informative for the field of

public health as it provides support for the well-utilized socio-ecological model (Bronfenbrenner 1979) to identify PHI unintended harms (Stokols 1996).

Based on the emergence of potential unintended harms to our environment, we must not forget that actions aimed to improve individual or population health may have unintended harms for the health of the physical environment in which we live. Consequently, for the evaluation of unintended harms, based on our typology, we propose that integrative biological, social and environmental determinants of health framework may be the most inclusive and appropriate for those conducting PHI evaluations and health impact assessment (WHO 2013). Hence, a trans-disciplinary team of researchers, government and local community representatives should be utilized when applying this typology to provide the breadth of knowledge and experience required to evaluate unintended harms (Brown et al. 2010; Parkes et al. 2005; Rashid et al. 2009).

In addition, we propose that this typology should be considered when planning evaluation procedures and reporting outcomes to improve transparency and move reporting standards for PHIs forward (Armstrong et al. 2008). Unintended harms need to be reported in the abstracts of peer-reviewed articles (Bernal-Delgado and Fisher 2008) to promote learning and creativity in PHIs that aim to address complex health issues in the face of uncertainty (McDaniel et al. 2003). We are making progress. There is evidence of public health professionals beginning to utilize this approach with the incorporation of mental health promotion with obesity prevention (McVey et al. 2013) and guidance for policy documents that consider physical, psychosocial and economic impacts of

obesity PHI targeting children and young people (NICE 2013).

An unanticipated consequence framework for PHI

This review begins to provide evidence for the value of incorporating Merton's UC mechanisms when planning, implementing or evaluating a PHI. For example, our identified factor of ignoring root causes relates to Merton's factor of basic values as those designing and implementing the PHI may be basing the felt necessity of action on a dominant set of values that may not be congruent with the new context (Merton 1936). Implementation of a PHI in a LMIC often disregards the importance of context and consideration of root causes leading to error. Limited and/or poor quality evidence relates directly to ignorance and in the case of a lack of contextual evidence also to error. The prevention of an extreme leads to another extreme (boomerang effect) may be based on basic values where the realization of values may lead to their renunciation due to an individual's adverse affective reaction in response to restrictions on freedom, autonomy and/or justice beliefs (Henriksen et al. 2006; Lucas et al. 2009; Merton 1936; Werle 2012). Lack of community engagement is associated with ignorance and the relevance paradox, as knowledge or evidence may exist, but it is not being utilized in specific populations or communities.

Limitations and next steps

A number of reviewed abstracts stated that no harms or adverse outcomes were evaluated and, therefore, could not be reported. This limitation likely leads to underreporting bias, where a number of PHI associated with unintended harms exist that are not represented within this review. If we were able to provide a quantitative analysis of the unintended harm effect size that was based upon standardized reporting, we may have been able to use Rosenthal's (1979) method for dealing with null or non-reported results (Cooper et al. 2009). Yet the reality is, there is likely a significant number of well-meaning PHI that did not evaluate unintended harms, and those that did, may have filed away the results due to the lack of standards requiring their discussion. Accordingly, reporting standards for PHI need to include unintended effects to improve the evidence base and our ability to synthesize it.

This review was conducted as an initial exploratory examination of the literature focused on PHI and unintended harm within circumscribed search parameters. Further review utilizing the terminology of unintended or unanticipated consequences should be conducted to identify and analyze PHI in other areas, such as tobacco (Bell 2011; Callery et al. 2011; Gallagher et al. 2010;

Leatherdale and Ahmed 2010; Williams et al. 2011) and physical activity (Bacon and Apheramor 2011) that are known to be associated with harmful intended effects. Harm reduction interventions (also excluded from this review) may also provide evidence of interesting negative side effects.

Conclusions

The evidence provided here demonstrates that unintended harms associated with PHI may occur in physical, psychosocial, economic, cultural and environmental contexts. As such, PHI planning and evaluation models need to be expanded beyond the current reductionist approach to deal with this type of complexity. Potential minimization of unintended harms will rely on the generation of transdisciplinary teams of PHI professionals and community members to sufficiently account for root causes, especially in LMICs. The current lack of comprehensive evidence on the socio-ecological impacts of PHIs is an impediment to our ability to accurately predict and minimize unintended harms. Thus, we conclude with a call for improved evaluation and systematic reporting of unintended harms and further synthesis of the underlying factors that are associated with the presence of harmful UC in well-meaning PHIs.

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