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Evidence for physical activity guidelines as a public health intervention: efficacy, effectiveness and harm – a critical policy sciences approach

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Evidence for physical activity guidelines as a public health intervention: efficacy, effectiveness and harm – a critical policy sciences approach.

Abstract

BACKGROUND: Evidence for the efficacy of physical activity in conferring health benefits is unequivocal, and this has led national governments to produce guideline recommendations for physical activity levels in their populations.

AIM: To evaluate how far evidence for the efficacy, effectiveness and comparative effectiveness of current physical activity guideline recommendations as a public health intervention is considered in developing guideline recommendations, including a consideration of the extent to which, in comparison to alternatives, they may result in harm.

METHODS: Utilising a critical policy sciences approach, national physical activity guideline recommendations in Australia, the UK and the USA, and those of the World Health Organisation, are examined, along with their stated underlying evidence bases, to analyse what evidence has been considered, how it has been interpreted, for what purpose, and with what outcomes.

RESULTS: All current guidelines recommend 150 minutes moderate physical activity per week. However, efficacy evidence shows 60 minutes is sufficient to provide some health benefits. None of the guidelines consider effectiveness evidence nor potential effectiveness. No evidence could be found for the effectiveness of a recommendation of 150 minutes in improving population health, and none of the guidelines consider whether a recommendation at a lower but still sufficient level of efficacy (e.g. 60 minutes) would be a more effective public health intervention.

CONCLUSIONS: Evidence considered in drawing up physical activity guidelines relates only to the efficacy of physical activity in conferring health benefits. The lack of effectiveness evidence, the failure to consider potential effectiveness, and related un-evidenced value judgements call into question the claim that the guidelines are evidence-based. Because neither effectiveness nor comparative effectiveness is considered, it is possible that current guidelines of 150 minutes may result in net harm to population health in comparison to the opportunity cost of recommendations at alternative levels.

Keywords

Physical Activity, Public Health, Efficacy, Effectiveness, Comparative Effectiveness, Opportunity Cost, Policy Sciences

Evidence for physical activity guidelines as a public health intervention: efficacy, effectiveness and harm – a critical policy sciences approach.

1. Introduction

Evidence for the efficacy of physical activity in conferring a range of health benefits and reducing all-cause mortality risk is now uncontested (Woodcock, Franco, Orsini & Roberts, 2011; Kokkinos & Myers, 2010), and this has led national governments to produce guidelines for physical activity levels for their populations (United States Department of Health and Human Services [USDHHS], 2008; Department of Health [DoH], 2011; Department of Health Australia [DoHA], 2013) and to the production of *global recommendations* on physical activity for health by the World Health Organisation (WHO, 2010a). It is broadly accepted that there is a *dose-response* relationship between physical activity levels and all-cause mortality (Wen et al., 2011; Physical Activity Guidelines Advisory Committee [PAGAC], 2008), and that the dose-response curve is inverse curvilinear, with the greatest benefits existing with a move from nothing to something and there being diminishing returns later in the curve. However, there remains some debate about the extent of benefits at different levels and intensities (PAGAC, 2008; Powell, Paluch & Blair, 2011). Nevertheless, the core common recommendation across WHO (2010a), USA (USDHHS, 2008), UK (DoH, 2011) and Australian (DoHA, 2013) guidelines is that 150 minutes of moderate intensity exercise per week provides *substantial health benefits* for adults. In addition, guidelines variously state that 300 minutes provides additional and more extensive health benefits (USDHHS, 2008; WHO, 2010a), that any physical activity is better than none (USDHHS,

2008; DoHA, 2013), and that adults should aim to be active daily (DoH, 2011), together with a range of further recommendations for other groups and at other exercise intensities¹.

While evidence relating to the *efficacy* of physical activity in conferring health benefits is clearly considered in developing physical activity guidelines, it is not clear how far evidence for the *effectiveness* of physical activity guidelines as a public health intervention is considered. Given that, in the USA, UK and Australia, from just over half to as low as one third of populations achieve guideline levels of physical activity (Centers for Disease Control and Prevention [CDC], 2014; Scholes & Mindell, 2013; Australian Bureau of Statistics [ABS], 2013), the effectiveness of guidelines as a public health intervention should be a primary consideration. However, some guidelines suggest (at least in places) that the public may not be an intended audience (DoH, 2011; WHO, 2010a), thus questioning whether guidelines should be considered a public health intervention, but the WHO definition of public health as “all organized measures [to]... promote health... among the population as a whole” (WHO, 2010b) suggests they should be so considered.

Drawing on a critical policy sciences approach, the aim of this paper is to evaluate how far evidence for the efficacy, effectiveness and comparative effectiveness of current physical activity guideline recommendations as a public health intervention is considered in developing the guidelines. In addition, the paper evaluates how far the development of the guidelines includes a consideration of the possibility that, when compared against the opportunity cost of alternative guidelines, current guidelines may result in harm to population health.

¹ While the universal “headline recommendation” is for 150 minutes at moderate intensity, guidelines also include a recommendation that 75 minutes at vigorous intensity, or an equivalent combination of moderate and vigorous intensities, will confer the same health benefits as 150 minutes moderate intensity. Guidelines also provide separate recommendations for children (5-18), and increasingly toddlers (<5) and further advice for older adults (>65).

2. Method

The methods for this paper draw on a critical policy sciences approach. The policy sciences originate in the work Lasswell (1951) and are simultaneously concerned with evidence of how and for what purpose policy is developed, and what evidence is drawn upon to develop policy (Lewin & Shakun, 1976; Sinclair, 2006). In the case of developing guideline recommendations with an explicit goal to be evidence-based, these two elements of a critical policy sciences approach are almost inseparable. Questions of how and for what purpose the guidelines have been developed are inextricably interlinked with questions of what evidence has (and has not) been assembled and how it has been interpreted. Therefore, a critical policy sciences approach is not concerned with a detailed analysis of the global evidence base for the health benefits of physical activity, rather with an analysis of what aspects of that evidence base have been considered in developing guidelines, how they have been interpreted, for what purpose, and with what outcomes.

The most recent physical activity guideline documents in the USA (USDHHS, 2008), UK (DoH, 2011) and Australia (DoHA, 2013) were examined, together with those of the World Health Organisation (WHO, 2010a), and the summary guideline recommendations were extracted, together with statements relating to the intended uses of, and audiences for, guideline recommendations. These statements were then compared to implementation in practice, drawing particularly on governmental advice and media releases, in order to understand both the intended and unintended purposes and uses of the guidelines and to establish the extent to which guidelines should be considered a public health intervention.

The four guideline documents were further examined to identify their stated underlying evidence bases, which were extracted for further analysis. Five review papers were cited as part of the evidence base for the relationship between physical activity and all-cause mortality in at least one of the guideline documents (PAGAC, 2008; Kesaniemi, Riddoch, Reeder, Blair & Sorensen, 2010; Warburton, Charlesworth, Ivey, Nettlefold, Bredin, 2010; O'Donovan et al., 2010; Brown, Bauman, Bull & Burton, 2012), some of which were specifically commissioned to inform that country's guidelines (e.g., Brown et al., 2012), some of which were not (e.g., O'Donovan et al., 2010), and some of which were initially commissioned to inform guidelines in another country (e.g., Warburton et al, 2010). The five review papers were examined in order to, firstly, extract the empirical data that provided the bases for the guideline recommendations and, secondly, establish whether the three national guideline documents and the global guidelines were each drawing on the same empirical data. This process showed that the latest of the review papers (Brown et al., 2012) drew on the same eleven empirical studies as the earliest review (PAGAC, 2008) to estimate the dose-response relationship between physical activity and all-cause mortality. In addition, later guideline documents cited multiple reviews as evidence of all-cause mortality impact (thus suggesting greater weight of evidence), despite those reviews each drawing on the same eleven empirical studies. Data from these eleven empirical studies were extracted and their interpretation in the reviews and guideline documents was analysed. The eleven studies are listed and collectively summarized in the results section.

Finally, the four guideline documents, the five review papers and the eleven empirical studies were examined to establish the extent to which efficacy and/or effectiveness evidence (Singal, Higgins & Waljee, 2014) underpins the guidelines. Specifically, the documents, reviews and empirical papers were evaluated in terms of: (a) evidence cited for the efficacy

of physical activity in conferring health benefits; (b) evidence cited for the effectiveness of the guidelines in increasing physical activity levels. Using this cited evidence, together with the wider extant evidence, the extent to which the guidelines have been informed by evidence of potential comparative effectiveness (Sox & Greenfield, 2009) against the opportunity cost of alternative guidelines was evaluated.

3. Results

3.1. Are physical activity guidelines a public health intervention?

The Nuffield Council on Bioethics (2007) has developed a public health intervention ladder that includes, towards the top of the ladder, interventions that restrict choice through regulation, such as a ban on smoking in public places, through interventions that seek to guide choice using incentives, such as tax breaks for the purchase of bicycles to be used to travel to work, to those at the bottom of the ladder that seek to inform choice through the provision of information. These universal information provision interventions are also recognised and endorsed by Public Health England (Newton, 2013), and if physical activity guidelines are used directly to inform and educate the public about their health, then clearly they should be considered a public health intervention.

Setting aside the WHO (2010a) guidelines which, quite legitimately, cite national-level policy-makers as the primary target audience, the national guidelines vary in the audiences they identify. The evidence report underpinning the Australian guidelines made a clear recommendation that “a set of resources, targeted to multiple audiences and users, should be developed and be available at the same time as the formal launch of the guidelines” (Brown

et al., 2012, p. 100), and the final guidelines for adults directly address the public in the first person (DoHA, 2013). The USA guidelines (USDHHS, 2008) note that they are “intended to be a primary source of information for policy makers, physical educators, health providers, and the public” (p. ii), and that “messages contained in these guidelines should be disseminated to the public” (p. 6). However, the UK guidelines (DoH, 2011) state that they are “intended for professionals, practitioners and policymakers concerned with formulating and implementing policies and programmes” (p. ii), and that the document “does not and indeed cannot set out the specific messages we need to reach communities across the UK with diverse needs, lifestyles and attitudes to activity” (pp. 3-4) and that there “needs to be careful and planned translation of these guidelines into appropriate messages for the public” (p. 46). This suggests that the Australian and USA guidelines should be considered direct public health interventions as the public is explicitly identified as an intended direct audience, but in the UK the public is explicitly excluded as an intended direct audience and the stated intention of the guidelines is to inform policy and practice.

However, regardless of the stated intention for policy-makers and practitioners to undertake careful and planned translation into appropriate messages to be communicated to the public, the use of the guidelines in practice in the UK is somewhat different. NHS Choices is a government website intended to be used by the general public, with a stated purpose to “provide a comprehensive health information service to help put you in control of your healthcare...it helps you make choices about your health, [and] decisions about your lifestyle, such as smoking, drinking and exercise”². The website repeats verbatim the recommendation from the UK guideline document regarding 150 minutes of moderate intensity activity and

² <http://www.nhs.uk/aboutNHSChoices/aboutnhschoices/Aboutus/Pages/Introduction.aspx> (accessed: 17/10/2014)

being active daily, prefacing it with the statement that to *stay healthy* adults must be active at this level and frequency³.

The launch of the UK guidelines was accompanied with a press release that, once again, repeated verbatim the 150 minute recommendation, but added that there is “a renewed focus on being active everyday” and “more emphasis on vigorous activity” (DoH, 2011b). This led to widespread press coverage of the 150 minute recommendation, but also of “concerns that activities like walking or cycling alone are insufficient” and that “[p]eople should be pushing themselves” and “should take up vigorous games...because moderate exercise is not enough” (Adams, 2011). Beyond government, translation for local campaigns tends to uprate messages, with one local authority’s “5x30 move more” campaign noting that the “Department of Health have recommended that in order to go from a sedentary to an active lifestyle you should *take up* 5 sessions of 30 minutes of exercise every week”⁴ (emphasis added).

Resources and toolkits do exist that could be used to help achieve the need for “careful and planned translation of...guidelines into appropriate messages for the public” identified in the UK (DoH, 2011, p.46). The Toronto Charter for Physical Activity (Global Advocacy Council for Physical Activity / International Society for Physical Activity and Health, 2010), for example, published the year before the UK guidelines were issued, provides specific advice on actions and interventions to “support health-enhancing physical activity for all” (p.1). This advice includes adopting evidence-based guidelines on physical activity and health, advocacy to engage the media, and developing mass communication and social marketing campaigns. Whilst the UK government has adopted guidelines, its media

³ <http://www.nhs.uk/Livewell/fitness/Pages/physical-activity-guidelines-for-adults.aspx> (accessed: 17/10/2014)

⁴ http://www.brighterliving.org.uk/?page_id=51 (accessed: 17/10/2014)

engagement via press releases and its mass communication with the public via its websites have made no attempt to translate messages for the public despite having explicitly identified the need to do so in its guideline document.

It appears, therefore, that although the UK guidelines clearly state that they are “intended for professionals, practitioners and policymakers” (DoH, 2011, p. ii), in every practical sense the guidelines are being treated and implemented as a direct public health intervention by government, the media and local practitioners. While this is clearly an unintended outcome, it is both naive and irresponsible to fail to consider, acknowledge and accept that in practice, and regardless of intent, the guidelines have become a direct public health intervention.

3.2. Evidence cited for the efficacy of physical activity in conferring health benefits

Efficacy evidence relates to the performance of an intervention under ideal and controlled conditions (Singal, Higgins & Waljee, 2014). For physical activity guidelines ideal conditions are that members of the public would adopt and adhere to recommended guideline levels. Consequently, efficacy evidence is concerned with the health benefits physical activity confers at various levels. In this respect, all four guideline documents agree that 150 minutes of moderate intensity activity confers substantial health benefits (USDHHS, 2008; DoH, 2011; DoHA, 2013; WHO, 2010a), and it is this 150 minute level that is the core recommendation in each of the guidelines.

The evidence for 150 minutes is most recently summarised in the report underpinning the Australian guidelines (Brown et al., 2012), which uses an all-cause mortality curve adapted from Powell et al. (2011), which was itself adapted from the report underpinning the USA

recommendations (PAGAC, 2008). Given that the UK guidelines (DoH, 2011) highlight the USA report as a primary source, all of the national guidelines are using the same summary all-cause mortality curve. The all-cause mortality curve was developed using data from 11 prospective cohort studies published between 1995 and 2006 (Lee, Hsieh & Paffenbarger, 1995; Fried et al., 1998; Kujala, Kaprio, Sarna & Koskenvuo, 1998; Lee & Paffenbarger, 2000; Rockhill et al., 2001; Tanasescu, Leitzmann, Rimm & Hu, 2003; Sundquist, Qvist, Sundquist & Johansson, 2004; Trolle-Lagerros, 2005; Carlsson, Andersson, Wolk & Ahlbom, 2006; Janssen & Jolliffe, 2006; Lan, Chang & Tai, 2006) that assessed at least five levels of physical activity, with 268,962 observations of individuals aged 25 and over and a total of 18,075 deaths.

The Australian commentary (Brown et al., 2012) on this all-cause mortality curve is that there is a steep initial slope, there is no obvious lower threshold for benefit, there is no obvious optimal amount, and there is no obvious upper threshold. However, the report notes that there are significant benefits from levels of activity below 150 minutes, but that these “have largely been ignored in public health recommendations” (p.84). In fact, in the unsmoothed version of the summary all-cause mortality curve (PAGAC, 2008; Powell et al, 2011), the steep initial slope appears to abate at 90 minutes a week, where an all-cause mortality risk reduction of 20% is conferred (compared to a baseline of 30 minutes or less activity per week). At 150 minutes, an all-cause mortality risk reduction of around 25% is suggested, with a 27% risk reduction shown at a specific data point at 180 minutes. This shows clear diminishing returns in terms of all-cause mortality risk reduction from 90 minutes of moderate intensity exercise per week, although protection against additional conditions such as some cancers is added with a more than three-fold increase in activity to around 300 minutes per week (Brown et al., 2012), where the all-cause mortality risk

reduction is around 35%. The interpretation of this evidence in the Australian report (Brown et al., 2012) is that the “optimal range” in terms of benefits secured versus effort invested is between 150 minutes and 300 minutes, for which the all-cause mortality risk reduction is from 25% to 35%. This is the central justification for the ubiquitous guideline that 150 minutes provides *substantial health benefits*. This is despite the evidence that a 40% drop in active minutes from 150 to 90 minutes would result in only a 20% loss in all-cause mortality risk reduction from 25% to 20%.

It is also acknowledged that there is increasing evidence that a lower risk of all-cause mortality and lower incidence of coronary heart disease is conferred at levels of no more than one hour of moderate intensity activity per week (PAGAC, 2008; Brown et al., 2012). Furthermore, summary reports, papers and guidelines (DoH, 2011; PAGAC, 2008; Powell et al., 2011; Brown et al., 2012) universally explicitly acknowledge that there are significant proportions of the population who are at the lowest end of the activity spectrum, and that the steep initial slope of the all-cause mortality curve that provides rapid improvement with a movement from nothing to something will bring both substantial health benefits to those individuals and the greatest public health benefit, and this is further supported by more recent evidence (De Souto Barreto, 2015; Sparling, 2015; Moore et al., 2012). However, it is difficult to estimate a specific all-cause mortality risk reduction at levels below 90 minutes because published guideline levels often provide the threshold levels for studies (PAGAC, 2008; Moore et al., 2012) and thus “research on the value of activity outside these parameters has been limited” (Powell et al., 2011). Of the 73 studies that provided the evidence base for the USA report (PAGAC, 2008), 59 studied three or more levels of physical activity, but only 12 studied five or more, and across these 59 studies, the lowest activity level studied mostly falls between 60 and 90 minutes. Therefore, although it is clear that there is an all-cause

mortality benefit at 60 minutes (PAGAC, 2008; Powell et al., 2011; Brown et al., 2012), the magnitude of that benefit is less clear, and the baseline comparator in the unsmoothed version of the curve is 30 minutes activity or less rather than zero⁵. Nevertheless, the smoothed version of the all-cause mortality curve (Brown et al., 2012) suggests that 60 minutes of activity confers an all-cause mortality risk reduction of 18% compared to a zero baseline, which translates to a circa 15% risk reduction compared to the baseline of 30 minutes or less used in the unsmoothed curve (PAGAC, 2008; Powell et al., 2011; Leitzmann et al., 2007).

Given both the lack of evidence relating to the impact of specific low doses of moderate intensity physical activity and the acknowledged individual and public health benefits that could be realized by increasing activity at these levels, it is surprising that there are not more widespread calls for research on such low doses. Particularly surprising is that the USA report (PAGAC, 2008), in listing research needs in relation to all cause mortality, suggests that “[s]tudies are needed to determine the point (if any) on the dose-response curve at which no further reduction in all-cause mortality occurs”, but makes no mention of a need to determine all-cause mortality reductions at low doses of activity.

In summary, the efficacy evidence cited to inform the three national guidelines suggests all-cause mortality risk reductions of 15% at 60 minutes of moderate intensity activity per week, 20% at 90 minutes, 25% at 150 minutes, 27% at 180 minutes and 35% at 300 minutes, compared to a baseline of 30 minutes activity or less.

3.3. Evidence cited for the effectiveness of the guidelines in increasing physical activity levels.

⁵ A baseline of zero is taken across all the cited guidelines, reports and studies to mean zero additional activity of at least moderate intensity over and above all sedentary and light-intensity activities of daily life.

Effectiveness evidence relates to the performance of an intervention under ‘real world’ conditions, and considers issues such as provider acceptance and target audience compliance (Singal et al., 2014). For physical activity guidelines, key real world conditions to consider are: firstly, the likelihood that target audiences – in general, the public; specifically, the least active – will adopt and adhere to recommended guideline levels; secondly, in the UK case, how far practitioners will recognise and accept the stipulated need to translate guidelines for public consumption (DoH, 2011). Effectiveness evidence goes beyond efficacy evidence for the health benefits of recommended levels of physical activity to consider the external validity of recommending those levels in the real world (Rothwell, 2005).

Given that efficacy evidence shows no obvious optimal amount of physical activity (Brown et al., 2012), rather an inverse curvilinear scale, it might be expected that effectiveness evidence would inform what level should be recommended to achieve the greatest public health benefit. However, no effectiveness evidence is cited in either the guideline documents (USDHHS, 2008; DoH, 2011; DoHA, 2013; WHO, 2010a) or in the documents that provide their stated underlying evidence bases (PAGAC, 2008; WHO, 2010b; Kesaniemi et al., 2010; Warburton et al., 2010; O’Donovan et al., 2010; Brown et al., 2012). While the lack of direct effectiveness evidence (Sparling, 2015) could be offered as an explanation for this omission, evidence does exist on compliance with other public health guidelines (Blackwell, Martinez & Gentleman, 2008; May, Kiefe, Funkhouser & Fouad, 1999) and, indeed, on compliance with physical activity guidelines (Pate et al., 2002; Rafferty, Reeves, McGee & Pivarnik, 2002; Tucker, Welk & Beyler, 2009), which could provide insights into the *potential effectiveness* of guideline recommendations. Evidence is also available on the communication and reception of science-based health recommendations (Jaime & Lock, 2009; Fineberg &

Rowe, 1998; Rowe, 2002), or such evidence could be commissioned from consumer panel research (Pollard, 2002). But no such evidence is cited in the guidelines or their supporting documents, nor is the issue of potential effectiveness recognized or discussed.

The report underpinning the Australian guidelines (Brown et al., 2012) notes that the universally recommended 150 minute threshold is “somewhat arbitrary” (p. 84), but is an “achievable quantum” (p.80) or “minimal...realistic behavioural target for the general population” (p.84). No evidence is given for these assertions other than the recognition of a convention that “most countries provide a recommended minimum target...[and] this minimal target is accepted as being about 150 minutes” (p.84). However, recent evidence on compliance with the 150 minute recommendation in the USA showed that, while self-reports suggested compliance of 62% among US adults, objective accelerometry measures demonstrated compliance was far lower at 9.6% in the same sample of 3,082 adults (Tucker et al., 2011). This is, of course, just one study, but neither this study, published 18 months before the Australian report, nor any other study on compliance or effectiveness, was used to reach the conclusion that the 150 minutes convention is an achievable quantum or a minimal realistic behavioural target.

All three national guidelines recommend 150 minutes as providing *substantial health benefits* (USDHHS, 2008; DoH, 2011; DoHA, 2013). However, there is no evidence to support the value judgment that populations will consider a 25% all-cause mortality risk reduction (conferred at 150 minutes) rather than a 20% risk reduction (at 90 minutes), or even a circa 15% risk reduction (at 60 minutes) to be a *substantial health benefit*. In fact, if the aim is to set guidelines at a level “representing a balance of benefit, compared with the effort required to do it” (Brown et al., 2012, p. 84), then the objective efficacy evidence would suggest

recommending 90 minutes, as this is the point after which the steep initial slope of all-cause mortality risk reduction abates to deliver diminishing returns (PAGAC, 2008; Powell et al., 2011).

In summary, neither the guidelines nor their stated underlying evidence bases cite evidence for effectiveness or potential effectiveness. Instead, unsupported value judgments are made about what populations will value as a *substantial health benefit*, and un-evidenced assumptions and assertions, based on nothing more than convention, are made about what represents a realistic behavioural target for the general population.

4. Discussion

4.1. Effectiveness, Comparative Effectiveness and Harm

The results above call into question the extent to which the universally recommended level of 150 minutes of moderate physical activity per week might legitimately be considered to be evidence-based. Firstly, although there is clear efficacy evidence that 150 minutes delivers an all-cause mortality risk reduction of 25%, the decision to recommend 150 minutes is not based on evidence, but on a value judgment that a 25% risk reduction represents a *substantial health benefit*, and that risk reductions of 20% (conferred at 90 minutes) or even 15% (conferred at 60 minutes) do not. Secondly, an objective consideration of the efficacy evidence suggests recommending 90 minutes, as this is the point on the all-cause mortality curve after which there are diminishing returns on additional time spent active. Thirdly, no evidence other than convention is provided for the assertion that 150 minutes represents a realistic behavioural target for the general population. In fact, objectively measured

compliance in the USA, UK and Canada across a combined sample of over 12,500 adults demonstrates that only 10% to 15% of adults achieve the recommended 150 minutes, thus suggesting that it is not an achievable target (Rafferty et al., 2002; Tucker et al., 2011; Garriguet & Colley, 2014; CDC, 2006). Finally, no evidence is cited for the effectiveness of a recommendation of 150 minutes in increasing physical activity levels, nor is evidence for the potential effectiveness of a recommendation at this level considered. Collectively, these insights suggest that national physical activity guidelines are an un-evidenced public health intervention.

Analyses in the UK have concluded that public health interventions “are likely to be ineffective or lack evidence to establish effectiveness” (Katikireddi, Higgins, Bond, Bonell & Macintyre, 2011, p. 3), and that un-evidenced public health interventions “...are experiments on the public and can be as damaging (in terms of unintended effects and opportunity cost) as unevaluated new drugs or surgical procedures” (House of Commons Health Committee, 2009, p. 115). Furthermore, “[s]uch wanton large-scale experimentation is unethical, and needs to be superseded by a more rigorous culture of piloting, evaluating and using the results to inform policy” (House of Commons Health Committee, 2009, p. 115). In respect of physical activity guidelines in the UK, there is no evidence of any evaluation of effectiveness that meets the standards government sets for itself (HM Treasury, 2013; HM Treasury, 2011a; HM Treasury 2011b; National Audit Office, 2013), nor of those set out by the then newly appointed Secretary of State for Health in 2010 that “public health services must meet tougher tests of evidence and evaluation . . . We must only support effective interventions that deliver proven benefits” (Lansley, 2010, para. 104, 106).

Physical activity guidelines, in the UK and elsewhere, do not meet these standards of evidence or ethics, and the potential for harm from unintended effects and opportunity cost are not considered. As noted earlier, an unintended outcome (rather than effect) in the UK has been that the guidelines have been treated and implemented as a direct public health intervention in the first place. However, once it is acknowledged and accepted that the guidelines have become a direct public health intervention, unintended effects relate to whether guidelines perceived to be “challenging goals will cause the public to reject the guidelines as unrealistic” (Brawley & Latimer, 2007, p. S181) and thus discourage them from trying in the first place (Sparling, 2015; Moore et al., 2012; Bethancourt, Rosenberg, Beatty & Arterburn, 2014; Couch, Han, Robinson & Komesaroff, 2015), which raises the prospect that the guidelines may cause actual harm by being less effective than doing nothing.

Opportunity costs relate to the possibility that recommendations at alternative levels may result in greater health benefits at a population level. Given that efficacy evidence shows a dose-response relationship in which there is no obvious lower threshold for benefit, no obvious optimal amount, and no obvious upper threshold (Brown et al., 2012), a consideration of the *comparative effectiveness* of different recommendation levels is clearly warranted. Comparative effectiveness evidence is concerned with the relative benefits and harms of alternative interventions (Sox & Greenfield, 2009). This includes the relative or net harm of interventions in comparison to the opportunity cost of not implementing alternatives (House of Commons Health Committee, 2009). Therefore, in terms of physical activity guidelines would, for example, a recommendation at 60 or 90 minutes deliver sufficiently greater compliance than the circa 10-15% compliance delivered by the current recommendation at 150 minutes (Rafferty et al., 2002; Tucker et al., 2011; Garriguet & Colley, 2014; CDC, 2006) to be more effective in delivering health benefits at a population level despite lower efficacy in reducing all-cause mortality? Neither existing objective

compliance evidence (Rafferty et al., 2002; Tucker et al., 2011; Garriguet & Colley, 2014; CDC, 2006) nor the dose-response nature of efficacy evidence (Brown et al. 2012) provide evidence to suggest that a recommendation at 150 minutes is more effective in delivering population health outcomes than potential alternative recommendations at 60 or 90 minutes. This raises the real possibility that, in terms of comparative effectiveness (Sox & Greenfield, 2009), current guidelines are inflicting net harm on the population in comparison to the opportunity cost of not implementing alternatives (House of Commons Health Committee, 2009). This is not to say that there is evidence that alternatives would be more effective but, equally, nor is there evidence that they would not. The key issue is that such possibilities have not been considered or evaluated, and this is both unethical (House of Commons Health Committee, 2009) and negligent.

5. Conclusion

Utilising a critical policy sciences approach, this paper has examined what evidence has been considered in developing physical activity guidelines, how it has been interpreted, for what purpose, and with what outcomes. The purpose of physical activity guidelines is recognized to be a public health intervention to inform health choices in Australia (DoHA, 2013) and the USA (USDHHS, 2008), and the implementation and use of the guidelines in the UK shows that, despite intent, they have become a direct public health intervention there, and to consider them otherwise would be both naïve and irresponsible. All three national guidelines, and the WHO global guidelines, draw on the same evidence base of efficacy evidence. However, no attempt has been made to explore effectiveness evidence, nor to consider potential effectiveness, and un-evidenced value judgements have been made about what represents a substantial health benefit and an achievable behavioural target. These value

judgements, together with the failure to consider effectiveness, have led to an interpretation of the efficacy evidence that appears to overestimate at 150 minutes the amount of physical activity required for health benefits. Ultimately, this calls into question the claim that the guidelines are evidence based.

An interesting concluding perspective is provided by the Global Observatory for Physical Activity's report cards on physical activity published in December 2015. The report cards for England (the largest part of the UK) and Australia, which are comparable in terms of life expectancy and percentage of deaths from non-communicable diseases, show that compliance with the physical activity guideline recommendation of 150 minutes per week in England is 59%, but percentage of deaths related to physical inactivity is 16.9%, whereas in Australia, physical activity guideline compliance is significantly lower at 43%, but so are deaths related to physical inactivity at 10.1% (Foster & Milton, 2014; Bauman, 2014). The source data for these activity levels (AHS, 2012; Craig & Mindell, 2013) shows that a further 36% of Australians are active at levels below the guideline recommendations, while for England only 21% are active below recommended levels. Although there are likely to be some measurement artefacts, these data show that in both Australia and England, around 80% of the population are active at some level, but in Australia, where mortality from physical activity is more than 40% lower than in England, the percentage of those active below the guideline recommendation levels is more than 70% higher. Accepting that these are the rawest of national statistics, might this at least suggest that health benefits are being conferred at physical activity levels below the 150 minute guideline?

Clearly, one outcome of the way in which evidence has (and has not) been considered and interpreted in developing physical activity guidelines is that there has been a sub-optimal

policy process which appears to have led to a sub-optimal policy. However, a further more significant outcome is that the failure of this sub-optimal policy process to consider both unintended effects and the potential comparative effectiveness of alternative recommendations raises the real prospect that the current guidelines may be resulting in actual and net harm to population health.

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