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Efficacy of a county-wide schools weight management intervention

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Abstract

Aims: This study aimed to evaluate the effectiveness of the Local Authority commissioned large-scale public health service that provided a 6-week school-based weight management intervention for children aged 4–19 years.

Methods: A quantitative retrospective cohort study identified participants from 130 schools consisting of 8550 potential children aged 4–19 years across a mixture of Lower Super Output Area (LSOA) deprivation groups. Participants were invited to take part in a 5- to 12-week Healthy Lifestyles intervention with a focus on weight management delivered by OneLife Suffolk between 1 January 2017 and 1 January 2020. This resulted in a final sample of 5163 participants. The following information for each child was collected anonymously: (1) age, (2) gender, (3) preprogramme body mass index (BMI), (4) postprogramme BMI, (5) weight category and (6) LSOA category.

Results: Following the 6-week school-based intervention, there was a significant decrease in mean ΔBMI SDS (standardised body mass index) of −0.07 (−14.89%) among participants. Wilcoxon signed-rank test showed a significant change in weight status post 6-week weight management programme (WMP): BMI ($Z = -15.87$, $p < .001$), BMI SDS ($Z = -21.54$, $p < .001$), centile ($Z = -20.12$, $p < .01$) and weight category ($Z = -7.89$, $p < .001$), whereas Mann–Whitney *U* test showed no statistically significant difference in mean BMI SDS change between gender groups ($p = .24$) and Kruskal–Wallis test revealed no statistically significant differences in mean BMI SDS change between child LSOA groups ($c^2(4) = 1.67$, $p = .796$), school LSOA groups ($c^2(4) = 4.72$, $p = .317$), ethnic groups ($c^2(4) = 2.53$, $p = .640$) and weight category at the start of the intervention ($c^2(3) = 6.20$, $p = .102$).

Conclusions: This study contributes to the growing body of evidence demonstrating the efficacy of multicomponent school-based weight management interventions and demonstrates that such interventions can be successfully implemented as part of a wider healthy lifestyles service, without widening health inequalities.

INTRODUCTION

The global prevalence of childhood obesity has increased more than eightfold among 5- to 19-year-olds over the past four decades, and continues to rise.[1] Although the increase in mean body mass index (BMI) is consistent on a global scale, obesity prevalence has accelerated in east and south Asia for both sexes, and southeast Asia for boys.[1] Hence, promoting the health of disadvantaged children, both in low- and low-medium-income countries and in disadvantaged groups in affluent countries, requires particular attention.

In England, 22.4% of reception-aged children suffer from overweight or obesity, rising to 34.3% for children aged 10–11 years and 40% for children aged 13–15 years.[2] Alarmingly, severe obesity among this age group continues to rise and has increased by more than a third since 2007 to 4.2%, the highest rate recorded to date.[2] Severe childhood obesity remains a growing yet under-recognised health problem.

Children who suffer from overweight and obesity are more susceptible to developing both physical (e.g. type II diabetes, musculoskeletal disorders and respiratory problems) and psychosocial (e.g. self-esteem, quality of life, stigmatisation and depression) issues.[3,4] When compared with children suffering from moderate obesity, children suffering from severe obesity are at an even greater risk of such health problems.[5] The model for mediating (i.e. factors which help

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explain the relationship between two conditions) and moderating (i.e. factors that might influence the strength of a relationship between two conditions) factors[6] shows that the relationship between childhood obesity and physical and psychosocial health is bidirectional. Moderating factors in children include the following: boys, older children (13–15 years), of a lower socioeconomic status (SES), disabled and of a Black ethnicity. Mediating factors include behavioural (e.g. diet and exercise adherence), biological (e.g. chronic disease and medication use), psychological (e.g. poorer perceived health, negative thoughts and low self-esteem) and social factors (e.g. stigmatisation and low social support).

Of particular importance in the UK is the influence of SES. In the most deprived areas in England, 12.8% of children in age 4–5 years suffer from obesity compared with 5.7% in the least deprived. Among children aged 10–11 years, this percentage is 26.8% in the most deprived areas, compared with 11.7% in the least deprived.[1] Furthermore, significantly higher levels of severe obesity have been reported in areas of low SES.[5] Families from low-income communities are faced with several potential barriers to preventing improvement in health statuses: access to physical activity (PA) opportunities, neighbourhood safety, cost, transport, and knowledge and education of healthy behaviours.[7,8] Furthermore, families with low SES are less likely to recognise a child as being in the overweight or obese categories[1] and thus do not believe that an intervention is required to change a child's eating and activity behaviours.[9] Recognising signs of childhood obesity is a key challenge to reduce further enhancing health inequalities, and hence, education for children and parents is key.[10]

Marmot[11] describes a gradient of inequity in health risks across the population and advises proportionate universalism to tackle this. In other words, that more effort be put into assisting those who are considered the most vulnerable (e.g. moderating risk factors). Childhood weight management interventions should strive for suitability and effectiveness across a universal spectrum of participant characteristics in order to decrease attrition as change in standardised body mass index (BMI SDS) is positively correlated to programme completion rates.[12] Despite this, such services are only available to a small number of those in need across England.[13]

A large amount of a child's time between the ages of 4 and 16 years is spent within a school environment. Between January 2017 and January 2018, the number of pupils enrolled in school in England was 8,735,098.[14] This offers an opportunity to use policies, staff, curricula and parental engagement to positively influence a child's health and wellbeing. Given the wide reach of schools and the fact that they provide a platform for equity and a relative consistency of information translation, they present an opportunity to address obesity without widening health inequalities further.[15] Despite this, evidence of weight management intervention impact in schools is mixed. A recent systematic review and meta-analysis of the overall effects of 50 randomised controlled trial (RCT) school-based obesity prevention interventions showed that short-term (6- to 12-week) interventions are more effective in reducing weight among overweight and obese children than long-term (>12-week) interventions.[15] Concurrently, recent evidence of the large-scale (n = 1467 pupils) 12-month West Midlands ActiVe lifestyle and healthy Eating in School children (WAVES) intervention[16] concluded no evidence of clinical effectiveness or cost-effectiveness. A lack of knowledge, awareness and skills to deal with the sensitivity and complexity of childhood obesity across all school stakeholders presents the most significant barrier to effective action.[17]

There is a recognition in the literature that obesity is a complex issue requiring system-based approaches (i.e. individually tailored approaches informed by theory about complex systems which propose new ways of organising, managing and evaluating activities).[18] Given findings that long-term RCT interventions may result in decreased child enjoyment, motivation and subsequent retention,[19] short-term (6- to 12-week interventions), pragmatic school-based weight management interventions, using some elements of systems thinking, could provide a more cost-effective way to evaluate effectiveness and subsequently test and modify through 'trial and error' intervention components within 'real world' settings.[20] Pragmatic interventions within 'real world' settings enable mutual learning and understanding about the activities, opinions, values and experiences of not only participants themselves, but also of organisational structures and diverse stakeholder groups (e.g. parents and teachers). This approach enables efficacious pilot interventions to be 'scaled-up' into county-wide trials across local authorities. This is in line with the physical and health education (PHE) guide to supporting local approaches in promoting a healthy weight.[21] The available global evidence indicates large benefits of promoting healthy eating patterns and limiting sugar-containing beverage consumption from early childhood onwards.[22] Regular PA and limited sedentary lifestyle and screen time alone have limited effects but are valuable elements in effective multicomponent strategies.[22]

Therefore, this study explored the impact of a pragmatic 6-week school-based local authority supported intervention on a large number of schools across an English rural county. Our secondary aim was to determine intervention impact on a number of variables (i.e. age, gender, ethnicity and SES) that are associated with health inequalities.

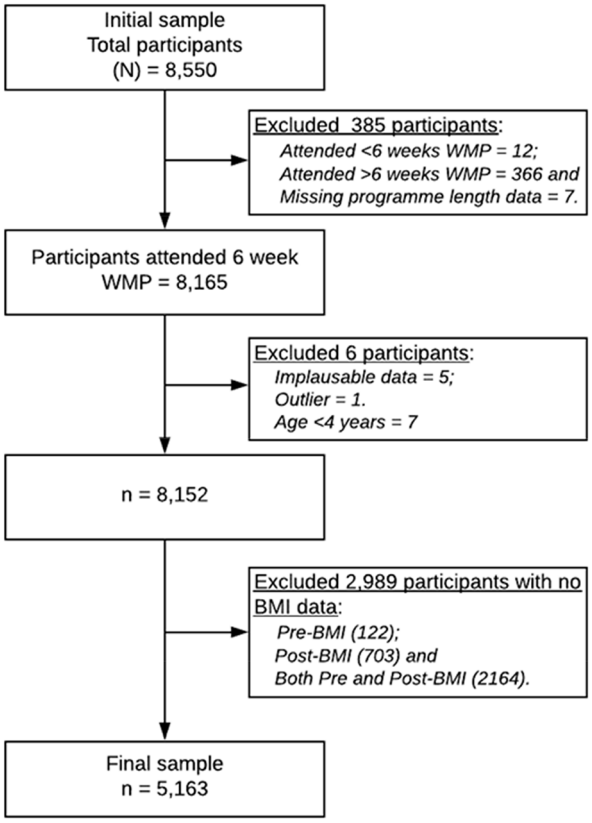
METHODS

This study provides quantitative data within a community-based Integrated Healthy Lifestyle Service (IHLS). The observed IHLS focuses on reducing health inequalities among vulnerable and hard-to-reach groups within areas of deprivation. The service is a partnership between a UK-based university and is commissioned by a local County Council in the south east of England.

Figure 1

Flowchart of data management

WMP: weight management programme; BMI: body mass index.



Participants and procedures

A quantitative retrospective cohort study was used to generate relevant data for this study. This study involved 8550 children from different socioeconomic backgrounds, aged 4–19 years from 130 schools attending a 5- to 12-week weight management programme (WMP). Of all participants, 8165 participants attended a 6-week WMP. After excluding participants with implausible data, outliers and missing BMI data, the final sample remaining was 5163 (Figure 1). All the participants involved in the analysis completed the 6-week WMP, between 1 January 2017 and 1 January 2020, delivered by OneLife Suffolk. Details of the flow of participants through the study from baseline to follow-up are displayed in Figure 1.

Ethical approval was provided by Leeds Beckett University's (LBU) Research Ethics Sub-Committee (Approval No. 72597). Secondary data sampling was implemented via the primary data source of the public health initiative OneLife Suffolk, to generate participants, that had provided parental consent for children who had completed the 6-week school-based weight management intervention. The study solely focussed on participants fitting the above criteria in interventions delivered in the county of Suffolk. To be eligible for inclusion, participants had to be aged between 4 and 19 years and completed OneLife Suffolk's 6-week school-based weight management intervention. Participation was voluntary with no incentives provided.

Intervention

The OneLife Suffolk Healthy Schools Programme is part of a wider healthy lifestyles service that is funded by the Public Health department at Suffolk County Council. The intervention is an evidence-based, multicomponent school-based WMP, developed by a specialist team of clinicians, including a dietician and health psychologist, with a strong knowledge of obesity. The programme follows the Standard Evaluation Framework (SEF) for Weight Management Interventions good practice in behaviour change guidelines.[23]

The intervention is delivered by trained OneLife practitioners and consists of six healthy lifestyle workshop style sessions (see Table 1). Sessions provide evidence-based, public health messaging around the key topics designed to support lifetime healthy lifestyle skills and knowledge to promote and encourage long-term maintenance of healthy eating choices and increased PA. Parents also receive healthy lifestyle parent manuals, and optional training specific to school staff and their role in children's health is provided where warranted. The programme has three different curriculums to ensure age-appropriate strategies are delivered to children from reception age (4–5 years old) through to year 12 (18 years old). The skeleton curriculum has been developed in line with the SEF for Weight Management Interventions' good practice in behaviour change guidelines.[24] However, the intervention further extends this by introducing the four key constituents of the self-theory,[25] which include self-awareness, self-regulation, self and others, and self-reliance. It also uses self-determination theory[26] which supports behaviour change by promoting competence (knowledge and skills of eating and activity behaviours), autonomy (planning, goal setting, monitoring) and relatedness (through the inclusion of peers, teachers and parents to achieve common goals).

To facilitate successful implementation of the intervention, OneLife practitioners invited school staff to a training session before the intervention began, to provide staff with the aims, objectives and ethos of the intervention. This was to prepare school staff themselves to best help motivate children and parents to take the healthy lifestyle message on board and encourage intervention attendance as well as address potential questions/worries school staff may have. Following full completion of the 6-week

Table 1

Example content from the OneLife Suffolk Healthy Schools Programme

Study week	Healthy lifestyle messages
Week 1	Healthy lifestyle, healthy body
Week 2	Healthy balanced diet and portion sizes
Week 3	Regular eating and healthy snacks
Week 4	Importance of PA and reducing sedentary behaviours
Week 5	Understanding food labels and sugary drinks
Week 6	The importance of sleep

PA: physical activity.

intervention, children received a certificate of achievement. Incentives and rewards for continued attendance, including certificates of achievement and progress reports, are noted as being particularly important for children.[26]

Measures

Height and weight

Height and weight measurements were taken preintervention and postintervention, and BMI centile was precalculated using the Microsoft Excel add-in LMSgrowth.[27] All measurements were carried out by a Healthy Lifestyle Practitioner employed by OneLife Suffolk. Weight measurements were taken in light clothing without shoes using portable digital scales (Seca 875 Flat Scales for Mobile Use) to the nearest 0.1 kg. Height was recorded to the nearest 0.1 cm using a portable stadiometer (Marsden HM-250P Leicester Portable Height Measure). BMI was calculated using the equation weight (kg)/height $(m)^2$, and BMI SDS was calculated using the 'LMS' method.[28]

SES status

Postal codes were used to estimate SES by generating Index of Multiple Deprivation (IMD)[29] using an online conversion tool (http://imd-by-postcode.opendatacommunities.org/). The IMD is a UK government metric used to rank area-level deprivation within and between different communities. The IMD scores rank each super output area in England from 1 (most deprived area) to 32,844 (least deprived area). The IMD considers seven domains which relate to health deprivation and disability, education skills and training deprivation, income deprivation, employment deprivation, barriers to housing and services, living environment deprivation, and crime.[29] For the purpose of this study, Lower Super Output Areas (LSOAs) were categorised into five subgroups for analysis: group 1 (lowest deprivation) = 0%–20%, group 2 = 21%–40%, group 3 = 41%–60%, group 4 = 61%–80% and group 5 (highest deprivation) = 81%–100%.

Gender and age

Before OneLife Suffolk delivered the 6-week intervention, a form was sent out to the parents for them to complete and sign. This form asked for the child's date of birth and gender. For anonymity purposes, OneLife Suffolk only shared the age of the child, not the date of birth.

Confidentiality and data storage procedures were adhered to as is set out in the Leeds Beckett Data Management Plan.[30] All participant data were anonymised and coded to prevent identification, and securely stored using password-protected files on the LBU computing network. Only research team members had access to the anonymised data. This was shared between the team strictly for the purposes of research.

Data coding and analysis

All data were analysed using IBM SPSS Statistics for Windows version 25.0 (IBM, Armonk, NY, USA). Most of the variables in the data were complete (82.96%); however, some variables had missing values as follows: Child LSOA: 360 (7.0%), Child IMD Rank: 360 (7.0%) and Ethnicity 2656 (51.4%). Multiple imputation was used to optimise power and maintain the sample size by generating several imputed data sets based on the observed data.[31,32] Independent analyses were conducted on each data set, and then a single estimate was finally generated by pooling results of each imputed data set.[31,32]

Descriptive statistics (e.g. frequency, mean and standard deviation (SD)) were calculated for participants characteristics and other measured variables. To guide a choice of the appropriate test for the analysis, tests of normality were performed. The assumption of normality for BMI SDS change was not satisfied as assessed by Shapiro–Wilk's test ($p < .01$) and by visual inspection of normal Q–Q plots. Due to violation of normality assumption, non-parametric tests such as Mann–Whitney *U* and Kruskal–Wallis *H* were used to examine mean differences of BMI SDS change between groups in binary variables (e.g. gender (male/female)) and variables with >2 categories (e.g. ethnicity), respectively. Wilcoxon signed-rank test was used to investigate change in BMI, BMI SDS and weight category after 6 weeks of intervention. Furthermore, logistic regression analysis was performed to assess the relationship between BMI SDS loss (outcome variable) and predictor variables (i.e. participants' sociodemographic characteristics, weight category and BMI SDS at the start of intervention).

RESULTS

The study involved children aged 4–19 years with mean age of 8.8 ± 2.3 years (Table 1). Around half of participants (50.1%) were males and the other half (49.9%) were females. Each child LSOA category contained roughly a fifth of all participants. Majority of participants (66.3%) were White and the rest were from other ethnic groups. The

Table 2

Participant characteristics	*n* (%)
Gender	
Female	2577 (49.9)
Male	2586 (50.1)
Age at the start of intervention (years): Min = 4; max = 19; mean ± SD = 8.8 ± 2.3	
Ethnicity	
White	3430 (66.4)
Black	993 (19.2)
Asian	336 (6.5)
Mixed	82 (1.6)
Any other	328 (6.3)
Child LSOA	
1	990 (19.2)
2	1089 (21.1)
3	1110 (21.5)
4	1073 (20.8)
5	901 (17.5)
School LSOA	
1	1009 (19.5)
2	998 (19.3)
3	1004 (19.4)
4	1401 (27.1)
5	751 (14.5)
BMI SDS maintained/loss	
No	1772 (34.3)
Yes	3391 (65.7)
Category at the start of intervention	
Healthy range	3645 (70.6)
Close to overweight	370 (7.2)
Overweight	349 (6.8)
Very overweight	799 (15.5)
Category at the end of intervention	
Health range	3723 (72.1)
Close to overweight	375 (7.3)
Overweight	316 (6.1)
Very overweight	749 (14.5)

SD: standard deviation; LSOA: Lower Super Output Area; BMI SDS: standardised body mass index.

mean BMI at the start and end of intervention were 17.62 ± 3.04 and 17.52 ± 3.04 kg/m^2, respectively. Likewise, the mean BMI SDS at the start and end of intervention were 0.47 ± 1.13 and 0.40 ± 1.14, respectively. Majority of participants (65.7%) had BMI SDS maintained or lost, whereas roughly a third (34.3%) of participants gained BMI SDS.

Following the 6-week school-based healthy living programme, there was an observed mean ΔBMI SDS of –0.07 (–14.89%) among participants. Importantly, while there were –9.43% and –6.25% decreases in children in overweight and very overweight categories, respectively, the healthy weight BMI SDS category had a 2.16% increase of children (Table 2).

A Wilcoxon signed-rank test showed that the 6-week school-based healthy living programme resulted in decreased BMI ($Z = -15.87$, $p < .001$), BMI SDS ($Z = -21.54$, $p < .001$), centile ($Z = -20.12$, $p < .01$) and weight category ($Z = -7.89$, $p < .001$). Meanwhile, the Mann–Whitney *U* test showed no statistically significant difference in mean BMI SDS change between males and females ($p = .24$). The Kruskal–Wallis test also revealed no statistically significant differences in mean BMI SDS change between child LSOA groups ($c^2(4) = 1.67$, $p = .796$), school LSOA groups ($c^2(4) = 4.72$, $p = .317$), ethnic groups ($c^2(4) = 2.53$, $p = .640$) and weight category at the start of the intervention ($c^2(3) = 6.20$, $p = .102$). This indicates equal effectiveness of the 6-week WMP across different groups of gender, ethnicity, LSOA and weight category at the start of the intervention. Furthermore, logistic regression analysis revealed increased odds of achieving BMI SDS loss by a factor of 1.3 (95% confidence interval (CI) = 1.093–1.464) for each unit increase in child BMI SDS at the start of the intervention. Other individual characteristics at the start of the intervention were not predictive of the BMI SDS loss (Table 3) or change (Table 4).

DISCUSSION

This is one of the first UK-based studies to examine the effectiveness of the large-scale pragmatic 6-week multicomponent school-based weight management

Table 3

Change in BMI, BMI SDS and weight category at the start and end of the intervention

	Min	Max	Mean ± SD	
BMI start	11.98	39.43	17.62 ± 3.04	
BMI end	11.66	39.43	17.52 ± 3.04	
BMI-SDS start	–3.72	4.77	0.47 ± 1.13	
BMI-SDS end	–4.18	4.77	0.40 ± 1.14	
Centile end	0	1	0.6 ± 0.3	
Centile start	0	1	0.6 ± 0.3	
	Start	**End**	**Δ**	**%Δ**
Mean BMI	17.62	17.55	–0.07	–0.40
Mean BMI SDS	0.47	0.40	–0.07	–14.89
Centile	0.614	0.595	–0.019	–3.09
Weight category start of intervention				
Healthy weight	3649	3728	79	2.16
Close to overweight	371	375	4	1.08
Overweight	350	317	–33	–9.43
Very overweight	800	750	–50	–6.25

BMI: body mass index; BMI SDS: standardised body mass index; SD: standard deviation.

intervention. Results revealed significant BMI and BMI SDS losses and weight category changes following the 6-week weight management intervention regardless of child age, gender, ethnicity, LSOA and weight category at the start of intervention.

An observed mean decrease in BMI SDS of 0.07 was reported in this study. A recent overview of Cochrane reviews among interventions for treating children and adolescents with overweight and obesity reported an overall reduction in BMI SDS of 0.06 among children aged 6–11 years and 0.1 among children ⩾12 years of age.[33] Furthermore, a recent meta-analysis of school-based weight management interventions outlined that across 50 trials, single-component interventions resulted in a BMI SDS reduction of 0.05, while multicomponent interventions resulted in a BMI SDS reduction of 0.07.[15] While any reduction in BMI SDS for children with overweight and obesity may be of clinical benefit, the BMI SDS reduction required to ameliorate any comorbidities is less clear. However, improvements in cholesterol were observed in children with obesity aged 7–17 years with a BMI SDS reduction of <0.1 unit,[34] and improvement in insulin and cholesterol was observed in 5- to 19-year-olds with obesity, following a BMI SDS reduction of 0.15 (SD = 0.5) units.[35] These findings highlight the potentially beneficial clinical effects of the OneLife Suffolk pragmatic intervention and its appropriateness among children of a wide range of ages, socioeconomic background and initial weight. This is of particular importance as the intervention further demonstrates the potential efficacy of pragmatic short-term (6- to 12-week) interventions,[15] as well as outlining their potential in reducing the widening of health inequalities among this population.[11]

School settings offer an opportunity to use policies, staff, curricula and parental engagement to positively influence a child's health and wellbeing.[36] Taken collectively, the evidence from recent systematic reviews and meta-analyses[15,37] suggests that multicomponent school-based intervention programmes involving activities to engage children and their parents are most effective in achieving small reductions in body weight status in children of all ages.[15] However, the review identifies significant between-study heterogeneity and acknowledges that most of the included studies have a moderate-to-high risk of bias. The large sample size and comparable age, gender and LSOA distributions in this study significantly reduced the risk of bias, and thus, results can be considered as representative. Furthermore, theoretically informed interventions have been found feasible and acceptable to schools, children and their families and have achieved the highest levels of engagement.[36] The OneLife Suffolk curriculum has been developed in line with the SEF for Weight Management Interventions good practice in behaviour change guidelines.[23] OneLife Suffolk further extends this by introducing the four key constituents of the self-theory,[24] which include self-awareness, self-regulation, self and others and self-reliance, supported by the use of self-determination theory[25] to deliver and promote individually tailored sessions (e.g. individualised goals based upon history, goals and ability). This method has shown to have the greatest likelihood of promoting sustainable long-term weight loss.[37] Specifically, OneLife Suffolk sessions sought to provide children with the necessary skills to identify and make healthy diet and activity choices and engage their parents and peers in supporting these behaviours. Children were given age-

Table 4

Results of a regression assessing associations between BMI SDS change (outcome variable) and individual characteristics

	β (95% CI)	*p* value
Constant	2.846 (1.039–7.792)	.042
Age start	1.021 (0.984–1.059)	.266
Gender		
Male	0.976 (0.868–1.098)	.692
Ethnicity		
White	1.054 (0.567–1.957)	.862
Black	1.002 (0.386–2.600)	.997
Asian	1.098 (0.461–2.615)	.826
Mixed	1.298 (0.589–2.860)	.509
Child LSOA		
1	0.941 (0.758–1.170)	.583
2	0.961 (0.779–1.186)	.712
3	0.783 (0.642–0.954)	.015
4	0.968 (0.791–1.184)	.749
BMI start	0.965 (0.909–1.025)	.248
BMI SDS start	1.300 (1.093–1.464)	.002*

BMI SDS: standardised body mass index; CI: confidence interval; LSOA: Lower Super Output Area; BMI: body mass index.
Variables entered in the model were gender, age start, ethnicity, child LSOA, BMI start, BMI SDS start.
*Reached statistical significance of $p < .05$.

appropriate levels of autonomy to select which behaviours they wished to change, and parents were encouraged to identify how they would support their child to achieve their goals.

Previous research shows that childhood obesity management tends to reproduce health inequalities between children.[10] Specifically, when accessing community-based WMPs, children with a high-SES encounter less difficulties in adapting their lifestyle to professionals' recommendations than low-SES children because their habitus facilitates the internalisation of health norms and they have greater access to economic, social and cultural capitals.[10] Consequently, schools are ideal locations for childhood weight management interventions given their near-universal reach of children across the socioeconomic spectrum, and the significant weight loss findings in this study across schools regardless of child age, gender, ethnicity, LSOA and initial weight support this.

Findings should be interpreted in the context. The reporting of intervention characteristics (dose, frequency and content) varied so much between sessions that no specific intervention content could be attributed as either being more or less effective. A 2005 Cochrane systematic review[38] recommended that interventions designed to prevent childhood obesity should have a rigorous assessment design that enables sufficiently powered analysis of what is working or not and for whom the intervention is working, and that stakeholders should be included in the development of the programme. However, it has been demonstrated that long-term RCT interventions adopting a strict protocol consisting of the same components for all clients regardless of ability may result in decreased child enjoyment, motivation and subsequent retention.[19] Consequently, pragmatic multicomponent interventions utilising the principles of systems thinking could provide a more cost-effective way to evaluate effectiveness and subsequently test and modify through 'trial and error' intervention components within 'real world' settings.[20] The scale of childhood obesity warrants future childhood weight management interventions to explore effectiveness across sectors (e.g. school, community, home-based) and levels (e.g. tier 1, 2, 3 and 4 services), as well as including detailed descriptions of approaches, content and embedded process and economic evaluations, as recommended by existing guidance on developing and evaluating complex interventions.[39] To achieve this, more qualitative research conducted to understand the barriers and facilitators to child weight management interventions is warranted,[37] as well as more process evaluations[39] to help guide implementation and tailor interventions specifically to this populations needs.

Since 2010, local governments in the UK have seen significant reductions in public health resources;[40] therefore, pragmatic interventions that demonstrate reach and impact are required to enable public health professionals to use financial resources wisely. Community weight loss programmes that specifically target children suffering from weight problems have been shown to be effective, but they can be difficult to run in isolation (which is how they are often commissioned) and recruit, especially in areas where the population is dispersed. Therefore, considerations about the appropriate mix of services, universal and targeted interventions, are warranted and

are likely to differ in each area dependent on needs and resources. This intervention demonstrates changes of magnitude (0.07 BMI SDS) similar to those reported in targeted community intervention programmes.[33] This suggests that those commissioning local services have more than just targeted interventions as part of their local actions, although ideally such intervention options should be led by the needs of children and young people as well as the health and wellbeing strategies of the local public health teams.

Methodological strengths include the large sample size and comparable age, gender and LSOA distributions which ensured results are representative of children aged 4–18 years of age across Suffolk county. In line with the SEF for weight management interventions,[22] the design, delivery and recruitment strategies were theoretically underpinned by conceptual behaviour change models.[24,25]

Limitations are also noted. The purposeful recruitment process prevents the calculation of a precise response rate and may limit the representativeness of the sample. The large proportion of children and families that did not consent to their data being used is a limitation; this was a pragmatic local intervention and we hope to address this issue in future programmes. Nonetheless, key characteristics of participants in this study such as age, LSOA, BMI and BMI SDS were very similar to those of previous school-based weight management interventions.[15] Furthermore, the cross-sectional design of the study ensures that the findings represent associations between BMI and the other variables, rather than imply a causal relationship.

CONCLUSION

This study contributes to the growing body of evidence demonstrating the efficacy of short-term, pragmatic multicomponent school-based weight management interventions and is a first step in demonstrating an increased understanding of systems thinking that may result in weight loss among children in the UK. Findings suggest that a 6-week multicomponent school-based weight loss intervention can be effective regardless of child age, gender, ethnicity, LSOA and weight category at the start of intervention. The accumulating evidence may also help inform national-level policy and intervention strategies aimed at reducing childhood obesity.

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CONFLICT OF INTEREST

The authors have previously worked with Honorary Editor of Perspectives in Public Health, Joanna Saunders at Leeds Beckett University. Joanna Saunders did not have any involvement with the research or authorship of this article and the article was independently reviewed as per the journal's stand procedure.

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CONSENT FOR PUBLICATION

In accordance with the ethical approvals mentioned, all participants consented for their data to be included in the published manuscript.

ETHICAL APPROVAL

Institutional ethical approval was received by Leeds Beckett University's Research Ethics Sub-Committee (Approval No. 72597).

AVAILABILITY OF DATA AND MATERIALS

Participants did not provide informed consent and assent for the study data to be shared beyond the research team; therefore, data are not available for open access.

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The Action Scales Model: A conceptual tool to identify key points for action within complex adaptive systems

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complexity; systems science; leverage points; complex intervention; health policy; complex adaptive systems

Abstract

Background: Systems thinking is integral to working effectively within complex systems, such as those which drive the current population levels of overweight and obesity. It is increasingly recognised that a systems approach – which corrals public, private, voluntary and community sector organisations to make their actions and efforts coherent – is necessary to address the complex drivers of obesity. Identifying, implementing and evaluating actions within complex adaptive systems is challenging, and may differ from previous approaches used in public health.

Methods: Within this conceptual article, we present the Action Scales Model (ASM). The ASM is a simple tool to help policymakers, practitioners and evaluators to conceptualise, identify and appraise actions within complex adaptive systems. We developed this model using our collective expertise and experience in working with local government authority stakeholders on the Public Health England Whole Systems Obesity programme. It aligns with, and expands upon, previous models such as the Intervention Level Framework, the Iceberg Model and Donella Meadows' 12 places to intervene within a system.

Results: The ASM describes four levels (synonymous with leverage points) to intervene within a system, with deeper levels providing greater potential for changing how the system functions. Levels include events, structures, goals and beliefs. We also present how the ASM can be used to support practice and policy, and finish by highlighting its utility as an evaluative aid.

Discussion: This practical tool was designed to support those working at the front line of systems change efforts, and while we use the population prevalence of obesity as an outcome of a complex adaptive system, the ASM and the associated principles can be applied to other issues. We hope that the ASM encourages people to think differently about the systems that they work within and to identify new and potentially more impactful opportunities to leverage change.

BACKGROUND

There is a rich and extensive history of systems science literature,[1] but only somewhat recently has there been interest in the field of Public Health.[2,3] Spearheading this interest, the UK Government Office for Science commissioned the 'Tackling Obesities' Foresight report.[4] The report postulated that population level obesity was the product of a complex adaptive system, comprising an interconnected web of many causal factors. However, despite this, the uptake of systems approaches to address obesity and other public health challenges has been slow. A recent systematic review concluded that the application of systems approaches largely remains theoretical.[5]

Complex adaptive systems are characterised by several factors.[6,7] They adapt over time in unpredictable ways in response to new policies, social norms, commercial interests and

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technological advancements for example. They are also characterised by interdependency and feedback; the component parts of the system influence one another, reinforcing or stabilising outcomes as they begin to emerge. For example, the increasing prevalence of convenience food reduces the need for people to cook. In turn, this reinforces the market demand for convenience food and leads to a greater supply, simultaneously, deskilling the population due to a reduced need to prepare and cook fresh meals. Other factors such as marketing of convenience food, the cost and availability of ingredients and the legislation around food policy all contribute to this complex interplay; an emergent property, among other things, being an increasing dependency on convenience food consumption. This example is nested within the overarching system that drives obesity at the population level.

It is now accepted that systems approaches should be adopted when aiming to fundamentally alter the obesogenic system.[4,5,8–10] A systems approach aims to corral the public, private, voluntary and community sectors to make their actions and efforts coherent in a way that addresses the complexity of obesity[8,11] – albeit that a formal definition is yet to be agreed upon.[5] However, a current and pressing concern is that much of the work that is undertaken to prevent population level obesity does not take a systems approach. For example, Nobles et al.[12] found that local government organisations were most likely to implement behaviour change programmes that encourage individuals to make healthier choices. Many of these interventions operate within a reductionist and medicalised paradigm (whereby interventions focus on specific elements of the system in isolation or aim to instigate change at the individual level rather than on populations and systems), are hypothesised to bring about predictable and consistent outcomes, and also assume that the context surrounding interventions will remain constant over time.[13] Such interventions seldom account for the underlying, multifaceted nature of obesity (Table 1). The challenge now faced is how to re-orientate efforts to account for the complexity of the systems that we live and work within.

Within systems theory, leverage points exist.[2,13–15] These are modifiable points within a system that, if altered, can lead to changes in how the system functions.[14] Identification of leverage points is deemed critical for achieving meaningful change, and practitioners and policymakers should aim to identify and modify these points within their own systems (which may lie within larger systems). Yet, moving from theory to practice is challenging. To move beyond this impasse, researchers have proposed tools to facilitate broader thinking about actions within complex systems.[14–16] These tools include Meadows' 12 places to intervene,[14] the Intervention Level Framework (ILF)[16] and the Iceberg Model.[15]

These tools have often been developed by researchers for researchers, which may make them difficult for people working in practice to utilise, given their dependency on systems science expertise. Consequently, we developed the Action Scales Model (ASM) to help practitioners and policymakers conceptualise, identify and appraise actions within a complex adaptive system. In doing so, it prompts people to think about, and identify, different leverage points and moves focus away from a reliance on traditional types of action (Table 1). Within this conceptual article, we aim to present the ASM and its component parts; explain the practical utility of the ASM; and illustrate how stakeholders can use the ASM to evaluate actions within a system.

METHODS

The ASM was created to sit within, and contribute towards, a larger body of work; the Whole Systems Obesity (WSO) programme.[17] The aim of the WSO programme was to co-produce a guide, and an associated set of resources/tools, that enable local government authorities (LAs) in England to implement a whole systems approach to obesity. During the development of the WSO programme, we identified the need for a practical tool to help LA stakeholders think about and identify different types of actions, and the extent to which those actions may help leverage systems change. While other models are available to identify leverage points,[14–16] formative assessment within the WSO programme (based on observation and discussion with LA stakeholders) suggested that these models were too abstract and complicated for real-world use (i.e. perceived as overly academic).

With this in mind, and taking on board the specific feedback from stakeholders during the development of the WSO programme, we developed a simpler tool that was relatively concrete. In doing this, we ensured that the new tool (the ASM) conceptually aligned with the three models aforementioned and retained some of the common features[14–16] (see Table 2). We aimed to use terminology and visuals that would resonate with practitioners and policymakers, so that they could be used in local contexts related to practical issues and interventions.

We developed the ASM using our collective expertise and our experience of working closely with many LAs as part of the WSO programme. Core members of the WSO programme included applied health researchers, public health professionals and policymakers (local and national). The outputs of the WSO programme (a guide and complementary resources) were tested and refined by seven LAs, with the last iteration of the outputs being reviewed and approved by national and international experts. The results of the process evaluation related to the development of the WSO guide and resources is available elsewhere.[18] The ASM formed one part of the WSO programme outputs.

The purpose of this conceptual article is to present the ASM to a wider audience, providing a more detailed account of its theoretical underpinnings and applicability than in the WSO programme outputs. We hope that this model encourages others to join the conversation around systems change efforts.

RESULTS

The ASM

The ASM aims to help enable practitioners and policymakers to both

Table 1

Common features of reductionist and systems mindsets

	Reductionist mindset	Systems mindset
Purpose of action	... align with a reductionist paradigm. Action seeks to influence an isolated element of the system (if the system is acknowledged).	... understand that actions operate within a complex system, with the action seeking to influence how the system functions. Recognise that many coherent actions are required across the system. Difficult to isolate effect to individual actions.
Focus of action	... target specific causal factors (e.g. individual lifestyle behaviours).	... considers the patterns, structures and drivers which give rise to a system behaviour (i.e. the factors which cause a problem to occur).
Relationships between stakeholders	... likely to be transactional in nature whereby a provider is commissioned to deliver a specified service.	... understand that collaborative relationships and trust are imperative between stakeholders when seeking action.
Longevity of action	... anticipate that the system will remain static over time. The action will continue to create the same outcomes overtime and in different contexts.	... anticipate that the system is dynamic and adaptive, evolving over time in response to actions. Each complex problem is unique and therefore a shared understanding of the problem is required by involved persons. Actions will be highly context specific and dependent on the system boundaries.
Availability of an evidence base	... have an extensive empirical evidence base for discrete interventions. Often have well-funded research streams.	... may have a limited evidence base. Evidence may be more theoretical or hypothetical.
Evaluating action	... are easily measurable in isolation (e.g. have a number of key performance indicators). Indicators tend to be focused on the main outcome and the reach of interventions. Evaluation aims to prove effectiveness.	... assess impact in the context of the system. Determine whether the action is helping to change the functioning of the system in the anticipated direction. Focus on proxy measures of success. Aim to improve effectiveness.
	Along a spectrum ⟷	

understand why the system functions as it does (which includes the people and organisations within it) and to identify opportunities to leverage change through action across the four levels. The ASM (Figure 1) is depicted as a set of scales, with the system made up of four levels: events, structures, goals and beliefs. Each level influences how the system functions, and in turn, the main outcome that the system produces (represented as the ball balanced atop the scales). In this article, the population prevalence of obesity could be regarded as the main outcome. The current system is configured in such a way that it promotes population level obesity – referred to as the obesogenic system.[19]

When seeking to understand the system functioning, *events* relate to the issues (behaviours and proxy outcomes) that can be observed around us and are symptoms of the system working as designed (both intentionally and unintentionally). For example, convenience food is readily available and widely consumed, cars are the dominant mode of transport, and workplaces observe high levels of presenteeism and absenteeism. *Structures* relate to the patterns, relationships, information flows and physical structures that cause events to occur. Related to the example above, transport infrastructure is predominantly designed to support car use, from the development and sustainment of road transport networks to the design and layout of new housing developments. *Goals* refer to the ambitions or targets that the system (or parts within the system) are working towards. These goals influence how the system is structured, and therefore, how it functions and the outcomes it produces. It is also important to differentiate between the stated goals (i.e. those *said* to be working towards) and observable goals (i.e. those *being* worked towards); a discordance is often present. A workplace, for example, may state that employee wellbeing is a key organisational priority but does little to change the organisational structures to influence staff wellbeing. Finally, it is the *beliefs*, norms, values and attitudes of systems architects (i.e. those who influence the structure and workings of a

Table 2

Leverage points – alignment between Meadows,[14] Malhi et al.,[16] Senge[15] and the ASM

Degree of leverage	Meadows' 12 Points to Intervene	Intervention Level Framework	Iceberg Model	ASM
+	Power to transcend paradigms	Paradigm	Mental models	Beliefs
	Paradigm that the system arises out of			
	Goals of the system	Goals		Goals
	Power to add, change, evolve, or self-organise system structure	System structures	System structures	Structures
	Rules of the system			
	Structure of information flow			
	Gain around driving positive feedback loops	Feedback loops and delays	Patterns	
	Strength of negative feedback loops			
	Length of delays			
–	Structure of material stocks and flows	Structural elements	Events	Events
	Size of buffers and other stabilising stocks			
	Constants, parameters and numbers			

ASM: Action Scales Model.
The alignment between the three models is not as distinct as presented here. For example, Malhi et al.[16] suggest that 'the rules of the system' and 'information flows' may also be viewed as 'structural elements' if they relate to a particular sub-system or actor within the system.

system) that cause the system to function as it does. People who hold power within a system can influence how resources are distributed and decisions are made across the system.[13] A senior executive within an organisation may believe that the sole purpose of the workplace is to generate revenue. In turn, this would influence the goals of the system (e.g. for employees to meet sales targets), which then dictates how the organisation is structured and how resources are managed, which then impacts its revenue. As can be seen, the four levels are interconnected.

The ASM has been designed to support practitioners and policymakers to identify leverage points in order to change how the system functions. The four levels within the ASM are graphically depicted as weights; the larger the weight, the greater the likelihood of leveraging systems change. In the context of obesity, many actions are currently implemented at the *event*-level (e.g. educating people about high-sugar drinks, provision of weight management programmes, implementation of the Daily Mile in schools). These are reactive actions, often thought of as quick fixes. They offer little leverage for system change and do little to reduce the likelihood of the event recurring in the future, hence why they are the smallest weight within the ASM. They are also likely to be the easiest to implement from resource, political and evaluative perspectives. At the *structure*-level, actions offer more leverage because they aim to reduce the likelihood of events happening again in the future (i.e. the patterns of an event) by anticipating where and how issues may arise. They seek to alter the physical (i.e. built or natural infrastructure), relational (i.e. the relationships and rules between the parts of the system and the actors within it) and informational (i.e. how information flows between parts of the system and the actors within it) structures known to be driving the problem, and thus necessitate a thorough understanding of the system (Table 2). They work to interrupt the relationships between the parts of the system, relationships which may form positive or negative feedback loops that reinforce the recurrence of a problem (refer back to convenience food example above). Actions targeting the *goals* and *beliefs* require fundamental alterations to the system and the way in which things are done – they seek a paradigm shift and to change the status quo. To do so, change efforts must seek to influence the system architects and dominant beliefs, but the mechanisms by which this is achieved will vary greatly. These levels offer the greatest leverage for change, as depicted by their size (see

Figure 1.

The Action Scales Model: (a) the current system which is imbalanced – for example, towards an obesogenic environment. It causes population weight to increase alongside compounding other issues associated with social inequality. The aim is for system architects (i.e. those who can influence how the system functions) to reorientate the system in a way which supports a healthier population weight (b). By leveraging actions deeper within the system (e.g. goals and beliefs), a tipping point is more likely to be reached which can cause rapid changes in the system structure to occur. Because goals and beliefs hold greater weight in the system, reorientating them towards a healthy weight system will require more effort than focusing on events.

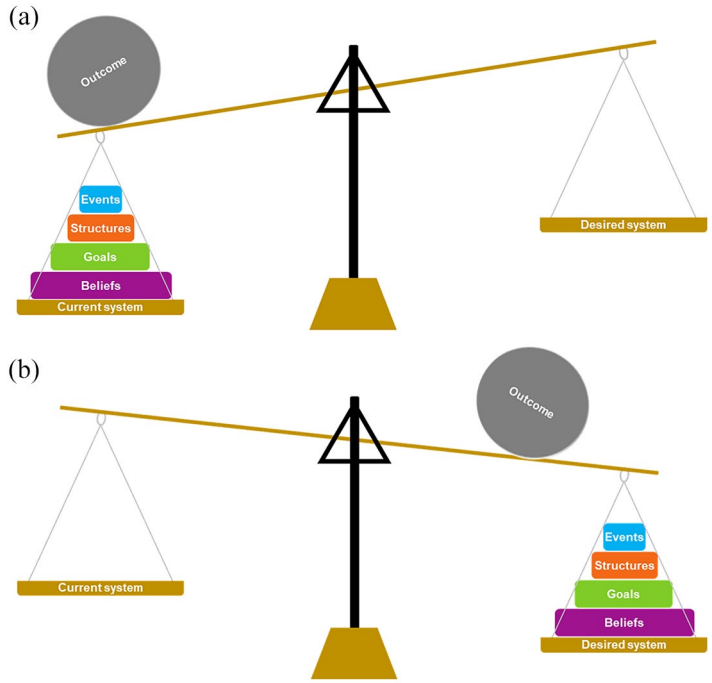

Figure 1), but will likely be the most difficult to change. Table 3 summarises this information and provides examples of action at each level.

Given the interconnectivity between the levels of the ASM, it is important to think about their *collective coherence* (i.e. the extent to which events, structures, goals and beliefs in the system reinforce one another).[8] The concept of coherence is applicable when aiming to understand the system and when identifying opportunities to intervene. To maximise the likelihood of systems change occurring, stakeholders should seek to intervene across *multiple* levels of the ASM, and in doing so, ensure that their efforts are mutually reinforcing. For example, implementing a 20-mph speed limit in a residential area may be best achieved by the following set of actions: (a) stakeholders promoting the benefits of the restriction to elected members and the public (i.e. targeting the system beliefs); (b) changing the goals of the system, from prioritising the speed of through traffic to the safety of local residents and the walkability of the local environment; alongside (c) creating the structures to directly implement the policy change (event or structural level). If the beliefs and goals are assessed and targeted prior to structural changes occurring, then this may increase the impact and sustainability of a change effort, and indeed, would make structural changes easier to implement. Additional examples of coherent actions are provided in Table 3.

Using the ASM in practice and policy

The ASM has three primary uses for stakeholders working in practice and policy: (a) to help understand how the system works, and explain why the system generates the outcomes it does, (b) to facilitate the identification of leverage points for systems change, and (c) to ensure that there is coherence among actions being implemented and/or planned.

There are many ways to create a shared understanding of how a system functions, from systems mapping, to producing causal loop diagrams, to root cause analysis, to the development of rich pictures.[13,20,21] As a minimum, the ASM can facilitate multistakeholder conversations to stimulate deeper thinking about a complex issue. Soft-systems methodologies acknowledge that the process of engaging in such conversations, and in understanding the different perspectives held between stakeholders, is more important than seeking an objective reality.[13] If stakeholders have developed a systems map, or similar (e.g. a concept map, a causal loop diagram, an agent map), the ASM can be used to critically think about the causes (of obesity) included within the map; to reflect on why the system functions as it does, the level at which the causes operate, and the extent to which causes are interconnected. Whether in conversations or through systems maps, questions should be posed that cause stakeholders to reflect on the structures, goals and beliefs which cause the events to occur within the system (Table 4); these should also consider the social, political and cultural aspects of the system. The ASM facilitates stakeholders in acquiring a deeper understanding of the system. Importantly, however, the emphasis of the conversation should be placed on thinking broadly, and differently, about the system and considering all levels of the ASM, rather than on the correct classification of causes against one of the four levels. By obtaining a better understanding of how the system functions, and why it functions as it does, it then becomes possible to think more broadly about actions to intervene within the system.

Table 3

Examples of coherent actions across the ASM

	Events	Structures	Goals	Beliefs
What we observe	These are the issues (behaviours and outcomes) that can be observed around us in the modern world, and are symptoms which arise from the system functioning as designed (both intentionally and unintentionally).	This relates to the underlying structures and patterns that cause the events to occur. This includes the organisation of the system; the structures, information flows, processes and relationships between parts of the system.	These are the goals, targets or ambitions that the system – or parts of the system – is working to achieve. Goals often drive the system to be structured as it is and therefore to work as it does.	These are the deeply held beliefs, norms, attitudes and values (i.e. the mindset) of the individuals and organisations within the system. They are the foundations that cause the system to keep functioning as it does, and are reflected in the system goals.
Actions at this level	Aim to suppress the *immediate* event. They do this by reacting quickly to the visible issues – i.e. 'quick fixes'. Quite often these actions are needed, but will not address the underlying issues which cause the issue to arise (i.e. the structures, goals and beliefs).	Aim to reduce the number or severity of the events occurring. They do this by reshaping or redesigning the organisational or relational system structures, and therefore require an understanding for how the system works.	Aim to re-orientate the goals that the system is working towards. They do this by changing the beliefs of those people setting the system goals.	Aim to change how individuals and organisations (who influence how the system works) think about the problem. They do this by challenging and changing the deeply held beliefs, norms, attitudes and values within the system.
Example actions	1.1. LAs provide cycling training to school children.	1.2. The LA assesses and improves the walkability of the environment surrounding the schools.	1.3. Schools work with parents and community to set a shared goal to reduce short car journeys to school by 20% in next 5 years.	1.4. LA creates a working group to champion and promote active transport to senior leaders in the council.
	2.1. Families can attend free workshops to learn how to cook healthy food.	2.2. Regulations are introduced that require food manufacturers to reformulate ready meals.	2.3. Supermarket chains set mandatory targets for suppliers on the nutritional quality of products.	2.4. Supermarkets work with suppliers to demonstrate that healthier food options can maintain company profits.
	3.1. GPs refer adults with obesity to commercial weight management programmes.	3.2. Medical students receive mandatory training about the complexity of obesity.	3.3. Ensure that everyone, regardless of their health status, has access to a GP within one week.	3.4. Senior clinicians reinforce across healthcare settings that obesity is the product of complex adaptive systems.
Evaluating actions using the ASM[a]	*Using 1.1 as an example*: LA assess the cycling self-efficacy of school children. Also able to monitor the number of trips to school via active transport. May also monitor wider impacts on child's educational attainment and engagement in class.	*Using 2.2 as an example*: Audit the alterations made to food regulations, and assess the impact of these regulations on (a) nutritional quality of products and (b) purchasing patterns of consumers. Ensure that unintended consequences are captured.	*Using 3.3 as an example*: Evaluate the number of people accessing their GP within 1 week. Assess the impact of this policy on patients, GPs, healthcare managers and administrative staff. Analyse patient data to understand equity of care.	*Using 1.4 as an example*: Interview senior leaders in the LA to determine their beliefs towards active transport, and whether these beliefs have changed due to intervention effort. Examine voting patterns of councillors with regards to active transport proposals.

ASM: Action Scales Model; LA: local government authority.
[a]When evaluating actions within a system, evaluators must ensure that they evaluate the collective impact of the actions, and the implications of these actions on their interdependencies (i.e. the parts of the system that may also be affected by these actions).

Table 4

Questions which can be used to understand system functioning

ASM level	Questions
Event	(a) What issues or problems keep arising despite efforts to rectify them? (b) Where are intervention efforts targeted? Do they tend to focus on those that are affected by the problem? (c) Are the actions likely to stop the problem reoccurring in the future? (d) Do the actions seek to generate outcomes quickly and are they unlikely to be opposed by systems architects?
Structures	(a) What elements make up the system? Consider physical structures, people and organisations, interconnections and relationships, and information that flows between the elements of the system. (b) How are these elements organised or arranged? (c) Which of these elements cause the problems or events to occur? Also consider the connections between the elements. (d) What is the nature of the relationships between elements in the system? Do they self-regulate (i.e. one increases, the other decreases) or do they self-reinforce (i.e. one increases, the other increases)? How long does it take for these changes to occur? (e) Who has access to information about the system, and the elements within the system?
Goals	(a) What are the system/organisations/key individuals aiming to achieve within their spheres of influence? (b) What purpose do these systems/organisations/individuals hope to serve? (c) How are the system structures organised and why are they organised in this way? (d) Do the goals of multiple systems influencers overlap? To what extent could they be aligned? (e) Are the goals of the system currently supported by actions?
Beliefs	(a) What are the prevailing assumptions, beliefs and values that explain why things are done as they are? (b) Who (people and organisations) are the key decision makers within the system? What values, perspectives and priorities do they hold? (c) To what extent do these key decision makers believe that change is necessary, feasible and/or desirable? (d) What beliefs do these people and organisations hold regarding how the system works, and the goals that the system is working towards? (e) What is of fundamental importance to these people and/or organisations? (f) What are the beliefs of others who may be affected by systems change? Do they support or oppose the dominant belief within the system or the goals that it is working towards?

ASM: Action Scales Model.

When stakeholders have identified a part of the system that they, as a collective or individually, can influence using their expertise, resources or networks, the ASM provides a framework to help understand where to intervene within the system to maximise the likelihood for greatest leverage (i.e. at what level of the ASM). Within the WSO programme, the team developed an action planning tool to help stakeholders identify actions and to ensure coherence between them.[17] This tool, taken in conjunction with the ASM, provides a structured approach to generating a coherent action plan. By this, we mean that actions are mutually reinforcing; that they work towards the same outcome and efficiently use available resources. The outcome does not necessarily need to be changing the prevalence of obesity, but may be more proximal such as improving the quality of food within newly established fast food outlets or enhancing the cohesion between multisectoral stakeholders. To remain efficient, stakeholders should seek to understand what actions are already underway within their system as well as considering how new actions may be introduced – all of which can be considered through the lens of the ASM. At all times, it is important that stakeholders focus on the part(s) of the system that they can influence to avoid becoming overwhelmed by the complexity of the system, and consequently disengaging in the process. Example scenarios are provided in Table 3 with regard to actions within systems.

Remaining pragmatic is important when using the ASM. Obesity, as with other complex issues, is often politically entangled in financially constrained contexts; for those working in public health, there is often a need to demonstrate tangible outcomes in short timescales, while working towards a longer term vision or strategy.[22–24] Such pressures have previously led to a focus on downstream interventions, commissioned by siloed and fragmented bodies, with an intention to demonstrate return on investment.[12] A systems approach aims to fuse these fragmented bodies together through collective, complementary and mutually beneficial agendas to make efficient use of available resources. Acknowledging this, the ASM should challenge multisectoral

stakeholders to look deeper into the system, to identify other opportunities to leverage systems change, and to improve the coherence between their systems change efforts.

Achieving systems change will require a substantial amount of time and sustained effort,[8,25] and thus, actions should be taken which are both episodic and continuous.[13] Episodic actions are planned, time-limited and seek incremental improvement – often operating at the event and structural levels of the ASM. Simultaneously, continuous efforts are needed to address the underlying goals and beliefs held within the system – the systemic root causes of a problem. The development of an agile monitoring framework, which includes a range of metrics that allow the system functioning to be regularly monitored, will help stakeholders to demonstrate progress towards the long-term vision (rather than a reliance on 'quick wins'). That said, stakeholders should not be overly reactive to contradictory or negative findings within their monitoring framework; within systems, things may worsen before they improve. Similarly, it is important to note that quick wins do serve a function in maintaining stakeholder enthusiasm in such an approach.

Using the ASM to guide evaluation

Public health actions and interventions are traditionally monitored via key performance indicators and outcome measures, with success often being defined as the reach of an intervention and the extent to which an intervention brings about a notable change in the main outcome (see Table 3). Measuring change within complex adaptive systems is perhaps more challenging; it acknowledges that changes to the main outcome (e.g. obesity) will occur when the system, and the parts of the system, are fundamentally reorganised.[3] However, outcomes which are the product of a complex adaptive system are unlikely to change quickly, and are very unlikely to change in response to single interventions.[3,8,26] As such, determining the success of an intervention based upon its ability to influence the prevalence of obesity is misplaced; the focus should instead be upon whether the action contributes to a change within the system.[3] A movement from the study of attribution to contribution, the ASM can be used to understand how and where such changes may have occurred across the various levels of the system, from events through to beliefs. Below, we outline several ways in which the ASM can be used to support evaluation efforts.

First, evaluators should understand the systems which are targeted by intervention efforts.[3,21,27,28] As aforementioned, methods such as systems mapping can be used to visualise the system, and evaluators can then use models such as the ASM to understand the factors which drive the system. Evaluators can also adopt the same approach to analyse intervention efforts. As an example for how this may work, Nobles et al.[12] applied the Wider Determinants of Health model to evaluate local government organisation efforts to prevent and treat population level overweight and obesity in the context of the local causes of obesity. This encourages local policymakers and practitioners to reflect upon their current approaches to obesity. The ASM could feasibly be used in place of the Wider Determinants of Health model. Other models akin to the ASM (e.g. the ILF)[16] have been used in a similar manner[2,10,16,29] to evaluate actions and policies on food/obesity systems,[2,16] the social determinants of health[10] and otitis media middle ear disease.[29] As such, these models provide useful frameworks by which to analyse intervention efforts within complex adaptive systems.

Second, several research groups have suggested that qualitative methods can be used to evaluate systems change efforts. For example, Egan et al.[21] highlight that 'qualitative research with a systems lens' is an accessible way to evaluate systems approaches, or aspects of one. They suggest that interview questions, may for example, aim to understand the different perspectives of various stakeholders, assess the intended and unintended consequences of implementation efforts, or determine the emergent and self-organisational properties as systems change occurs. We would add that evaluators can frame interview questions around the ASM. We have compiled a list of questions that can be used to help understand how the system functions, and subsequently, how actions may work within these systems (Table 4). In a similar vein, the ASM can then guide a deductive analytical framework.

Third, the ASM can help evaluators to identify proximal and intermediate outcomes to focus upon. Given that the main outcomes of complex adaptive systems (e.g. population levels of obesity) are unlikely to change within a short timeframe, proxy indicators are needed to help determine whether intervention efforts are bringing about favourable changes in the system.[3] This information can be of great importance to stakeholders with a vested interest in the intervention. For example, if systems change efforts were being implemented to increase the number of families walking their children to school (i.e. the main, long-term outcome), then using the ASM, evaluators may wish to collect data on the quality of active travel infrastructure surrounding schools and the presence of cycle storage at schools (i.e. structures). They may also wish to monitor the explicit goals that local stakeholders are working towards, for example, those which are written in key documents published by schools and local government organisations. Again, the ASM would then provide the analytical framework to create a coherent evaluation narrative for a system change effort such as this.

Finally, evaluation designs such as comparative case analysis can create compelling accounts for how a system may have changed over time. These designs take a mixed-methods approach (e.g. using informant interviews, social network analysis, epidemiological analysis) to describe the current state of the system, and then repeat this approach after a given time frame, to describe the features and workings of the new system. Matheson et al.[30] provide a good example of this design in the context of a community-based public health intervention in New Zealand. These comparative case designs can be guided by models such as the ASM,

both from the viewpoint of data collection (i.e. to guide interview questions as aforementioned) and from an analytical standpoint. However, given that these designs use mixed methods, the ASM can provide an underpinning theoretical model to triangulate and synthesise research findings.

DISCUSSION

Comparison to other tools

The ASM has several similarities with the other available models – the ILF,[16] the Iceberg Model[15] and Meadows' 12 places to intervene [14] (Table 2). First, each model aims to stimulate broader thinking about actions within systems. They are hierarchical models which stipulate that certain types of actions (e.g. mental models (Iceberg), paradigms (ILF) and system beliefs (ASM)) hold more leverage than others for systems change. The models, including the ASM, also outline that the greatest leverage will come about when there is coherence between actions at the respective levels. Re-orientating the beliefs (or mental models (Iceberg)) held within the system should then enable the goals of the system to be changed, and the structures within the system can then be altered accordingly. Each model therefore posits that actions should target multiple levels of the system simultaneously, to create a collective effort in the same direction. Finally, the ILF, the Iceberg Model and the ASM correspond with the 12 places to intervene,[14] and given Donella Meadows' prominence in the field of systems science, alignment with her work adds credibility and robustness to the simplified models.

However, the simplification of Meadows' work also means that our model, the ILF, and the Iceberg Model are less nuanced. These models group several of Meadows' 12 leverage points together and categorise them into one of four or five levels (see Table 2). In doing so, these models limit the opportunity for discussion around the omitted points of feedback loops, the length of delays, stocks and flows and so on. Consideration though needs to be given to practical utility of a model. If a 12-item model was to be used to identify leverage points, how feasible would it be for stakeholders to use it? Illustrating this point, the ILF was devised to improve the coding of qualitative survey data when evaluating actions within systems, as interrater reliability was poor when attempting to apply Meadows' list.[16] For the ASM, the objective was to create an understandable model that could be applied by practitioners and policymakers. Our scoping work in the WSO programme would suggest that the adoption of Meadows' list of leverage points would require substantial systems science expertise, therefore making it unsuitable for these purposes. We also considered the depiction of the model; in representing it as a set of scales and weights, users can see the leverage held by the various levels of the ASM which differentiates it from the ILF and Meadows' 12 places to intervene.

Strengths and limitations of the ASM

The ASM was created in response to the challenges of *applying* existing models (Table 2) in local contexts by practitioners and policymakers. For example, the Iceberg Model[15] is used predominantly within the private sector to facilitate change management efforts, and the ILF[16] has been adopted by researchers in the public health field to evaluate interventions, policies and systems change.[2,10,29,31] We hope that the ASM can be used for several purposes: to understand why the system works as it does, to identify and subsequently appraise actions and finally, to guide elements of an evaluation. Thus, the purpose and use of the ASM differs from previous models in that its application is broader, but due to the simplicity of the model and the ease of understanding, it can be applied without the expertise of a third party. Although not yet applied in another context, we also believe that the model can be used to better understand other problems that are entwined with complex adaptive systems.

As with other models, and as noted previously, there are limitations to the ASM. The model was developed to sit within the WSO programme. The WSO programme provides a framework by which stakeholders can consider how they may work as a collective to implement a systems approach. This broader work introduces some of the systems science theory. Knowledge of this is anticipated to support stakeholders as they progress through the WSO framework. As such, the application of the ASM in isolation of this wider work is likely to be more challenging than if used alongside it. Similarly, whilst use of the ASM is not hinged upon the presence of a systems map, we do believe that these visual depictions will help stakeholders to use the ASM as they promote a collective understanding of a complex problem. In absence of a systems map, the ASM is still likely to be useful in thinking more critically, and systemically, about challenges currently being faced. Aligned with the two points above, some training may still be required to use the ASM – particularly if it is not being used as part of the wider resources within the WSO programme.

CONCLUSION

The calls to adopt systems approaches within fields of public health and healthcare have grown substantially in recent years. Given the complexity of the challenges we face in the 21st century, linear and reductionist ways of working are insufficient. Systems approaches are needed but are difficult to implement. We have presented a novel tool to help stakeholders to explore how the system is currently functioning, to question why some of the issues may be arising, and finally, to identify where and how to intervene in the system. It can also serve as a mechanism to bring together cross-sectoral stakeholders in order to reflect on current practice, and to think broadly about the future approach. Finally, we see that the ASM can be used as a tool to guide evaluation. The ASM will hopefully enable stakeholders to create a coherent approach which may bring about greater systems change.

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CONFLICT OF INTEREST

The author(s) declared the following potential conflicts of interest with respect to the research, authorship and/or publication of this article: Joanna Saunders, a core member of the Whole Systems Obesity team, is an editor of Perspectives in Public Health. None of the other listed authors have a conflict of interest to declare. Public Health England funded the Whole Systems Obesity programme. Members of Public Health England – aligned to the oversight of the Whole Systems Obesity programme – reviewed the final version of the submitted manuscript.

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ETHICAL APPROVAL

Ethical approval was not required for the purpose of this article.

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The effect of a hand hygiene intervention on the behaviour, practices and health of parents of preschool children in South Africa

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Keywords

hand hygiene; parents; behaviour; intervention; diarrhoea; preschool; COVID-19

Abstract

Introduction: Diarrhoea and upper respiratory diseases are a leading cause of child mortality in children under 5 years of age both in South Africa and worldwide. Hand hygiene (HH) interventions play a critical role in reducing HH-related diseases, and the inclusion of all stakeholders in such interventions has improved the success of such interventions. The purpose of this study is to determine the effect of an HH intervention on the behaviour, practices, and health of parents of preschool children.

Methodology: Seventeen preschools were randomly selected and placed into intervention (IG = 8) and control groups (CG = 9). Parents ($N = 191$) were requested to complete questionnaires both pre- and postintervention. An intervention was applied to IG preschool respondents. The data were analysed and compared pre- and postintervention between IG and CG.

Results: Parents of IG showed a significant difference pre- and postintervention in HH practices such as washing hands after coughing and sneezing, and after using the toilet while parents in CG also indicated significant differences in HH practices of washing hands after coughing and sneezing, and after wiping children's noses. Postintervention, IG families reporting runny tummies were significantly less than pre-intervention and a decrease in doctor's visits. There was a 5% improvement of all HH practices in both IG and CG.

Conclusion: Over 90% of parents in both groups washed hands after using the toilet, both pre- and postintervention. All HH practices for both groups showed increases both pre- and postintervention. By making use of available resources and regular communication with parents of preschoolers they are able to make the small changes necessary to improve their HH and that of their families.

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Graphical abstract

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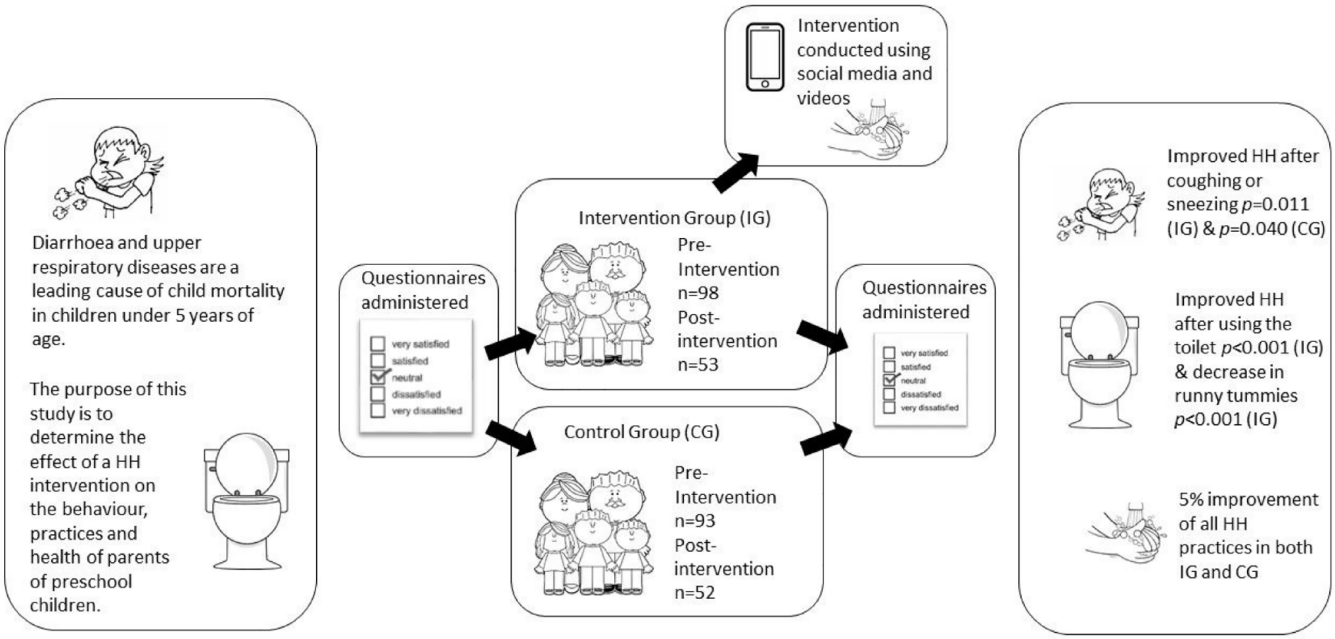


INTRODUCTION

It is well-documented that diarrhoea and upper respiratory infections are leading causes of death in children under the age of 5 years both in South Africa and worldwide.[1–4] Both of these diseases have been linked to hand hygiene (HH) and studies have shown that such HH-related diseases can decrease as a result of improved HH practices.[5,6] Improved HH forms part of water, sanitation and hygiene (WASH) initiatives most commonly implemented in communities and are implemented singularly or together in an attempt to reduce HH-related diseases and improve the health and wellbeing of communities.[7] In the case of water and sanitation, interventions most often include the provision of infrastructure, the improvement of infrastructure or the implementation of methodologies to provide safe water. Hygiene interventions are broader and can take the form of provision of HH materials such as soap and hand sanitizer; education of communities including parents, school children and educators; and practical demonstrations and distribution of information.

Research has shown that the success of interventions is determined through the inclusion of the people who are affected by poor HH.[8] In a preschool setting, caregivers at the school spend the majority of the day with the children, with parents taking over the responsibility of caring for the child once the child is at home after school or over weekends and school holidays. Therefore, the persons who would play a role in not only improving the HH of the child but also in providing an enabling environment for the child are the caregivers at the preschool and the parents. Many parents seem unaware of the vulnerability of children's health, that HH could reduce disease transmission and not washing their hands after handling their children's faecal waste or before feeding them.[9,10] In an observational study of infants under 2 years, conducted in rural Zimbabwe, researchers reported that 30.0% of the primary caregivers (mostly mothers) of these children had visibly dirty hands, washed their hands 44.0% of the time but only used soap in 6% of those times, with 50.0% of the caregivers' hands being contaminated with *Escherichia coli*.[11]

While reviewing literature on HH interventions, the interventions which proved successful where those that included not only the child but also the caregiver or parent or both.[7,12,13] This article examines the effect that a simple intervention, which was conducted on preschool children, their school caregivers and their parents, would have on the parent's practices, behaviour and health.

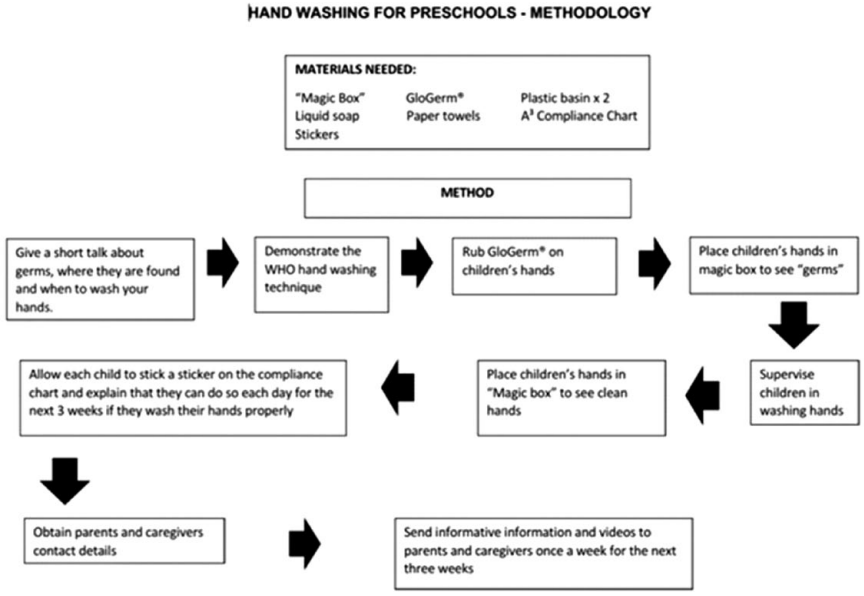
METHODOLOGY

Study population and sample selection

Seventeen preschools who were randomly selected and who agreed to participate in the study formed the sample population. The preschools were all in the Kempton Park area, which is a primarily residential part of Ekurhuleni, a metropolitan municipality in Gauteng, South Africa. The schools were randomly selected from a list compiled by the local environmental health division and comprised of schools which complied with the legislative prescripts of national and local legislation. Each school was approached, and the study was outlined to the principal of the school. When the principal agreed to participate, information packs were left at the schools to be distributed to the selected sample class. The preschools normally had one class for preschool children

Figure 1

Flow diagram of methodology for HH intervention.



aged 4–5 years, although in two schools there were two classes, and all these classes were included in the study.

Data collection

Data for the study was collected between February and November 2019, prior to COVID-19 being declared a pandemic by the World Health Organization (WHO) on 11 March 2020. The 17 participating preschools were randomly placed into an intervention group (IG) or a control group (CG) and were blinded to which group they belonged. Parents received an information pack with consent forms, an assent form for the child to participate and a household questionnaire for the parent to complete. This study included children aged 4–5 years; therefore, care was taken to develop information and assent letter that children could understand making use of pictures. Consent was given by the parents to allow the child to participate in the study and the child gave assent to the participation by placing a sticker on the form.

Questionnaires were returned to the school by the parent and collected by the researcher. The household questionnaire completed by the parents had three sections. The first section requested demographic information such as age, gender, educational status, age of children and number of persons in the household. There was also a request for structural information relating to the number of wash hand basins (WHBs) and toilets per household. The second part of the questionnaire dealt with the HH practices of the parents and their perceptions of their children's HH practices. The statements were required to be answered in a 7-point Likert-type scale, with '0' as never and '6' as always. The final section dealt with the HH-related health of the respondent and their family. Respondents were required to answer yes or no to questions such as 'Have you had a runny tummy in the past month?' of 'Have members of your family been to a doctor for any of these symptoms in the past month?'. The same household questionnaire, which had been completed by all parents in both groups prior to the intervention, was then administered to them approximately a month after the intervention was completed.

HH intervention

The information requested from the parents included a request for email addresses and cellular telephone numbers so that the parents could be contacted by the researcher. In the case of the intervention group parents received a number of health messages sent electronically to them for 3 weeks after the intervention as described in Figure 1 was conducted at the preschools with their children. They were also sent information in the form of a video showing them how the intervention was conducted at the preschools with their children as well as a WHO video demonstrating the correct way to wash hands.

Analysis of data

The results were captured on an excel spreadsheet and then exported to SPSS where they were checked again for accuracy before analysis. Results were analysed for frequencies and answers were displayed in percentages. The answers for 'almost always' and 'always' were added together to provide a combined percentage. Comparisons were made in IG and CG pre- and postintervention as well as between IG and CG parents postintervention. Several of the statements in the questionnaire are attributed to activities which could help prevent the spread of colds and flu and diarrhoea. These statements have been linked together to form two new variables. These variables were tested for reliability using Cronbach's Alpha and labelled: 'Activities to prevent the spread of diarrhoea' ($\alpha = 0.702$) and 'Activities to help prevent the spread of colds and flu' ($\alpha = 0.572$). Only parents who completed the questionnaire and the statements pre- and postintervention ($N = 102$) were included for this specific analysis. All results were subjected to an independent *t*-test and significance of results was determined as $p = 0.05$.

RESULTS

Pre-intervention there were 191 (52.5%) parents at the selected preschools who completed the questionnaire and consented to be part of the study. The IG consisted of 98 (51.0%) parents and 93 (49.0%) parents in CG. Parents completing the questionnaire postintervention were 105 (55.0%) with 53 (54.0%) IG parents and 52 (56.0%) CG parents completing the questionnaire postintervention. The demographic information was reported according to

Table 1

Demographics of respondents of IG and CG.

	IG, $n=98$ (51%)	CG, $n=93$ (49%)	p value*
Gender			0.949
Male	18.0%	18.0%	
Female	78.0%	76.0%	
Age			0.495
18-29 years	22.8%	18.8%	
30-49 years	76.1%	81.2%	
50-65 years	1.1%	0.0%	
Level of education			0.333
Primary	0.0%	0.6%	
Secondary	16.7%	17.3%	
Tertiary	82.2%	79.2%	
Other	1.1%	2.9%	
Number of household members			0.023
Mean	4.3	4.7	
Minimum	2	2	
Maximum	14	6	
Number of children < 6 years in household			
Mean (0–18 months)	1.1	1.0	0.419
Minimum (0–18 months)	1	1	
Maximum (0–18 months)	2	1	
Mean (19 months–3 years)	1	1.1	0.160
Minimum (19 months–3 years)	1	1	
Maximum (19 months–3 years)	1	2	
Mean (4–6 years)	1.1	1.1	0.968
Minimum (4–6 years)	1	1	
Maximum (4–6 years)	2	2	

CG: control group; IG: intervention group.
*p<.05.

gender, age and education level of the respondent and is reported in Table 1. The majority of respondents were female in both IG (77.4%–78.0%) and CG (76.0%–80.8%) and mostly in the 30–49 years' age group. Close to 80% of respondents in both groups have a tertiary education. There was a significant difference between the number of household members in IG and CG ($p=0.023$); however, there was no other differences found between the groups in any of the other socio-demographic categories. On average there was one 4- to 6-year-old child although some households indicated two to three children in this age group.

Respondents were asked to indicate the number of toilets and WHBs available for the household. There was no significant difference between the IG and CG regarding HH facilities available in the households with a minimum of one toilet and one WHB available for each household. The maximum number of toilets per household could be found in CG where some households had six toilets. In IG, there were households with eight WHB although the mean for both groups was 2.2.

PARENTS HH PRACTICES

Table 2 indicates the responses of parents pre- and postintervention for IG and CG. An overall improvement in HH practices of 5.7% in IG and 6.88% in CG was reported.

Parents of IG showed a significant difference pre- and postintervention in HH practices of washing hands after coughing and sneezing ($p=0.011$); after using the toilet ($p<0.001$); after treating a wound ($p<0.001$); before giving medication ($p=0.005$); before preparing food ($p<0.001$), and after touching household pets ($p<0.001$). There was a significant difference ($p=0.019$) in IG postintervention where there was a 1.1% decrease in children washing hands after they had used the toilet.

Data for parents in CG also indicated significant differences in HH practices of washing hands coughing and sneezing ($p=0.040$); after wiping children's noses($p=0.043$); before eating($p=0.001$);

Table 2

HH practices and HH related symptoms of parents pre- amd post-intervention

	IG Pre, *n* = 98 (51%)	IG Post, *n* = 53 (54%)	*p* value[a]	CG Pre, *n* = 93 (49%)	CG Post, *n* = 52 (56%)	*p* value[b]	IG & CG Post *p* value[c]
HH practices							
My children have become sick because I did not wash my hands correctly	3.3%	0.0%	0.001	4.9%	1.9%	0.001	0.555
I wash my hands correctly even when I am very busy	53.2%	55.8%	0.054	48.8%	51%	0.099	0.459
I wash my hands after coughing or sneezing	19.2%	35.8%	0.011	22.4%	22.6%	0.040	0.471
I wash my hands after wiping my children's noses	31.9%	53.8%	0.081	28.9%	43.4%	0.043	0.881
I throw a tissue away once I have used it and do not keep it in my hand	62.8%	69.2%	0.179	63.8%	80.7%	0.182	0.329
I wash my hands after I have been to the toilet	94.7%	96.2%	0.000	90.3%	90.5%	0.008	0.637
I wash my hands after treating a cut or wound	86.1%	90.4%	0.000	84.3%	92.5%	0.003	0.530
I wash my hands before treating a cut or wound	69.1%	61.6%	0.066	63.4%	65.4%	0.011	0.689
I wash my hands before giving my children medication	39.4%	46.2%	0.005	19%	47.2%	0.034	0.243
I wash my hands after giving my children medication	24.5%	33.7%	0.128	20.4%	30.2%	0.032	0.116
I wash my hands before preparing food	91.5%	98.0%	0.000	91.5%	90.6%	0.000	0.403
I wash my hands after touching household pets	37.3%	36.0%	0.000	43.3%	44.3%	0.000	0.676
HH practices (children)							
My children wash their hands after using the bathroom	64.6%	63.5%	0.019	59.3%	73.6%	0.008	0.254
My children wash their hands before eating	56.4%	75.0%	0.120	62.7%	61.6%	0.016	0.455
HH equipment							
I have the correct equipment to be able wash my hands correctly	80.3%	81.2%	0.000	67.1%	77.3%	0.621	0.502
There is soap and towels available at all basins for hand washing	85.4%	88.5%	0.008	81.4%	83.0%	0.000	0.849
I use soap when I wash my hands	75.6%	82.7%	0.001	73.5%	82.7%	0.001	0.573
I use a clean cloth to dry my hands	78.8%	78.9%	0.000	68.6%	75.0%	0.007	0.470
HH symptoms							
In the past month, I have experienced a runny tummy	25.0%	24.5%	0.305	29.8%	17.3%	0.013	0.363

(Continued)

Table 2 (Continued)

HH practices and HH related symptoms of parents pre- amd post-intervention

	IG Pre, *n* = 98 (51%)	IG Post, *n* = 53 (54%)	*p* value[a]	CG Pre, *n* = 93 (49%)	CG Post, *n* = 52 (56%)	*p* value[b]	IG & CG Post *p* value[c]
In the past month, members of my family have experienced a runny tummy	42.1%	38.5%	0.000	37.3%	19.2%	0.429	0.013
In the past month, I have experienced cold symptoms such as coughing, sneezing, blocked nose	62.1%	56.6%	0.330	71.4%	55.8%	0.301	0.931
In the past month, members of my family have experienced cold symptoms such as coughing, sneezing, blocked nose	77.1%	66.0%	0.081	82.1%	82.7%	0.916	0.051
In the past month, I have experienced vomiting and a runny tummy	8.4%	13.2%	0.482	9.6%	7.7%	0.703	0.356
In the past month, members of my family have experienced vomiting and a runny tummy	21.1%	17.0%	0.931	24.1%	13.5%	0.292	0.616
In the past month, I have been to the doctor for treatment of any of the above symptoms	22.1%	17.0%	0.060	20.2%	25.0%	0.088	0.313
In the past month, members of my family have been to the doctor for treatment of any of the above symptoms	43.8%	20.8%	0.067	1.9%	34.0%	0.424	0.131

CG: control group; HH: hand hygiene; IG: intervention group.
[a]Difference IG pre- and postintervention.
[b]Difference CG pre- and postintervention.
[c]Difference IG & CG postintervention.

after using the toilet ($p = 0.008$); before ($p = 0.011$) and after treating a wound ($p = 0.003$); before ($p = 0.034$) and after giving medication ($p = 0.034$); before preparing food ($p < 0.001$) and after touching household pets ($p < 0.001$). A difference ($p = 0.016$) was seen in CG with a 1.1% decrease of children washing hands before eating.

There was a significant difference between IG and CG respondents' families reporting a runny tummy postintervention ($p = 0.013$) with CG reporting less than IG. However, postintervention, IG families reporting runny tummies were significantly less than pre-intervention ($p < 0.001$).

There was an average decrease in symptoms and treatments pre- and postintervention in IG of 6.0% and CG 7.3%. In a few instances respondents listed the symptoms that they had sought a doctor's assistance for which were listed as cold and flu, diarrhoea and other illness. There was no significant difference pre and post between IG and CG regarding the listing of these symptoms. There was an increase in reported visits by respondents to doctors for colds and flu in CG postintervention but it was not significant ($p = 0.983$).

The overall average improvement in HH practices postintervention in parents of IG was 5.7% with a 6.8% improvement in CG.

ACTIVITIES TO HELP PREVENT THE SPREAD OF DIARRHOEA, COLDS AND FLU

There were 53 (51.9%) IG and 49 (48.0%) in CG respondents who were eligible to be part of the combined variables described in the methodology section. The combined variable of 'Activities to prevent the spread of diarrhoea' showed a significant difference ($p = 0.035$) in IG pre- and postintervention. In the combined variable dealing with 'Activities to help prevent the spread of colds and flu' CG showed a significant difference ($p = 0.003$) between pre- and postactivities.

A multivariate analysis for risk factors for the presence of diarrhoeal symptoms, including runny tummies and vomiting, and respiratory symptoms was performed. A stepwise process was followed. Significant associations for experiences of diarrhoeal symptoms were found for the educational status of the parent and number of household members. A higher level of education (tertiary and above) was significantly associated with a lower odds ratio (OR) of diarrhoeal symptoms (OR: 0.755; 95% confidence interval (CI): 0.009, 0.588; $p = 0.014$). Having more than four household members was significantly associated with a higher OR (OR: 1.187; 95% CI: 0.179, 0.980; $p = 0.045$). The same analysis was conducted in the group for respiratory symptoms such as coughing, sneezing and runny noses. No

significant associations were found for these symptoms.

PARENTS COMMENTS IN THE QUESTIONNAIRE

A comments section was provided for at the end of the questionnaires both pre- and postintervention for each group. In IG, there were 37 comments of which 13 (35.1%) were pre- and 24 (64.9%) were postintervention comments. Postintervention for IG 11 (46.0%) of the comments was related to the intervention and how well their children interacted with the intervention. These comments from parents included statements such as:

> *Ooh, he was teaching me to wash my hands exactly the way you are doing it*
> *I got a lecture as well about hand hygiene and germs and how to wash my hands from my daughter.*

In CG, there were 22 comments with 7 (31.8%) being pre- and 15 (68.2%) postintervention comments. There were 9 (40.9%) of comments in CG which were questionnaire related, that is, the participant had learned something from the questionnaire and the same amount (40.9%) which were HH-related comments. The remaining 18.2% of comments in CG were general comments, for example, 'Good luck'.

As part of the questionnaire for IG postintervention parents were asked if they had learned anything new about HH and if they found the information useful. There were 52 (98.1%) of the 53 postintervention IG respondents who affirmed that they had learned something new about HH. Of the 53 IG respondents 35 (66.0%) answered the question as to whether they found the information useful or not with 9 (25.7%) answering 'yes'; 24 (68.6%) answering 'maybe' and 2 (5.7%) parents answering 'no'. This group of parents indicated that 46 (86.8%) of them were happy to receive HH health messages and information electronically.

DISCUSSION

Parents of IG and CG showed at least a 5% improvement in HH practices postintervention with CG improvement slightly higher (6.8%) than IG (5.7%). The improvements in IG as a result of the intervention correspond with similar research where parents have improved their own and their children's HH.[14,15] There could have been a form of social desirability bias in the answering of the questions, in that parents may have wanted to be seen by the researcher as a "good' parent and therefore gave answers to the statements depending on what they thought the researcher would want to know. This type of social desirability was found among preschool children who displayed better HH when someone was accompanying them as a social influence.[8] The notion of disgust, and being seen as a "dirty" person has also been reported as a driver for improved HH[16] and similarly could have influenced the answers of the parents. If this is the case, it would indicate a good knowledge of HH practices initially and improved knowledge postintervention, based on, in the case of IG, the intervention and in the case of CG the possible prompting brought on by statements in the questionnaire which created a thought process for improvement in practices.[17] There was a significant improvement in the nose-hygiene practices of parents in CG and a less-significant improvement in IG; however, there was also a decrease in respiratory illnesses in the families of both groups according to the reporting of the parents. Diarrhoeal disease–related practices improved significantly in IG and also improved in CG which was indicated in diarrhoeal illnesses and symptoms. Households with respondents with a tertiary education were 0.75 less likely to experience diarrhoeal symptoms. A similar study of primary school pupils in Wuhan showed that children of mother's with a tertiary education were 0.68 times more likely to adhere to good HH, which was found to be significant.[18] It is possible to draw an association between good HH and the parental level of education, with 82.2% of parents in IG and 79.2% in CG reporting a tertiary education.

Whether from social desirability or improved knowledge of HH and the effect it could have on the health of their children and families, parents of IG and CG both improved on their statement that their children could have become sick because they did not wash their hands properly (3%). This statement is confirmed by the significant improvements of CG in the respiratory infection-related activities ($p = 0.003$) and IG improvements in diahrroea-related activities ($p = 0.035$). There was a 23% and 7.9% decrease in doctor's visits for IG and CG, respectively.

Parents of the IG were targeted with electronic messaging information as part of the intervention. A video showing how the children were taught to wash their hands was sent to the parents via WhatsApp. Almost all the parents (98.1%) indicated that they had learned something new from these messages. This feedback from parents indicated they were happy to receive health messages through electronic and social media (email and WhatsApp) and showed to be an effective way of increasing knowledge of parents and caregivers, as reported in previous studies.[10,19]

Information regarding use of hand sanitizers, critical times to wash hands, and how to wash hands was forwarded to the parents regularly during a 3-week period after the intervention. Comparing the pre- and postintervention data on HH, HH-related diseases, and doctor's visits in IG could be influenced by the information received by the parents and also the influence of the children on their parents. This was reported as effective in an HH intervention where one of the sources of information for the parent was the passing of information from the school-going child, who has also been exposed to an intervention, to the parent.[20,21] There have also been slight improvements found in the health of children under 5 with siblings attending schools who are part of an intervention.[7]

During analysis, many of the results showed significant improvements by CG and therefore, as the CG was not exposed to the intervention an explanation for the improvements in CG needs to be sought. Several possible explanations for these increases have been explored. Research of itself is a type of intervention, as from the time that a participant provides informed consent, whether they are in IG or CG, they are no longer in a usual situation as they are

now research participants.[22]

Another explanation could be the testing effect which occurs when participants improve their scores in the postintervention test as they have learned from the statements or questions asked[22] or the statements or questions have stimulated new thinking thereby acting as a type of intervention in IG and CG.[23] This can be seen as a type of learning tool, which proved effective with students who were exposed to a pretest and who then performed better in a post-test than their counterparts who did not conduct a pretest.[24] Some of the statements that formed part of the questionnaire for parents could be a driver for behaviour change or provide an opportunity to stimulate thinking with regard to hygiene, which could explain the improvements in both IG and CG.

A third effect which could affect the improvement of results in both IG and CG is a reactivity of measurement whereby mere fact of being measured against a previous measurement may provide an improvement.[22] The questionnaires were administered approximately 4 months apart and contained the same statements pre- and postintervention, providing a possibility for participants to recall and improve on their previous score.

The importance of continued HH interventions has been highlighted during the COVID-19 pandemic. Keeping in mind that pre-COVID-19, correct hand washing was practised by 19% of the world's population[6] one would expect vast improvements as a result of the emphasis placed on hand washing as a means of preventing transmission of COVID-19. Numerous studies have shown that there was a significant decrease in HH compliance over time, once the initial crisis period had passed, despite the pandemic. These studies indicated that healthcare workers reverted back to old HH habits and practices, sometimes within 14–20 weeks of initial restrictions and school closures implemented as preventive measures for the pandemic.[25,26] These studies show that even in the face of a pandemic where hand washing is indicated as a primary preventive tool, continued reinforcement through effective interventions are needed to improve and maintain HH compliance in all sectors.

STRENGTHS AND LIMITATIONS

The study provided similar results to previous studies which indicate that interventions can improve HH and reduce HH-related diseases.[27,28] The study provided numerous significant results while following the published study protocol,[29] validating the protocol.

As with any HH intervention study the major weakness of the study was the lack of blinding of study participants.[30] There was partial blinding in that participants were not aware of all aspects of the study or its anticipated outcomes. Participants were also not aware of an IG or CG nor did they know which group they were part of.

A limitation of the study was that due to time and manpower constraints, the study did not start simultaneously in all preschools but was a rolling start in that some schools enrolled earlier than others. The study used diarrhoea and upper respiratory tract infections as an indicator, but data were collected based on parents own perceptions of these to symptoms.

CONCLUSION

HH practices of these parents were considered to be of a high standard compared to the previously stated practice of 19% of persons worldwide washing hands with soap after defecating.[31] Over 90% of parents in both groups washed hands after using the toilet, both pre- and postintervention. All HH practices for both groups showed increases both pre- and postintervention. The knowledge of the parents increased as was shown by how they answered the question as to whether their children had become ill due to their own hygiene practices. Pre-intervention parents answered this statement by denying that their actions had health implications for the children; however, postintervention parents in IG and CG answered the statement in a way that implied that they had come to the realisation that they may have contributed to children's illnesses through their HH practices. Simple interventions such as the one administered to the respondents in this study is a cost-effective way of educating parents and improving HH in the home as well as improving the health of young children. Administering questionnaires can be a form of intervention and stimulation of knowledge and learning. By making use of available resources such as simple WhatsApp messages and regular communication with parents of preschoolers, they are able to make the small changes necessary to improve their HH and those of their families.

RECOMMENDATIONS FOR FURTHER RESEARCH

A recommendation regarding further study would be to determine the HH practices of preschool parents as a result of the pandemic, as it has been previously mentioned that HH compliance improves during epidemics, or in this case, a pandemic.[32]

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CONFLICT OF INTEREST

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ETHICAL APPROVAL

Permission was obtained from the University of Johannesburg Ethics Committee as well as Ministerial Consent for Non-Therapeutic Research on Minors for Department of Health National Ethics Research Council.

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DATA AVAILABILITY

Data set available on request from the corresponding author.

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The forensic implications of food hypersensitivity – a review of cases in United Kingdom courts: January 2014–February 2020

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Keywords

food hypersensitivity; food allergy; coeliac; prosecution; regulation; food law; inquest; coroner; food labelling; food safety; offence; health and safety; manslaughter

Abstract

Aims: Food allergy is a major public health concern. Failures of food allergen avoidance and the consequences for those with food hypersensitivity (allergies, intolerances and coeliac disease) have a forensic context. The aim of this study was to collate and analyse the use of action in the United Kingdom (UK) courts as redress following adverse food allergy reactions or failures of allergen management.

Methods: Details of prosecutions during the study period (1 January 2014 to 31 January 2020) were recorded from regular key word Internet searches. National and local news reports were primary sources, along with commentary from enforcement and regulatory professionals. Information was also collected from coroners' inquests by attending hearings and direct contact with coroners and participants in the hearings. Freedom of Information requests were made to local authority enforcement departments. In several cases, the authors had direct involvement in investigations.

Results: From 2014 to 2020, there was an increase in reports. Seventy prosecutions were recorded as well as two associated appeals and two applications for Hygiene Emergency Prohibition Notice. This resulted in 68 convictions; seven individuals received custodial sentences, three of which were suspended although one individual had a tagged curfew imposed. Fines ranged from £50 to £93,000. Details of the law applied and the evidence gathering processes are reported.

Conclusion: Legal action, including landmark prosecutions for Gross Negligence Manslaughter and Preventing Future Deaths reports from coroners, with salience of criminal penalties, has led to changes in labelling law and improved allergen management practices better to protect the interests of patients with food hypersensitivities. A central system of collation of such data, and on 'near misses', will enable more focused root cause analysis to further improve allergen management and reduce patient risk.

INTRODUCTION

Food allergy is a major public health concern. Food hypersensitivity avoidance (allergies, intolerances and coeliac disease) has a legislative (Table 1) and forensic context. Contravention of legislation may lead to prosecution and conviction of food business operators.

In the UK consequences of non-compliance with the law described in Table 1, include criminal sanctions, a Food Information Regulations Improvement Notice (FIRIN), a proven breach of which is a criminal offence. A temporary Hygiene Emergency Prohibition Notice (HEPN) may be used if there is an imminent food hypersensitivity risk to health.[1,2] A coroner investigating a food allergy fatality may issue a 'Regulation 28 Preventing Future Deaths' (PFD) report[3,4] to named food businesses and other bodies for response, and openly published.[5]

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Table 1

Legislative context for allergen management

Jurisdiction and statute	Provisions as they apply to allergens[a]
European legislation[b]	
Regulation (EC) No 178/2002 . . . *on the general principles and requirements of food law* . . .[1] Implemented domestically by The Food Safety and Hygiene Regulations 2013.	Food businesses must provide safe food 'determining whether any food is injurious to health' should take into account the 'particular health sensitivities of a specific category of Consumers'.
Regulation (EU) No 1169/2011 *on the provision of food information to consumers* . . . (The 'Food Information (to Consumers) Regulations' (FIR)) Implemented domestically by the Food Information Regulations 2014.	Identifies 14 priority allergens (Annex II) ('Substances or Products Causing Allergies or Intolerances') determined at EU level from a global list of eight priority allergens set by Codex Alimentarius. Only two have quantified limits; sulphur dioxide (sulphites) >10 mg/kg (as SO_2) and gluten-free foods may be so labelled so if their gluten content is below 20 mg/kg. FIR requires prepacked foods to bear a legible ingredients list in regulated text size, with any priority allergens present highlighted and the information made available throughout the supply chain from business to business and to the final consumer via labelling, other written information or dialogue with staff supported by signage. Food businesses operators are required to keep, manage and make available correct and up to date accurate, consistent and verifiable information about which allergens had been included in which product or dish. From 1 October 2021 a UK-specific amendment to FIR requires previously exempt items prepared and packed on site (prepacked for direct sale, PPDS) to carry the product name and full ingredients with any of the 14 priority allergens highlighted.
Regulation (EU) No 852/2004 *on the hygiene of foodstuffs*	Requires food business operators to identify hazards in their activities and put in place procedures to control them
UK (only) legislation	
The Food Safety Act 1990, (Chapter 16)	Provides for criminal offences including rendering food injurious to health (Section 7), selling, to the purchaser's prejudice, food which is not of the nature or substance or quality demanded (Section 14) and falsely or misleadingly describing or presenting food (Section 15)
The Health and Safety at Work Act 1974 (1974 c 37) Section 3	Requires businesses to ensure that people not employed by them, but who may be affected by their business activities are not exposed to risks to their health or safety, and also to provide such people with information about their business activities to ensure their health and safety.

EU: European Union.
[a]For authoritative text see EUR-Lex, https://eur-lex.europa.eu/homepage.html.
[b]On UK Exit day (11 pm on 31 January 2020) extant EU law was transposed into UK legislation.

To date, there is no regulation specifically governing Precautionary Allergen Labelling (PAL) ('May contain') where allergens not used as ingredients may be present as contaminants.[6] However, the general risk of allergen cross-contamination is recognised in hazard analysis and risk assessment in food businesses.

Eight sample food allergy cases from UK courts were published in 2014.[7] These included an initial conviction for supplying peanut labelled as almond. The business later successfully appealed the conviction.

This study includes UK court reports from January 2014 to the end of January 2020. Its purpose is to understand the circumstances in which prosecutions may (and may not) take place, the law used, the food allergens involved, the evidence and the penalties applied. In addition, background data may inform those at risk and their advisers to improve understanding and reduce risks.

METHOD

Data were collected from 1 January 2014 for continuity with our previous work[7] to 31 January 2020, when the COVID-19 pandemic supervened, by regular Internet searches using key words (Supplementary Material Table S1) and national and local news reports, and recorded (Supplementary Material Table S2) with occasional commentary from professional (regulatory) organisations and other stakeholders. Full details of the two cases involving Gross Negligence Manslaughter are available on public websites.[8,9] Information was collected from coroners' inquests by attending in person and through direct contact with

coroners, families, clinicians, local and national regulators and others (MHG). MHG has also been directly involved in some investigations. Charges were confirmed for some cases through 19 Freedom of Information requests to local authorities. One new source of dissemination is social media, cases reported online sometimes in real time via Twitter™ and elsewhere.

RESULTS

There has been a steady increase in the number of food allergy court hearings since 2014 (Figure 1). Food allergy-related prosecutions ($n = 70$), two associated appeals and two applications for HEPN were recorded in the United Kingdom from 1 January 2014 to 31 January 2020.

One catering outlet (a 'takeaway') was acquitted of food allergy-related offences because undeclared peanut was due to the fault of their supplier (which ceased trading). Of the 69 remaining cases, 4 involved prepacked and labelled foods, 64 were takeaway or restaurant dishes and 1 was prepacked for direct sale (PPDS). In all, 68 cases led to convictions. In four reports, the takeaway order was made using a delivery platform.

In two cases, prepacked imported food was not labelled in English. One prepacked product had no allergen labelling, and one was a product containing unlabelled milk, which caused a severe reaction in a young child with milk allergy.

The UK geographical spread of the 68 convictions is shown in Table 2.

WHICH FOOD ALLERGENS WERE INVOLVED?

Five prosecutions involved failure to label, provide information or signage generally for all food allergens. The most common allergen cited in prosecutions was peanut, followed by egg and milk. All cases cited allergens in the Annex II list (Figure 2).

WHICH COURTS WERE INVOLVED?

Most cases were heard by a bench of lay magistrates. Four were before a District Judge. Sixteen cases were heard in the Crown Court, owing to the gravity of the charges, or because the defendant availed of the right for the case to be so heard. Two cases proceeded to the Court of Appeal.

WHO TOOK THE PROSECUTIONS?

The investigation of three recorded allergen fatal reactions involved the police; in North Yorkshire following the death of Paul Wilson[8] and in Lancashire following the death of Megan Lee,[9] which both led to prosecutions for Gross Negligence Manslaughter, and in Bath following the death of Chloe Gilbert.[10]

The remaining prosecutions were taken by local authority trading standards officers (TSOs), and/or environmental health officers (EHOs). Some businesses,

Figure 1

Allergy-related UK court hearings from 1 January 2014 to 31 January 2020

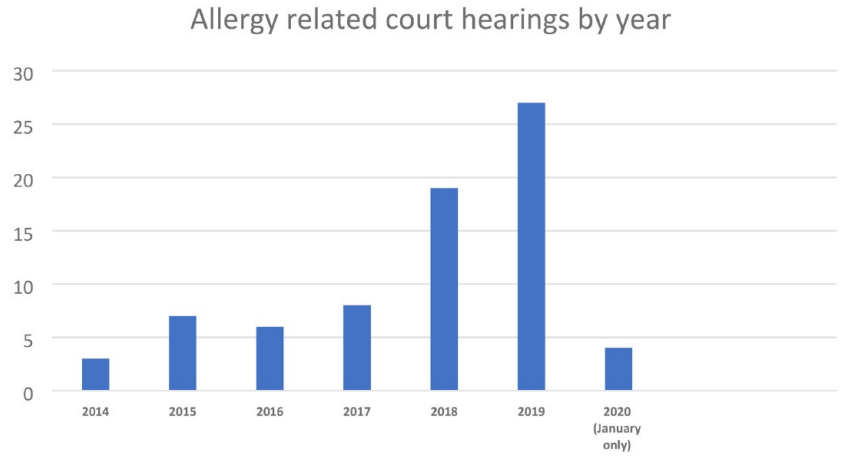


Table 2

UK geographical spread of allergen-related criminal convictions from 1 January 2014 to 31 January 2020

Nation	Number of convictions		
England	51		
		Of which	
		North West of England	14
		North East of England	11
		Midlands	12
		South East of England	12
		South West of England	2
Wales	14		
Northern Ireland	2		
Scotland	1		
Total	68		51

Figure 2

Number of cases by priority allergen

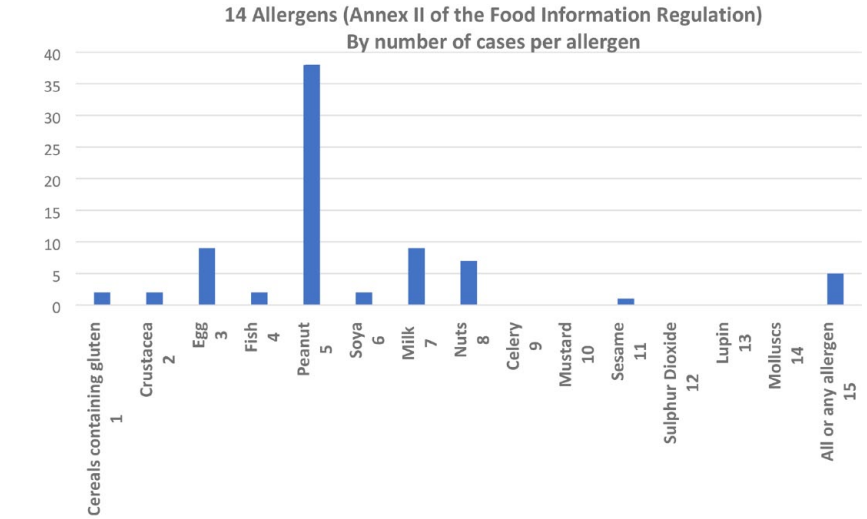
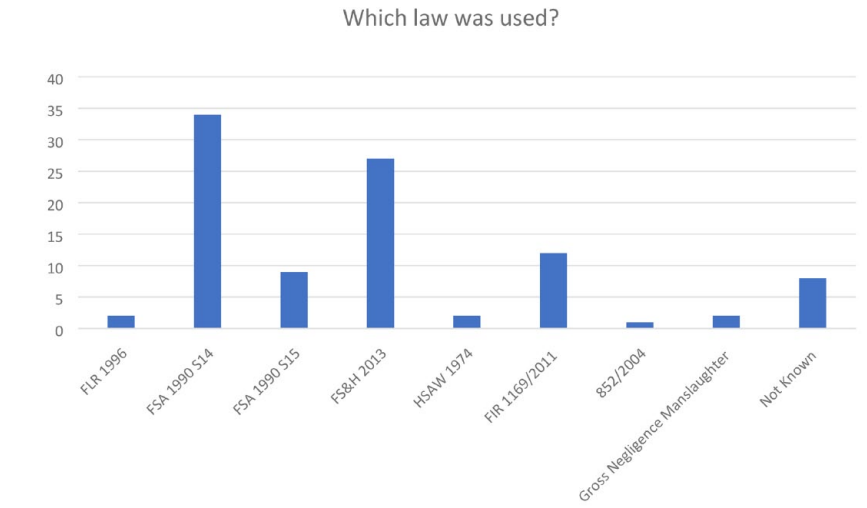


Figure 3.

Which law was used?

FLR 1996	Food Labelling Regulations 1996
FSA 1990 S14	Food Safety Act 1990 Section 14
FSA 1990 S15	Food Safety Act 1990 Section 15
FS&H 2013	The Food Safety and Hygiene (England) Regulations 2013
HSAW Etc 1974	Health and Safety at Work etc Act 1974
FIR 1169/2011	Regulation (EU) No 1169/2011 of the European Parliament and of the Council
852/2004	Regulation (EU) No 852/2004 of the European Parliament and of the Council



and particularly those with multiple sites, may have a primary authority arrangement with one local authority to access assured guidance and tailored advice on meeting regulations. In general, this can bring laudable consistency and efficiency to the regulatory process. However, on occasion there is tension between a prosecuting authority and a primary authority.[11]

WHICH LAW WAS USED?

The applicable law in the recorded prosecutions varied; most involved alleged offences under more than one regulation (Figure 3). One case specifically mentioned Regulation (EU) No 852/2004, which relates to the management of food safety, two cases involved Gross Negligence Manslaughter. In eight cases, details of the legal measures cited in relation to the alleged offences were not recorded in the news reports, or local authority press releases and could not be elicited by direct contact with those involved (Figure 3).

EVIDENCE – TEST PURCHASES

Evidence included data obtained through analysis of a test purchase or food samples ($n = 41$) collected front and back of house during an investigation, food labels, menus, signage, product specifications and promotional information in physical and electronic format, including emails, websites and from telephone, Internet or digital platform ordering. In some cases following a reaction, if the food was no longer available, the business was asked to re-create the meal ordered under observation to be analysed for the suspected allergen. Lip swabs and other postmortem food samples were analysed. Dialogue between investigating officers, food business operators and other staff provided key background evidence about allergen policies and procedures. Photographs of signage and other information, kitchen, storage, service and delivery practices were also used. Businesses which had been advised not to sell food to people with a particular allergy were telephoned to test whether they would implement this instruction. Although

rarely reported, food analysis was assumed generally to have been carried out in official food control (Public Analyst)[12] laboratories.

CONVICTIONS

Only two acquittals were recorded, though it remains challenging to gather acquittal information which, being of less media interest, is infrequently reported and has no public protection benefit in alerting consumers to potential risks. From anecdotal evidence, some local authority investigations of allergen incidents may not have proceeded to prosecution owing to disparity in legal support between the authority and the intended defendant.

THE SENTENCING GUIDELINES

The Sentencing Council for England and Wales[13] developed Sentencing Guidelines which came into force on 1 February 2016 in England and Wales. In Northern Ireland, Sentencing Guidelines for Food Safety and Hygiene offences were also published.[14] (The Scottish Sentencing Council was established in October 2015 but has not to date addressed Health and Safety or Food Safety offences.)

The Sentencing Guidelines take into account the seriousness of the crime committed and the harm caused, the culpability, the risk posed by the offending behaviour, the way in which the individual has interacted with the local authority prior to the offence, the financial circumstances of the defendant (as an individual) and (through its directors) the business turnover and number of employees.

PENALTIES

Custodial Sentences: Four individuals in three cases received custodial sentences. Three individuals in two cases received suspended prison sentences and one also had a tagged curfew between 9 pm and 7 am for 3 months.

Community sentences: One individual was required to do 300-h community service over 12 months. Two individuals in another case were required to do 100 h each over 12 months and another individual, 150 h over 12 months. Two individuals with suspended sentences were also required to do 120 h each. Another individual was required to do 20 days over 12 months.

Fines: Where data were available, fines ranged from £50 for a street trader who failed to make allergen information available to £93,000 for a large manufacturer supplying a product with undeclared egg. Of the 62 cases where fines were reported, the average was £6189, and the average costs awarded were £2063. Thirty-eight cases mentioned a Victim Surcharge.[15] During the study period, these ranged from £20 to £170 with an average of £97.

PFD REPORTS

PFD reports following allergy-related deaths include the report for Jackie Scott[16] who was allergic to peanut and died in 2013 after eating a curry suspected to contain peanut. The published report does not include a reply from the business which supplied the food. More recently, a report was published following the death of Owen Carey after he ate chicken containing milk (having requested food without milk).[17] This report was addressed to the restaurant chain involved and others.

In autumn 2018, following the widely publicised inquest into the death of Natasha Ednan-Laperouse, the PFD Report[18] addressed alleged inadequate labelling of PPDS foods. This led to a statutory measure requiring PPDS foods to carry full ingredients and allergen labelling.[5] This law (informally known as *Natasha's Law*) is in force from October 2021.

PROSECUTION ABROAD

The death of a UK citizen on holiday in Italy in 2015 from hypoxic brain injury and cardiac arrest after consuming milk or a milk derivative was recorded in a UK inquest during which it was reported that a prosecution in an Italian court led to a suspended sentence for a waitress found guilty of manslaughter.[19]

DISCUSSION

Food-hypersensitive consumers should be able to access correct information about all relevant allergen ingredients in their food, including those which are not listed in Annex II of FIR. Anaphylaxis Campaign (AC) data indicate that kiwi, banana, legumes such as peas, beans, lentils and chickpeas are more commonly avoided by its AC members than some of those listed on Annex II – for example mustard, celery, lupin, molluscs (Personal communication to MHG from Anaphylaxis Campaign helpline manager, 11 July 2017). In addition, such consumers need to be able to discuss and assess the controls in place to prevent allergen cross-contamination throughout the supply chain.

The prosecutions for Gross Negligence Manslaughter were significant and involved inadvertent consumption of peanut in Indian-style cuisine. Close partnerships between the police and local authority food officers and prompt and thorough evidence collection led to custodial sentences. Peanut allergy is common and reports of deaths and 'near misses' to unexpected peanut in curries date back to 1988.[20,21]

The Health and Safety at Work Act 1974 (S.3) does not impose a time limit for laying information. This is helpful (e.g. in the Lancashire case) because fatal (and 'near miss') reaction investigations are complex, often taking more than the year allowed to bring charges under food law.

The Food Safety Act (S.14) offence has been widely used and generally depends on proof (e.g. from analysis or sometimes from ingredients information) that the allergen was present, following a request for their absence. The Food Safety and Hygiene Regulations,[2] 'Placing unsafe food on the market', can be used even where a food sample is not available for analysis.

Accessing case reports often depends on news journalists who report from local Magistrates and District Judge hearings but may not always record full details of the charges or penalties. In 2017, it was possible to download Local Authority and Food Standards Agency (FSA) prosecution outcomes from the FSA website including details of the businesses, offences, penalties and local authorities, and to search for key words of likely relevance to the protection of food-hypersensitive consumers. This

information no longer seems to be accessible, a shortcoming in research and trend analysis on local authority legal activity generally and food hypersensitivity prosecutions in particular.

The advent of the Sentencing Guidelines led to a requirement to demonstrate not just actual but potential harm requiring Public Analysts and other experts to explain to magistrates, juries and judges the likely or possible impact of the unlabelled presence of a food allergen.

The study period covers major reductions in national and local food control budgets[22] although, encouragingly, local authorities still respond to consumer complaints and undertake sampling and analysis[23,24] to identify unlabelled allergens. However, it has sometimes taken a severe or even fatal reaction to ensure that funding for such initiatives is available. Similarly, local authorities continue to engage with businesses, helping them to undertake allergen risk assessment and management, delivering formal and informal training. Many also engage with one another through regional workshops to ensure that they are up to date on food hypersensitivity issues and best practice, and some have reviewed the Memorandum of Understanding in place between Environmental Health and Trading Standards Officers involved in food control to improve investigation of complaints and support businesses (Personal communications MHG and Helen Dodds, Food Safety Manager, Hyndburn Borough Council. From 18 July 2018 and on-going).

In general, defendants were food business operators, but it is interesting to note one prosecution of a staff member under the Food Safety Act who sold a pizza containing milk (with vegetarian cheese) for a child with a declared milk protein allergy when he had promised 'vegan' 'cheese' without milk. He is reported to have pressed the wrong button on the ordering terminal. The child suffered a reaction requiring hospitalisation and the staff member tried (unsuccessfully) to change the order retrospectively on the terminal. The food business was able to demonstrate responsibility lay with the staff member rather than the business. This case serves as a salutary lesson for catering businesses and for staff training.

The current trend for plant-based or 'vegan' products represents a risk to those consumers who are highly sensitive to milk and eggs, but who may not wish to 'make a fuss'. Businesses providing plant-based food may not be able to eliminate these key allergens at parts per million levels required for the most sensitive allergic consumers. While ingredients may not include egg or milk, without the kind of 'positive release' and batch testing controls used in the production of 'free from' foods, the necessary segregation is unlikely to be in place.

Food business reputations are increasingly shaped online. Companies with online ordering and delivery platforms now require businesses to implement higher food safety standards to appear on their sites[25] which in turn is causing businesses dependent on their platform-presence to undertake training and more effective food safety risk assessments. Some platforms now require customers declaring a food hypersensitivity to contact the business directly, and not purchase via their platform. Some restaurants and takeaways will not provide food for delivery because although they can implement controls within their businesses, they cannot guarantee its allergen integrity while in the care of the delivery driver.

Finally, individuals who are undergoing or who have recently suffered an allergic reaction attributable to food may well report their reaction in real time on Facebook™, Twitter™, Instagram™, Trip Advisor™ or elsewhere. Public complaints and allegations suggesting that a business may be responsible for a reaction may lead to reputational damage which could have a significant impact on their trade, and lead to further intervention by local authority food officers.

CONCLUSION

From 2014 to 2020 in the UK, there has been a steady increase in local authority investigations leading to prosecution and conviction of food business operators for offences involving unidentified food allergen presence, and failure to retain, manage, advertise and provide correct allergen information. Takeaway businesses selling unidentified peanut in curry represent a real risk to consumers and are still the focus of sampling projects in many areas of the UK. Similarly, unidentified egg in Chinese cuisine has led to prosecutions following sampling programmes in Wales. Reports of only two (manufactured product) prosecutions in Northern Ireland and one case of peanut in curry in Scotland during the study period may indicate less allergen enforcement activity, or use of alternative approaches to controlling allergen risks in local businesses.

The FIR are being used in enforcement and cases have been taken for failure to make information available or failure to have a notice inviting consumers to ask about allergens. The Food Safety and Hygiene Regulations[2] provide a clear offence of selling unsafe food which has been used where the allergen information provided is incorrect.

Key investigations of takeaway businesses in the north of England have led to landmark prosecutions for Gross Negligence Manslaughter and related food offences, while major restaurant brands have received requests for PFD reports from coroners following high-profile inquests in London and elsewhere.

Purchasing and selling behaviour is changing. The use of digital platforms to order food for delivery ready to eat or for later consumption has required a major review of risks throughout the supply chain, and significant effort to ensure brand protection continues. High-profile cases, the apparent increase in young adults with multiple food allergies (particularly milk, egg and sesame), media interest and the immediacy of social media all play their part. More recently, ordering and delivery platforms have excluded food-hypersensitive customers from their services, insisting instead they attend the business and order in person. This is intended to reduce the risk of misunderstanding the request, or tampering with the order during delivery. However, as ordering online is now a way of life for many, particularly during the COVID-19 pandemic, there is a risk that some consumers will order without declaring their allergen avoidance need, preventing optimal allergen controls being implemented.

RECOMMENDATIONS

The data reported here have been collected primarily through public domain sources which limit the extent of data analysis. In autumn 2021, the FSA and Food Standards Scotland (FSS) announced a pilot scheme to collect and investigate reports of food hypersensitive reactions,[26] including where possible analysis of food samples. Data on the foods, amounts of allergen, communication, preparation and service practices involved may be gathered and with further engagement with local authority teams, regulatory advisory and enforcement action may lead to improved root cause analysis, lessons learned and consumer, business and wider public awareness to reduce risk. Pilot 'Citizen Science' projects have been commissioned by the FSA and UK Research and Innovation (UKRI)[27] to engage food-hypersensitive communities to improve food safety standards in online food procurement. The FSA is also supporting research to establish the UK Anaphylaxis Registry and to continue to monitor anaphylaxis trends in the UK and beyond.[28] Finally, the FSA through the British Society for Allergy and Clinical Immunology (BSACI) is funding the UK Fatal Anaphylaxis Registry (UKFAR) to review fatal anaphylaxis cases, optimising understanding and potentially reducing risks.[29]

Future best practice in food allergen management and the investigations of its failure would benefit from an overarching meta-analysis of the outcomes of the above studies augmented by official collection, collation, review and reporting of court cases and research on the disparity between legal resources available to local authorities to mount complex food allergen mismanagement prosecutions. Otherwise, systems opportunities for root cause analysis and associated lessons learned may be missed and inadequate allergen management practices unchallenged.

Food businesses, catering organisations and hospital trusts may also collect instances of food allergy reactions, including 'near miss' occurrences. Existing Health & Safety legislation has established the 'Reporting of Injuries, Diseases and Dangerous Occurrences Regulations' (RIDDOR), to report certain serious workplace accidents, occupational diseases and specified dangerous occurrences (near misses)[30] that ought to include food allergy incidents, while General Practitioners (GPs) must report cases of food poisoning to their local environmental health department. Systematic collation of health-related 'near miss' data collected and investigation of the datasets generated are key to optimising root cause analysis for food allergy adverse incidents.

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AUTHOR CONTRIBUTIONS

MHG and MJW jointly conceived the approach and experimental design. MHG carried out the data collection and analysis. Both authors drafted the manuscript. MJW secured part funding, both authors have read and agreed the final version of the paper.

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CONFLICT OF INTEREST

The author(s) declared the following potential conflicts of interest with respect to the research, authorship and/or publication of this article: MHG provides expert opinion in cases involving food allergens for which modest fees may be paid. She provides training and consultancy to food businesses and local authorities, supports and trains trainers, and lectures on university and other professional development programmes. She is a project adviser/researcher on FSA-funded studies including Citizen Science Projects for Queen's University, Belfast and the University of Bath, the UK Anaphylaxis Registry (with Imperial College, London) and the UK Fatal Anaphylaxis Registry (with Manchester University NHS Foundation Trust (MFT)), both registries supported by the BSACI. MJW is the owner of a chemico-legal consultancy which may receive modest fee income related to allergen risk assessment and is an unpaid (*pro bono*) advisor to a FSA-funded Citizen Science project in Queen's University Belfast.

CONSENT FOR PUBLICATION

Not required (all data collected were already in the public domain).

DATA AVAILABILITY STATEMENT

The datasets generated and/or analysed during the current study were self-funded by the authors (principally MHG), hence are not publicly available but may be available from the corresponding author on reasonable request.

DISCLAIMER

The views expressed in this paper are those of the authors alone. The paper should not be taken as an authoritative statement or interpretation of the law, as that is a matter for the courts.

ETHICAL APPROVAL

Not required (all data collected were already in the public domain).

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SUPPLEMENTAL MATERIAL

Supplemental material for this article is available online.

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