

## **The relationship between body mass index (BMI) and health-related quality of life using the CHU-9D in children: implications for the practice of economic evaluation.**

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### **Abstract**

**Background:** Economic evaluations of obesity-prevention interventions rely on the use of utility values to capture the health-related quality of life (HRQL) effects. We have limited knowledge of the utility - body mass index (BMI) relationship in adults, and even less knowledge of this relationship in children. The situation is further complicated by the rate of development in children so whilst there may not be a relationship between BMI and utility in preadolescent children, this relationship may change as the child grows through adolescence and to adulthood. This has implications for how we evaluate obesity-prevention initiatives particularly when the intervention is delivered to young children (as young as 6), but where we are assessing cost-effectiveness at programme end, by which time children may be post-pubertal. Understanding how weight status affects HRQL in children is a key priority area for research within obesity.

**Objective:** Using baseline data from a large trial that has collected data from a multiethnic population in 54 primary schools throughout the West Midlands UK, this study will investigate the relationship between HRQL and weight status in children aged 5-6 years.

**Methods:** Height and weight data is available for 1369 trial participants (663 boys and 705 girls). All participants completed the CHU9D, a newly developed paediatric utility-based HRQL measure. Participants were selected to include a diverse Sociodemographic profile, with 30% being South Asian, 10% from black or Afro-Caribbean background, and the remainder mainly from white background. Over half the children were from the most deprived quintile of the UK population, while 12% are from the two most affluent quintiles. The relationship between utility and BMI z-score will be assessed using multivariate analyses, adjusting for Sociodemographic factors. We will test for differences between children who are classed as obese, overweight, normal and underweight defined by BMI using cut-offs at the 85<sup>th</sup>, 95<sup>th</sup> and 2<sup>nd</sup> percentiles on the UK 1990 reference charts for boys and girls. Stepwise regression models will be used to explain the utility scores.

**Discussion:** The practical implications of these utility valuations will be discussed and conclusions drawn regarding the responsiveness and validity of the CHU9D in this patient population and clinical area. Obesity-prevention is a key priority for public health decision makers and evidence has shown that most effective policies need to be targeting a young population. The results of this study will help us to understand the relationship between BMI and utility in a paediatric population which in turn will help guide practice for economic evaluation.

## Introduction

Childhood obesity is a growing problem worldwide, and in the United Kingdom (UK) prevalence has markedly increased in the last three decades[1]. The direct annual costs of obesity and associated health consequences to the NHS are approximately £4.2 billion, with an estimated cost of £16 billion to the wider economy[2].

There is increasing evidence that weight status has an effect on health-related quality of life (HRQOL)[3-7]. HRQOL is a construct that attempts to provide a general assessment of well-being measured along multiple dimensions, including functional, psychological, physical and social well-being[8]. In economic evaluation, HRQL is measured using utility measures whereby the outcomes of interventions are compared on a common scale (where zero equals death and full health equals one). Whilst the physical and psychological health outcomes associated with a child being overweight are well documented[9], very few studies have looked at the impact when HRQOL is measured in utility terms. This is important as the UK National Institute for Health and Clinical Excellence (NICE) requires HRQOL to be measured in utility terms when assessing the cost-effectiveness of comparative interventions[10,11].

Child health is different to adult health and requires a different conceptual approach due to rapid rates of development, dependency on parents/caregivers and differences in disease epidemiology[12]. It is often correlated with age but achievement of developmental milestones can vary according to the individual child[13]. Overweight and obesity has a range of short and long term health consequences both in childhood and adulthood[14-16], and currently just under 1 in 3 children and 2 in 3 adults are overweight or obese in the UK[17]. Whilst there is evidence to show that overweight/obesity has a negative effect on utility-based quality of life, this evidence is almost exclusively within an adult and adolescent population[3,6]. To inform resource allocation decisions, there is an urgent need to explore this relationship in children. This is even more important within obesity prevention as evidence suggests that for lifestyle changes to be sustained there is a need to intervene early and to target children and young families. From a methodological perspective, health economists need to establish the underlying relationship between weight status and utility-based HRQOL in children to inform the design of economic evaluations within trials evaluating the effectiveness of obesity prevention interventions. The assumption with using utility measures within these trials (in which children are often followed up for several years) is that the utility-based QoL of young children is negatively affected by being overweight but this relationship is yet to be explored in practice.

This paper will contribute evidence using baseline data from a large childhood obesity prevention trial (WAVES study) that has collected data from a multiethnic population in 54 primary schools through the West Midlands, UK. The objective of this analysis is to investigate the relationship between utility-based HRQL and weight status in children aged 5-6 years.

## **Methods**

### *Participants and trial design*

The WAVES study is a cluster-randomised controlled trial to assess effectiveness and cost-effectiveness of a childhood obesity prevention intervention targeting children aged 6-7, funded by the NIHR Health Technology Assessment Programme (ISRCTN 97000586). Fifty four primary schools (recruited from a random sample of 200) are participating in the study. The random sample was weighted to try to ensure that in the final sample of participating children there would be sufficient representation (to enable sub group analysis) from the two most prevalent ethnic minority groups in the West Midlands (South Asian and Black). Children in year 1 (aged 5-6) and their families were invited to participate. Parental consent for participation was gained from 1462 of a possible 2470 children (59%), and baseline measurements were obtained for 1391 children (95% of those consented / 56% of those eligible).

### *Body mass index*

BMI is a widely used measure of weight status and is the most commonly used measure to define overweight and obesity in children[18]. It is calculated by dividing weight (in kilograms) by height (in metres) squared ( $\text{kg}/\text{m}^2$ ). In children, BMI is interpreted relative to a child's age and sex (BMI z-score). This is because the amount of body fat changes with age and varies by sex. Growth charts are used to determine BMI percentiles for boys and girls of each age (based on reference data from a 1990 UK cohort of children)[19] and these percentiles are used to classify weight as: underweight, normal weight, overweight, or obese. Underweight is at or below the 2<sup>nd</sup> percentile, normal weight is between the 5<sup>th</sup> and 85<sup>th</sup> percentiles, overweight is between the 85<sup>th</sup> and 95<sup>th</sup> percentile and obese is the 95<sup>th</sup> percentile and above[20].

For all children recruited into the trial, height and weight measures were taken at school by trained researchers using standardised instruments and procedures. Height was measured to the nearest

0.1 centimetres using a Leicester height measure. Weight was measured in light clothing and no shoes to the nearest 0.1 kg using a Tanita SC-331S body composition analyser. BMI was calculated and percentile cut-off points were used to categorise the children into weight status groups.

### *CHU9D*

The CHU9D is a newly developed utility-measure initially designed for use in children aged 7-11 years[21]. Recent evidence has shown the instrument to be acceptable/feasible in children as young as 6 years[22]. The dimensions of the instrument were developed using data from qualitative interviews with children who had a variety of chronic and acute health problems. The instrument contains 9 dimensions: school work/homework; tired; sleep; worried; sad; annoyed; daily routine; ability to join in activities; and pain, and each dimension contains 5 levels indicating the severity of the dimension. Using an algorithm, each of the 1,953,125 unique health states are assigned a health utility value ranging from 0.33 to 1[23].

The CHU-9D was administered to children by researchers on a one-to-one basis. Each item was read out to the child along with the possible responses. The response given by the child was recorded by the researcher.

### *Statistical analyses*

The sample was summarised by comparing sample characteristics by weight status (normal weight, overweight, obese) using appropriate summary statistics and examining for differences using the chi-squared test for trend. CHU9D scores and domain measures of children were then compared by weight status, again using the chi-squared test for trend. Adjusted and unadjusted differences in CHU9D and domains, were evaluated for children who were overweight and obese, in comparison to the normal weight category, using logistic regression and reporting unadjusted and adjusted odds ratios. Finally, a multiple linear regression analysis was used to compare the CHU9D outcomes between the weight groups whilst controlling for the potential confounding factors of age, sex, ethnicity and deprivation quintile. The CHU9D scores of children in the obese and overweight groups were compared to the CHU9D scores of normal weight children. A *P*-value of less than 0.05 was regarded as statistically significant. The analysis of the data was done using STATA.

## Results

Table 1 shows the summary descriptive characteristics of the children measured at study baseline. We have CHU9D and weight status data for 1,357 children. Approximately half the sample are boys (52%) and the mean age is 6 years. Significantly more children in the overweight and obese category were boys (57%, P-value 0.04). Within the White and Asian group, more children were normal weight compared to overweight or obese, and in the Mixed and Black ethnic group, more children were overweight or obese compared to normal weight. Children from the most deprived quintile were significantly more likely to be recorded as overweight or obese.

**Table 1: Summary descriptive characteristics of children measured at study baseline by weight status**

	Normal weight	Overweight	Obese	P-value
Number	1,057	120	180	
Age (years), mean (SD)	6.28 (0.31)	6.26 (0.30)	6.30 (0.31)	
Males	531 (50%)	67 (56%)	104 (58%)	0.11
Ethnicity				
White	497 (48%)	59 (50%)	66 (37%)	<0.01
Mixed	65 (6%)	9 (7%)	17 (10%)	
Asian	371 (36%)	31 (27%)	64 (36%)	
Black	87 (8%)	16 (14%)	29 (16%)	
Other	18 (2%)	2 (2%)	2 (1%)	
Not known	19	3	2	
IMD Quintile				
1 Most deprived	553 (54%)	65 (57%)	121 (68%)	0.02
2	190 (19%)	23 (20%)	22 (12%)	
3	118 (12%)	12 (10%)	20 (11%)	
4	97 (10%)	5 (4%)	8 (4%)	
5 Least deprived	67 (7%)	10 (9%)	7 (4%)	
Not known	32	5	2	

\*There are 121 children in dataset with missing weight status – these are excluded from this table  
P-values are Chi-squared tests, except for ^ which is a *t*-test

The mean CHU9D scores across each of the weight categories are reported in table 2. It can be seen that there is no statistical difference in the CHU9D score between children who are classed as overweight or obese and normal weight. There are no statistical differences in the response to each of the CHU9D domains between children classed in different weight categories apart from in the

Sleep domain. Children who are overweight or obese are significantly more likely to report difficulties with sleep compared to children who are normal weight ( $p=0.02$ ).

After adjustment for age, sex, IMD quintile and ethnicity, table 3 shows that there is still no relationship between the CHU9D scores and the weight category groups when the overweight and obese groups are compared to the normal weight group. However children who are obese are 1.36 times more likely to report sleep problems than children who are normal weight ( $p = 0.08$ ), and 0.57 times more likely to report problems with school work compared to normal weight children ( $p=0.04$ ). So although being overweight does not seem to be negatively affecting the utility score, it is affecting both sleep and the ability to do home/school work.

**Table 2: CHU9D scores and domain measures of children by weight status**

	Normal weight	Overweight	Obese	P-value (test for trend)
Number*	1,022	113	175	
CHU9D	0.83 (0.14)	0.82 (0.14)	0.83 (0.13)	
Mean (SD)	0.85 [0.76, 0.93]	0.84 [0.74, 0.93]	0.84 [0.75, 0.93]	0.45
Median (IQR)				
Domains (scored 4 or 5)				
Worried	155 (14.8%)	13 (11.1%)	22 (12.3%)	0.26
Sad	154 (14.7%)	20 (16.5%)	29 (16.2%)	0.50
Pain	139 (13.3%)	12 (10.2%)	30 (16.8%)	0.37
Tired	284 (27.1%)	28 (23.9%)	43 (24.3%)	0.35
Annoyed	157 (15.0%)	18 (15.2%)	30 (16.8%)	0.56
School/homework	143 (13.8%)	21 (17.9%)	16 (9.0%)	0.21
Sleep	280 (26.7%)	39 (33.9%)	62 (35.0%)	0.02
Daily routine	118 (11.3%)	14 (11.9%)	19 (10.7%)	0.86
Activities	110 (10.5%)	13 (11.0%)	21 (11.9%)	0.59

\*This number refers to number of completed questionnaires. The questionnaires were mostly completed in full, but some children answered some but not all questions. Hence denominators for the domain sections vary slightly between domains.

**Table 3: Adjusted and unadjusted differences in CHU9D and domains by weight categories with comparison to normal weight category**

	Overweight			Obese		
	OR (95% CI)	Adjusted* OR (95% CI)	P-Value (adjusted)	OR (95% CI)	Adjusted* OR (95% CI)	P-value (adjusted)
CHU9D						
Mean	0.57 (0.14, 2.24)	0.49 (0.12,2.00)	0.32	0.96 (0.30,3.09)	1.08 (0.33, 3.57)	0.89
Domains (scored 4 or 5)						
Worried	0.74 (0.41, 1.35)	0.79 (0.43, 1.45)	0.44	0.83 (0.52, 1.34)	1.04 (0.67, 1.62)	0.26
Sad	1.16 (0.70, 1.93)	1.05 (0.61, 1.79)	0.87	1.10 (0.72, 1.69)	1.04 (0.67, 1.62)	0.85
Pain	0.71 (0.38, 1.32)	0.74 (0.39, 1.38)	0.34	1.35 (0.88, 2.08)	1.37 (0.89, 2.13)	0.16
Tired	0.86 (0.55, 1.34)	0.88 (0.56, 1.39)	0.60	0.88 (0.61, 1.27)	0.83 (0.57, 1.22)	0.35
Annoyed	1.00 (0.59, 1.69)	0.98 (0.57, 1.69)	0.95	1.14 (0.75, 1.74)	1.00 (0.64, 1.55)	0.99
School work	1.45 (0.88, 2.40)	1.43 (0.85, 2.42)	0.18	0.60 (0.35, 1.02)	0.57 (0.33, 0.98)	0.04
Sleep	1.31 (0.87, 1.96)	1.27 (0.83, 1.92)	0.27	1.40 (1.00, 1.96)	1.36 (0.97, 1.92)	0.08
Daily routine	1.07 (0.59, 1.91)	1.08 (0.59, 1.97)	0.80	0.93 (0.56, 1.55)	0.81 (0.48, 1.38)	0.44
Activities	1.03 (0.56, 1.88)	1.10 (0.60, 2.04)	0.75	1.14 (0.69, 1.86)	1.07 (0.64, 1.79)	0.78

\*Adjustment is for age, sex, IMD quintile and ethnicity

Finally the multiple linear regression (table 4) shows that weight, age, gender, ethnicity and the IMD quintile are only explaining 0.8% of the distribution of the CHU9D scores. Children who are overweight or obese have a lower CHU9D score but this effect is not significant, after controlling for other factors. There is a similar result for the ethnicity and IMD quintile variables. Children from a non-White ethnic group have a lower CHU9D score (compared to children from a White background), and children from the most deprived background also have a lower CHU9D score (compared to children from the most affluent background) but neither of these effects are significant when controlling for other factors.

**Table 4: Results of multiple linear regression to estimate variation in CHU9D between weight groups**

	<b>Mean Difference</b>	<b>95% CI</b>
Mean value *	0.746	(0.582, 0.910)
Underweight	0.033	(-0.010, 0.076)
Normal weight	-	-
Overweight	-0.044	(-0.094, 0.005)
Obese	-0.031	(-0.077, 0.016)
Age (years)	0.019	(-0.006, 0.043)
Males	-0.00	(-0.018, 0.012)
Ethnicity		
White	-	-
Mixed	-0.002	(-0.034, 0.029)
Asian	-0.018	(-0.036, 0.001)
Black	-0.008	(-0.036, 0.020)
Other	0.000	(-0.054, 0.055)
IMD Quintile		
1 Most deprived	-	-
2	0.003	(-0.019, 0.024)
3	0.029	(0.004, 0.055)
4	0.011	(-0.018, 0.040)
5 Least deprived	0.044	(0.012, 0.077)
Adjusted R-squared	0.0087	

\*Mean value represents normal male child, of white ethnicity and from the most deprived IMD quintile



## Discussion

This paper has started from the perspective that we should measure the benefit of weight-prevention interventions using QALYs. Of course, other alternative benefit measures are available, such as attaching a monetary value to outcome, but a discussion of these alternatives and a debate about which is the 'correct' approach is not the focus of this paper. What this paper is about is, if we take the view that we will use QALYs to measure the benefits of health care, then in this clinical area, what is the underlying relationship between weight and quality of life in young children, can the CHU9D measure this effect, and what do our findings mean for the practice of economic evaluation within this clinical area.

It is widely recognised that early intervention to prevent obesity is essential. Evidence shows that by targeting families and children at a young age there is real potential to change lifestyles and eating habits and for this effect to be sustained into adulthood. The study population for weight-management interventions tends to therefore be young children (and families of) and this has implications for the choice of measures for the assessment of cost-effectiveness.

Despite there being an established negative relationship between utility-based HRQL and weight in adults[24] and adolescents[25,26], using a large cohort of children aged 5-6 years, this paper has shown that children's utility values in this age group are not negatively affected from being overweight. Understanding the reasons behind this result remains a challenge because we cannot deduce from our dataset whether it is the CHU9D instrument that is failing to detect a negative association between weight and QoL, or whether there is no underlying relationship there in the first place. We suspect that it is the latter reason but we are unable to categorically say that from our data.

The association between problems with sleep and obesity is an interesting result and one that has been reported in the literature. Previous studies have found that obese children tend to sleep for a shorter duration at night and the effect of this is associated with adverse metabolic outcomes [27].

So what do these findings mean for the practice of economic evaluation of weight prevention interventions? How do we operationalise a longitudinal analysis of the cost-effectiveness of weight-prevention initiatives when the starting population is young? We know that at age 5 there is no negative effect from being overweight (certainly not in utility-terms) but at some point in the transition from age 5 to adolescence we know that weight starts to have a negative impact. What we don't know is if this is a gradual effect (sloping downward curve over time) or if it is a sudden negative effect that happens at some point in time between age 5 and adolescence.

Let's assume for discussion that we have been tasked with assessing the cost-effectiveness of a weight-prevention intervention with a starting population aged 5-6 years and we have been asked to extrapolate this model into the future. To keep the model simple, it will adopt a Markov-type structure with 4 health states: Underweight, Normal weight, Overweight and Obese. The model will have a cycle length of 1 year. Utility values (and associated distributions) are therefore required for each of these 4 health states in the model. Based on the findings of this paper we have a number of options as to how we model the utility data.

Option 1: It is conventional practice when estimating mean values (and their distributions) to pool the trial data, and where appropriate, information from other sources. At the end of the trial we will have utility data for children age 5 years (baseline) and children age 9 years (follow-up) within different weight categories. Assuming that weight is starting to have a negative impact on utility at age 9 years (although we will not know that until we have the data), we could assume a gradual reduction in utility that is age-related, so a smooth downward sloping curve with the 5-year old mean utility value and the 9-year old mean utility value as the end-points. The model could then 'look-up' the appropriate age-related utility value for each cycle of the model. Beyond the 5<sup>th</sup> cycle of the model, so for children age 10 years and over, we could assume a continuing decline in utility associated with being overweight until we reach the level of utility that adolescents have reported in the literature. Adolescent-reported levels of utility could then be used to extrapolate into adulthood.

Option 2: This option could follow the same approach as option 1 only instead of assuming a gradual decline in utility from age 5 years to age 9 years associated with being overweight we could use the actual data from the trial and assume a 'stepped' change in utility at age 9 years. This would mean that for children aged 5-8 years we assume no negative impact from being overweight. The negative impact would only start to take effect in the model at age 9 and older.

Of course what we need to bear in mind is that both option 1 and 2 above will have the overall impact of diluting the effects of interventions that target young populations as any future gains from preventing children from becoming overweight will be discounted to the present value. This runs counter to the evidence in the public health literature that the earlier we intervene to change lifestyle behaviours, the more effective and sustainable the outcome. There are many interventions

currently being assessed in trial settings that are targeting children as young as 2 years. So that leaves us with option 3 to consider.

Option 3: If we know that weight has no impact at age 5 but has some impact at age 9 then we could impose our own judgement that 5-year olds are just not in a position to judge their own health state. This is because they do not have the maturity and self-awareness to judge the true effects of being overweight. We could therefore assume the 9-year old utility value for all 5-8 years olds and model accordingly. We could also take this option one step further and use the adolescent utility values for the children aged 5-9 years as we know with certainty that eventually the children will end up having these values as they become more mature. Clearly this option goes against all the principles of why we should measure utility values children separately to adults in the first place but in the unique situation where we have a condition that has an increasing effect as one ages then perhaps this is the 'appropriate' approach to take from a modelling perspective.

To see the impact of all 3 options above then we could explore them as part of a sensitivity analysis but a decision still has to be made as to which option to adopt for the base case analysis.

It is worth recognising that there are alternative means to eliciting utility values (although some of these may not be feasible within a childhood population). One alternative is to use descriptions of health states (vignettes) and have these valued using an established valuation method such as the standard gamble or the time trade off approach. It is unlikely that this direct approach would involve children. Alternatively a condition-specific instrument can be used which can then be mapped on to a utility scale. Condition-specific instruments focus on the specific problems of being overweight and although these methods are feasible they will tend to focus children towards the problems of being overweight and not on aspects of their life that are not affected (such as daily routine). It also does not help decision makers who are after a consistent use of methodology to enable them to make resource allocation decisions using consistent explicit criteria. The merits of using condition-specific versus generic instruments have been well documented in the literature and the focus of this paper is not about reporting yet another example of where the generic preference-based measure might be accused of lacking sensitivity. What this paper is highlighting is that obesity is slightly unique as we seem to be witnessing a changing relationship between utility and weight over time so a *within* individual change as the child grows older. The chosen time points for data

collection is therefore an important issue and is particularly pertinent to decision-analytic modelling that is extrapolating trial data into the future.

For decision makers to appraise the cost-effectiveness of interventions across different disease areas, consistency in methods is important. There does seem to be an agreement that child health needs to be conceptualised differently to adult health but there currently exists no guidelines for the practice of economic evaluation in children. NICE have produced reports for the methods of technology appraisal that had no mention of children in the 2004 report and limited reference to children in the 2008 guidance. We have shown in this paper that there are conceptual issues that need further consideration when modelling the long term cost-effectiveness of obesity prevention interventions that target young children.

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