WHO European Childhood Obesity Surveillance Initiative COSI & COVID-19 Survey

Impact of the COVID-19 pandemic on the daily routine and behaviors of school aged children in Europe

STUDY PROTOCOL

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1. Background

Childhood obesity is an important public health problem in the WHO European Region: for this reason, is the greatest challenge of the 21st century (1). In recent years, indeed, it seems to be plateauing in some countries, albeit at high levels, in an endemic and epidemic way (2,3,4). Childhood obesity significantly compromises the person's future development. As the values increase, they cause a wide range of serious health and social consequences. In adults, obesity increases the likelihood of morbidity in such as dyslipidemia, hyperinsulinemia, hypertension and early atherosclerosis, as well as mortality (5,6). The health consequences of overweight for children during childhood are less clear, but strongly associated with risk factors for cardiovascular disease, type 2 diabetes, orthopaedic and musculoskeletal problems and mental disorders (7). Furthermore, scientific literature shows that childhood overweight and obesity might represent a social burden in terms of lower school attendance, poorer school performance, and an increased probability of having a low-income job (8). From a lifecourse perspective (9, 10), all events during childhood and adolescence have effect on the physical, but also the cognitive and social health of an individual in the future. Furthermore, approximately more than a third of children and about half of adolescents with obesity will likely continue to live with obesity through adulthood (11).

The programs of primary prevention (adoption of interventions and behaviours), secondary (diagnosis, treatment) and tertiary (management and prevention even in the long term) are recognized as the only feasible option for curbing the epidemic, since current therapeutic practices largely aim to bring the problem under control rather than providing a cure (12).

The reasons for childhood overweight and obesity are complex and multifactorial (13): the child's personal characteristics and individual risk factors are nested within the family context, incorporating parenting style and other family characteristics but also within the community and the wider social context (14, 15).

The year of 2020 was hit by a global pandemic caused by a new coronavirus (SARS-Cov2), with rapid human-to-human transmission. Each government was faced with an unprecedent challenge of the COVID-19 disease, that affected the economy, health, social and at individual level a complete shift within family's daily lifestyles.

One of the most frequently government-mandated strategies, to slow down and reduce the spread of this virus, included physical distancing restrictions through mandatory lockdown period(s), which led to a constraint people's mobility forcing families to stay at their homes for a long period of time. Particularly in children, the lockdown complete modified their lifestyle with homeschooling, stress to cope with the situation, and lack of structured activities and social interactions (16,17).

Hereditary, environmental, metabolic, behavioral, mental, cultural, and socioeconomic factors (together with having a family history of obesity) all together not only play a role in the development of obesity (18) but these factors have currently been exacerbated by the Covid-19 pandemic. Previous and recent studies underline that the containment measures and the face-to-face interruptions of the school program led to a decrease in children's physical activity, longer screen time, changes in sleep patterns and food intake (19-21) - with higher intakes of

comfort food and food high in fat and sugar - and increased sedentary lifestyle, mental health problems and social inequalities (22-26).

The World Health Organization European Childhood Obesity Surveillance System (COSI/WHO Europe) is a continuous and systematic process of collecting, analyzing, interpreting, and disseminating descriptive information for monitoring excess body weight in the WHO European Region (27).

The aim of the system is to measure routinely trends in overweight and obesity in primary schoolchildren, in order to form a correct understanding of the epidemic in this population group and to permit intercountry comparisons within the European Region.

Although each country is free to find a system suitable to its circumstances, it is imperative that data be collected according to an agreed, common protocol and that they include the stipulated core items. The system is designed to be as simple as possible and should not demand a major investment of public resources. There is no intention to replace health, anthropometric and dietary surveillance systems that are already in place or planned; on the contrary, the system should be integrated within them, if possible.

In this system, each country is responsible for collecting data relating to its capital and identifying an institution responsible for overall coordination. WHO is responsible for protocol development, international coordination of the surveillance initiative, data analysis and facilitation of investigator meetings. Each participating country signs a collaboration agreement with WHO, stating that a copy of the clean data file will be sent to the WHO Regional Office along with a detailed report of the data cleansing procedures.

In addition to the WHO/Europe COSI and within its system and network, the WHO European Office for the Prevention and Control of NCDs aims to develop the study "Impact of the COVID-19 pandemic on the daily routine and behaviours of school aged children in Europe" during the school year 2021/2022. This study aims to understand the effect of the COVID-19 pandemic situation on children's daily routines, wellbeing, eating habits, behaviors, physical activity and perception of the nutritional status of school-aged children in participating WHO European Region COSI countries.

2. Schedule

The estimated total time frame for the data collection is approximately six months, during one school year targeting one age group (Table 2). This is only an indication and may need to be adjusted to local circumstances, seasonal considerations and countries' ability to provide staff for the study.

Table 2. Schedule for a data collection round

Activity	Month						
Activity	1	2	3	4	5	6	
Establish the Country Coordination Team	Х						
Select the sample frame	Х						
Make agreements with the sampled schools	Х	Х					
Obtain ethical approval	Х	Х					
Print and translate form(s) and instructions for their administration	Х						
Organize an information event for teachers (and parents) of the selected classes	Х						
Approach the parents of the pupils in the selected classes	Х	Х					
Obtain informed consent from parents	Х	Х					
Schedule data collection in the schools	Х	Х					
Recruit examiners, data clerks and data managers	Х						
Train examiners in administering the form (if applicable)		Х					
Train data entry clerks and data manager on data management		Х					
Data collection			Х	Х			
Data entry, cleaning and validation			Х	Х	Х		
Produce detailed report on data cleaning procedures					Х		
If data is not entered online in the OpenClinica and/or LimeSurvey							
databases, send final cleaned data file along with the report on data cleaning procedures to the Regional Office					Х		
Conduct national data analyses					Х	Х	
Produce country report						Х	

3. Study design and sample

3.1 Study design, site and setting

The study aims to collect comparable, valid and reliable data on impact of the COVID-19 pandemic on the daily routine and behaviours of primary school aged children (6.0-9.9 years) in countries in Europe and in the capital cities of a select group of countries, following the COSI approach.

The COSI surveillance system targets primary school-age children, the group that is most sensitive to environmental influences and is showing the greatest increase in incidence of

overweight and obesity (reaching as high as 2.0 percentage points in some countries by the 2000s (28). Education is compulsory in all countries in the European Region and thus most children should be reachable through the education system.

Thus, primary schools are the setting of enrolment: these schools are the settings through which children will be selected to participate in the study and the place where children will be measured and data will be collected.

A cross-sectional design based on a sample of children who represent the target population is applied.

3.2 Study population and subjects

The target population consists of children who are enrolled in the primary schools of the European countries that participate in the study. In particular, the study targets the primary school grades that are mostly attended by children aged 6.0-9.9 years. Countries have the flexibility to collect data across these primary school grades and thus the option of targeting one or more grades. Countries that have participated in one or more rounds of COSI data collection are suggested to select the same school grades that were included in COSI. In general, the study covers the whole national territory of the participating countries. Nevertheless, if this approach is not feasible due to financial or operational constrains, a country can opt for reducing the coverage to a part of the national territory, such as one or more specific regions or the capital city.

3.3 Sampling design

If a country decides to implement the study together with the 6th round of the COSI/WHO Europe (see paragraph 4.4), in the 2021/2021 school year, the sample design will be decided following the COSI Protocol. The parents/care givers of children selected to participate in the 6th round of COSI will be invited to answer the COSI-COVID questions.

The rest of the paragraph illustrates the sampling design that a country should adopt <u>if the study</u> is implemented separately from the 6th round of the COSI/WHO Europe.

In this context, a two-stage cluster sampling design should be used with primary schools acting as primary sampling units and classes as secondary units. Once a country has decided which grades they want to target, the process of selecting the children will be the following: i) a random sample of primary schools is selected from the complete and most updated list of primary schools that is available for the territory covered by the study; ii) in each selected school, two classes are randomly selected, and iii) all children enrolled in these classes are invited to participate in the study. As this sampling design has been largely used within COSI, countries can decide to include in the study the sample of schools which was drawn for the last round of COSI data collection (i.e. COSI round 5). In each school belonging to COSI round 5 sample, a new sample of classes/children will be selected following the above-described steps ii) and iii).

Countries can also opt for a cluster sampling design with targeted primary school grades acting as sampling units. In this case, the classes will be randomly selected from the most updated list of all classes that belong to the targeted grade(s) in the territory covered by the study.

A stratification of primary sampling units – i.e. primary schools or classes – by territorial divisions or socio-economic levels of the area where the school is located will be applied where possible.

Countries may also opt for the inclusion of all children of interest in the respective primary school grades in a country.

3.4 Sample size

This paragraph illustrates the sample size when the study is implemented separately from the 6th round of the COSI/WHO Europe.

If a country wants to be able to calculate national representative estimates, the suggested final effective sample size (i.e., the number of children whose parents/care givers filled out the questionnaire) for each school grade is 2,800 pupils. This sample size allows for an absolute margin of error equal to 0.03 maximum for a proportion of 0.50 - given a 95% confidence interval level and a design effect equal to 2.5. A design effect greater than 1 was chosen to consider the cluster nature of data since children are selected through schools/classes.

Oversampling is necessary to meet the above-mentioned final effective sample, since not all parents/care givers of the selected children will fill out the questionnaire. The extent of oversampling could vary among countries depending on the expected level of participation in the study. The proportion of parents/care givers who will participate could be estimated based on the experience within COSI (if any) and considering other similar studies carried out in the country. Particular attention should be paid to not underestimate the level of parents' participation, especially if the country opts for collecting data through an online questionnaire and has never gathered COSI data in this way before. As a general rule/indication, if we assume that 90% of children will participate in the study, the final sample size should be increased to around 3,100 (and to 3,500 and 4,000 with a participation proportion equal to 80 and 70% respectively).

Due to financial or operational constrains, the effective sample size can be reduced up to 1,600 pupils. This minimum value of the sample size allows a 0.04 margin of error around a proportion of 0.50 under the above-mentioned conditions.

The number of schools to be selected in order to reach the desired sample size can be estimated considering the average class size in the targeted grade(s). For example, if we consider a class average of 20 pupils, the selection of around 88 schools will achieve the final desired sample size of 3,500 children (20 pupils times 2 classes per school times 88 schools).

If a country wants to include just a part of the national territory, the effective sample size should be recalculated considering the real size of the targeted population. More specifically, the possibility/opportunity of reducing the sample size while maintaining a level of precision like the one established in case of national coverage of the study should be assessed.

If a country wants to cover the national territory but wishes to produce estimates at sub-national level, the effective sample size should be increased. The extent of this increase will mainly depend on the number of sub-national entities for which the country wants to produce estimates and on the desired level of precision of these estimates.

4. Data collection

4.1 COSI &COVID-19 Survey Family record form

Information on children's behaviours regarding physical activity/inactivity, eating habits, behaviors daily routines, wellbeing, and family's background during the COVID-19 pandemic confinement periods, will be collected through the COSI & COVID Survey family record form (CC Family Form) which will be completed by the parents or caregivers.

This CC Family Form can be attached to the letter that is given to the parents to inform them about this initiative and ask for their consent. The country may also choose to use the online program called *LimeSurvey*, set up for completing this CC Family Form.

The CC Family form includes mostly closed questions with pre-coded answers (if applicable) and are kept as short as possible to improve responsiveness and sample retention. The form include mandatory questions, which are marked by M or C (e.g. M1, or C2), and voluntary questions marked by O (e.g. O1, or O2), which countries can decide to use or not. A brief description of the CC Family form is provided below; and the form attached in Annex 1.

4.2 Child identification code

Child identification code. This is a code that univocally identifies each child involved in the study and should be pre-entered before data collection. The code is composed by the following information/codes.

Co	untr	У	Ye	ar	School code		Grade	Class code	Child's code		

Country code. The country code must be entered into the designated boxes on all pages of the record form. The three-letter country codes of Member States of the WHO European Region are listed in section 4.3. (e.g. POR, for Portugal)

Year of data collection. The year is designated by the last two digits (e.g. 21, for 2021).

School code. This is the numerical code assigned to each school included in the survey. The code is composed of four digits and must be entered into the designated boxes on all pages of the examiner's record form. For example, school code 1 is entered as "0001", school code 10 is

entered as "0010", school code 100 is entered as "0100", school code number 1000 is entered as "1000", and so on.

Grade. The grade should be obtained from the school register and be entered numerically. (e.g. 01, 02,03,04 for grade 1,2,3 or 4, respectively)

Class code. This is a numerical code assigned to each class included in the survey. The code is composed of one digit and must be entered into the designated boxes on all pages of record form. Classes belonging to the same school should be coded numerically with one digit starting with 1, even though, in some schools, classes are designated by letters.

Child code. This is a two-digit code assigned to each child invited to participate in the survey, even to those children who refuse to participate in the study. The code must be assigned class by class and its format may differ by country.

4.3 Country codes of Member States of the WHO European Region

Country name	Country code	Country name	Country code		
Albania	ALB	Lithuania	LTU		
Andorra	AND	Luxembourg	LUX		
Armenia	ARM	Malta	MAT		
Austria	AUT	Monaco	MON		
Azerbaijan	AZE	Montenegro	MNE		
Belarus	BLR	Netherlands	NET		
Belgium	BEL	Norway	NOR		
Bosnia and Herzegovina	BIH	Poland	POL		
Bulgaria	BUL	Portugal	POR		
Croatia	CRO	Republic of Moldova	MDA		
Cyprus	CYP	Romania	ROM		
Czechia	CZH	Russian Federation	RUS		
Denmark	DEN	San Marino	SMR		
Estonia	EST	Serbia	SRB		
Finland	FIN	Slovakia	SVK		
France	FRA	Slovenia	SVN		
Georgia	GEO	Spain	SPA		
Germany	GER	Sweden	SWE		
Greece	GRE	Switzerland	SWI		
Hungary	HUN	Tajikistan	TJK		
Iceland	ICE	North Macedonia	MKD		
Ireland	IRE	Turkey	TUR		
Israel	ISR	Turkmenistan	TKM		
Italy	ITA	Ukraine	UKR		
Kazakhstan	KAZ	United Kingdom	UNK		
Kyrgyzstan	KGZ	Uzbekistan	UZB		
Latvia	LVA				

4.4 Guidance for administration of COSI &COVID-19 Family record form

The country can decide to adopt the CC Family Form separately or within the 6th round of the COSI/WHO Europe, in the 2021/2022 school year. In case of the latter, the questions of the CC

Family Form will be added at the end of the COSI Family Form (please check updated WHO/COSI Manual of data collection procedures). Nevertheless, if the country wish to adopt the CC Family Form separately, it is free to use any of the questions from the COSI Family Form, in addition.

The CC Family Form provides Information on children's behaviours regarding physical activity/inactivity, eating habits, behaviours daily routines, wellbeing, and family's background during the COVID-19 pandemic periods. This record form is completed by parents or caregivers, possibly with their child.

In the CC Family form, parents have to indicate in question C1 which times the schools were closed due to the pandemic. If your country <u>did not have any school closure due to the pandemic</u>, please adapt question C1 by defining COVID-19 Pandemic period as the period during which the country underwent the severest level of restriction, the country/regions were classified as 'red zone area' etc.

Completion of the family record form is voluntary, however some of the questions are mandatory.

The CC family form can be delivered and completed in paper format and/or completed online, in the *LimeSurvey* programme, in the country's national language or families can choose a preferred language for multilingual countries. In either case, countries should provide a translation of the CC family form into the national and/or other language(s) to the WHO NCDs Office.

The child's identification code should be pre-entered on the form; if the parents choose to fill in the family record form online, the country may use this code or add pre-printed stickers with a code sent by the developer to be used by the parent or caregiver to log-in to the *LimeSurvey*. This code corresponds to the code generated in *Open Clinica* and will allow linkage of the family record form to the corresponding child record form.

4.5 Parents' informed consent form

If the country decides to adopt the CC Family form within the 6th round of the COSI/WHO Europe, in the 2021/2021 school year, it should follow the instructions on the updated WHO/COSI Manual of data collection procedures, regarding parent's informed consent form (passive or active approach) (37).

This is an example letter that is given to the parents to inform them about this initiative and ask for their consent and should be adapted to each country's situation as necessary, applicable and appropriate.

Dear Parent/Guardian parent or guardian,

This questionnaire has been sent to you from theinsert coordinating institute....... which is working with the World Health Organization Regional Office for Europe in the "European Childhood Surveillance Initiative" (COSI/WHO).

We are aware that these are challenging times, especially for parents. COVID-19 has changed our lives completely. Within the scope of tackling Childhood, the study "Impact of the COVID-19 pandemic on the daily routine and behaviors of school aged children in Europe" is being developed within the scope of COSI/WHO, during the scholar year 2021/2022 which aims to know and understand the impact of the COVID-19 pandemic situation on daily routines, wellbeing, eating habits and behaviors, physical activity and perception of the nutritional status of school aged children in Europe.

This study is also taking place in other European countries. The [name of coordinating institute], jointly with the World Health Organization Regional Office for Europe, will analyse the data collected in all [insert number] participating schools.

We are seeking your permission to participate in this study and transfer the data to the national database of [name of coordinating institute] and the international database of the World Health Organization for this purpose. The information will be used to develop better health programmes for children like yours

The information provided is confidential and will not be disclosed to anyone. It will be made anonymous and will be used only for research and monitoring. The Principal Investigator, [insert name], will be available to listen to any concern you may have.

Much as we hope that you decide to participate, you are free to withdraw from the project at any time.

COSI & COVID 19 Survey Parent's Consent					
I, Miss/Ms/Mrs/Mr/Dr having read and understood the objectives of the study "Impact of the COVID-19 pandemic on the daily routine and behaviours of school aged children in Europe" wish/do not wish to participate in this study, being aware that data is to be used for further analysis by the [name of coordinating institute] and the World Health Organization Regional Office for Europe.					
(If applicable) I do not give consent because (please give	the reason)				
Signature					
Date:					

Child's name	
Child's date of birth	
Child's class grade	
Email	address:

5. Ethical considerations

WHO COSI study is implemented in accordance with the International Ethical Guidelines for Biomedical Research Involving Human Subjects (38), thus ethical protocols should follow WHO Guidelines (ref who Protocol). For this study and depending on local circumstances, ethical permission should be requested from relevant ethical committees.

Parents are fully informed about the study procedures and data treatment and their informed consent (written in local language) obtained on a voluntary basis. This is done either through a letter or through a school information meeting. The objectives of the study and data treatment are explained. Depending on local legal circumstances, countries have the option of choosing passive or active informed consent. The approach that would provide the highest response rate is to be preferred. In exceptional circumstances, there may be no need to obtain informed consent from the parents.

Confidentiality of all collected and archived data is ensured. Identification numbers are assigned to the children and each register mentions only those numbers. Only one person in the school has a full list of identification numbers and the corresponding names and addresses of the children sampled. No information on the subjects is given to outside people. Forms are stored in safes at the national coordinating centre.

The children's names are not included in the electronic data files.

School-specific results are not provided to the schools.

6. Data management

6.1 Data processing

After the completion of data collection of the CC Family record form, this should be forwarded to the national coordinating centre for processing.

The data are entered to either *Open Clinica* system or another system of the country's choice.

Country teams are responsible for entering data collected on the paper forms and/or in an electronic system and for archiving the paper forms. The data entry system has been developed

for the purpose of the study by WHO and participating countries will be provided free access to it. The system is web-based, ensures that access to the data is regulated with secure account-management and keeps a full audit trail of all changes. Moreover, it automatically runs data checking procedures for out of range values, format and inconsistencies and data can be extracted at any time. The training materials and tests are available in separate manuals.

The data manager is responsible for archiving the forms as well as the data cleaning, validation and back-up. If a country does not use the online system (ie, *Open Clinica* and/or *Lime survey*), the country sends a copy of the cleaned data file to the Regional Office, along with a detailed report of the data cleaning procedures.

Common data checking procedures will be carried out both at the country and European level in order to validate the datasets. Furthermore, data analysis will be implemented at both levels.

6.2 Data quality control

Data quality assurance begins with the supervisor/examiner checking the returned forms for completeness and correct coding, or in case the country chooses to use Open Clinica data entry system, built-in range and consistency checks for validation purposes are already incorporated in the system. Additional checks for inconsistencies and incompleteness are made, as well as data cleaning, validation (e.g. checking for outliers, data entry errors and out-of-range values) and back-up by the data manager, at the country level. A manual reporting the guidelines on data processing and cleaning is prepared by WHO and will be shared with country teams.

Once the data quality control is completed at country level, the child, family and school datasets will be sent to WHO Regional Office where they are reviewed in a standard manner before being merged in pooled datasets for intercountry analyses.

Based on validated pooled datasets, country-specific sampling weights are calculated to infer results from the sample to the target population. To this extent, firstly the design weights are calculated considering the probability of inclusion of sampling units at each stage, then a procedure of adjustment is applied to correct the sample selection bias and the total non-response bias.

6.3 Data analysis

Data are analysed both at the country level and at the European level (common cross-country analyses of the pooled dataset). All analyses are carried out by a common statistical package such as Stata (StataCorp LP, Texas, USA) or SPSS (SPSS Inc., Chicago, USA).

Findings will be produced and reported only at the country level and through a weighted data analysis.

Each country is asked to sign a collaboration arrangement with WHO, in which it declares that a copy of the cleaned data file will be sent to the Regional Office and that it will comply with the data copyright policies and procedures.

6.4 Data reporting

A report of the main results will be produced including all countries that participated in the study. Other options for disseminating the outcomes of the study may be publications in peerreviewed scientific journals. Inter-country publications will have to be agreed by the Surveillance Initiative Investigators Team. Vice versa, each country is free to decide how and when disseminating the results based on its own data.

A detailed publication and presentation policy for the dissemination of the results is included in the collaboration arrangement between WHO and the participating countries.

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