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Impact assessment of a raw coal ban on maternal and child health outcomes in Ulaanbaatar: a protocol for an interrupted time series study

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ABSTRACT

Introduction Despite a decade of policy actions, Ulaanbaatar's residents continue to be exposed to extreme levels of air pollution, a major public health concern, especially for vulnerable populations such as pregnant women and children. In May 2019, the Mongolian government implemented a raw coal ban (RCB), prohibiting distribution and use of raw coal in households and small businesses in Ulaanbaatar. Here, we present the protocol for an interrupted time series (ITS; a strong quasi-experimental study design for public health interventions) that aims to assess the effectiveness of this coal ban policy on environmental (air quality) and health (maternal and child) outcomes.

Methods and analysis Routinely collected data on pregnancy and child respiratory health outcomes between 2016 and 2022 in Ulaanbaatar will be collected retrospectively from the four main hospitals providing maternal and/or paediatric care as well as the National Statistics Office. Hospital admissions data for childhood diarrhoea, an unrelated outcome to air pollution exposure, will be collected to control for unknown or unmeasured coinciding events. Retrospective air pollution data will be collected from the district weather stations and the US Embassy. An ITS analysis will be conducted to determine the RCB intervention impact on these outcomes. Prior to the ITS, we have proposed an impact model based on a framework of five key factors, which were identified through literature search and qualitative research to potentially influence the intervention impact assessment.

Ethics and dissemination Ethical approval has been obtained via the Ministry of Health, Mongolia (No.445) and University of Birmingham (ERN_21-1403). To inform relevant stakeholders of our findings, key results will be disseminated on both (inter)national and population levels through publications, scientific conferences and community briefings. These findings are aimed to provide evidence for decision-making in coal pollution mitigation strategies in Mongolia and similar settings throughout the world.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Assessment of a city-wide air pollution intervention impact using a highly regarded interrupted time series analysis.
⇒ Assessment of Ulaanbaatar-wide data for multiple outcomes set over multiple years.
⇒ Use of an evidence-based five factor framework to form a proposed impact model prior to the interrupted time series analysis.
⇒ Lack of a representative control group will limit ability to control for unknown or unmeasured confounders, for which the use of a health outcome, unaffected by the intervention, has been chosen as an alternative.

INTRODUCTION

Ambient and household air pollution exposure is responsible for more than 7 million premature global deaths annually, with many more suffering from long-lasting adverse health effects.[1] In the past decade, there has been increased focus on identifying pollution sources, mitigation strategies and the aetiology by which air pollution harms health. Pregnant women and children are particularly susceptible to the harmful impacts of poor air quality.[2] Exposure to high levels of air pollutants such as fine particulate matter (PM) and nitric oxide (NO) during pregnancy has been associated with increased risks of maternal hypertensive disorders, including pre-eclampsia and gestational hypertension.[3] Development of such hypertensive disorders, in turn, is linked to an increased risk of adverse pregnancy outcomes, such as preterm birth.[4] Furthermore, exposure to air pollutants during pregnancy is consistently linked to adverse perinatal health outcomes ranging from low birth weight, stillbirth, intrauterine growth retardation and even mortality.[2 4 5]

Early life health events linked to air pollution exposure include increased risks of acute lower respiratory infection and asthma, impaired neurodevelopment and all-cause mortality.[6–8] The harmful effects from exposure to high levels of air pollution are, therefore, likely to have an effect throughout the life course, which in turn can limit a population's ability to thrive and prosper and thus leading to rising opportunity costs, an intergenerational impediment and a vicious circle of social deprivation, economic and health inequity.[9]

While solutions to reduce air pollution emissions and exposure, such as shifts to cleaner fuels and protecting citizens from harmful exposure sources, seem straightforward, such initiatives face many implementation barriers and realisation and longevity of such initiatives are heavily dependent on end user acceptability and needs.[10 11]

Study setting

Mongolia's capital, Ulaanbaatar, is recognised for its dangerously high levels of seasonal winter ambient air pollution, with annual average $PM_{2.5}$ concentrations of 75 µg/m^3 exceeding the WHO health-based Global air Quality Guidelines of 5 µg/m^3 by 15 times.[6] A steady increase in rural-to-urban migration since Mongolia's independence in 1990, combined with shortcomings in urban planning and an economic crisis has led to Ulaanbaatar's urban air pollution challenges: due to lack of affordable housing and lack of jobs, rural migrants have been settling within the expanding 'Ger Districts' surrounding the city. Originally containing mainly traditional Mongolian ger tents, households in these districts often lack basic infrastructure such as water or electricity supplies, and have been relying on coal-fuelled stoves for cooking and heating during the harsh winters in which temperatures often dip as low as −30°C.[12 13] Residential solid fuel combustion in these households (Gers or basic cement houses) has been identified as the main source of Ulaanbaatar's high air pollution levels, followed by power plants and road traffic.[14]

The Ulaanbaatar raw coal ban

Despite a decade of multidisciplinary air pollution mitigation strategies, including introducing subsidised improved stoves and discounted night-time electricity tariffs, in winter Ulaanbaatar's residents continue to be exposed to dangerous levels of air pollutants associated with coal combustion such as PM and sulphur dioxide (SO_2), and therefore, at risk of adverse health effects.[15 16]

Consequently, on 15 May 2019, the Government of Mongolia (GoM) implemented a ban on raw coal distribution and consumption in households and businesses, as a short-term to medium-term solution to its ongoing air pollution crisis. As an alternative, the GoM introduced refined coal briquettes at a subsidised price and heavily invested in its production and distribution. While no official preinvestigations have been published, this raw coal ban (RCB) aimed to decrease Ulaanbaatar's air pollution by 50%.[17] Independently assessing health and air quality trends before and after implementation of the RCB will enable an accurate determination of its impacts using a natural experimental approach. Due to high turnover in governmental positions within the Mongolian political system, accompanied by changes in political priorities, providing clear and independent evidence-based information can be crucial for achieving sustained effectiveness of this air pollution mitigation policy.[18]

Public dissemination of this evidence can in turn be useful to reduce public misinformation on coal reduction strategies, improve its adoption and to inform air quality interventions in similar settings throughout the world.

Aims and objectives

The aim of this study is to assess the impact of the RCB on air quality and maternal and child health outcomes in Ulaanbaatar, Mongolia. Specific objectives to achieve this aim are to determine the impact of the RCB implementation on:

a. Air quality.
b. Related maternal health outcomes.
c. Related child health outcomes.

Our hypothesis is that successful implementation and adoption of the RCB may have significant environmental and health benefits, which can be reflected in decreased concentrations of both ambient and indoor air pollutants. Consequently, this can lead to a reduction in air pollution exposure and related adverse child and maternal health events.

This paper aims to outline the protocol of proposed interrupted time series (ITS) study, to give insights on the study characteristics and predefine statistical methods, which are thought to be crucial for future interpretation of study findings.[19]

METHODS

Study design

A non-randomised quasi-experimental ITS study design will be used for the assessment of the impacts of the RCB intervention.

Data sources

Setting

Ulaanbaatar has over 1.6 million inhabitants, more than half of whom are estimated to live in the Ger districts surrounding the city centre.[20]

With maternal and child healthcare being fully publicly funded by the state, there is relatively barrier-free and equal access to perinatal and child care within the Ulaanbaatar population, reflected by comparable distributions of prenatal care attendance between the patient population living in the capital as well as surrounding districts.[21] All levels of care are accessible through self-referral. Little over 10% of the capital's inhabitants are aged under 5 years and care for the paediatric population primarily provided in family health centre setting or secondary district hospitals.[22] More specialised paediatric care is

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provided in the tertiary paediatric hospital (National Centre for Maternal and Child Health, NCMCH) located in on the border of the city centre.

Prenatal care is predominately covered by family health practitioners (50%), obstetricians (44%) or midwives (1.5%). Each year, there are approximately 40 000 births of which over 95% are delivered in the 4 main maternity hospitals. The remainder of pregnant women give birth in private hospitals (2%), outside of the capital (2%) or to a lesser extent at home (0.2%).[21]

Study population

Pregnant women, infants and children under the age of 5 who have been living and receiving healthcare between 15 May 2016 and 15 May 2022 in Ulaanbaatar will be included in this study. Data on the health outcomes will be collected from routine birth records from the three main public maternity hospitals (First Maternity Hospital Urguu, Second Maternity Hospital Khuree and Third Maternity Hospital Amgalan), the NCMCH and the National Statistics Office (NSO) of Mongolia. Due to the high rate of hospital births (90%) and newborns receiving postnatal care (98%), it is assumed that nearly all births occurring in Ulaanbaatar will be captured.[23] From these birth records, we will calculate weekly incidence rates per health outcome over the duration of our study period. Due to low rates of our selected outcomes, a range of 6 years of data will be collected, equally spanning 3 years before and after the RCB was implemented (May 2019) to increase power.[24] As a result, this study will have 312 time points (156 before and after the intervention). Given Ulaanbaatar's annual birth rate of 40 000, it is estimated that data of at least 240 000 birth outcomes (mother and child) will be assessed during this 6-year period. Expected weekly counts for key pregnancy outcomes such as low birth weight (4.5% of births), pre-eclampsia (4.1% of pregnancies) and spontaneous abortion (5% of pregnancies) in Ulaanbaatar are 35, 32 and 38, respectively, based on country-specific data.[25–27] Furthermore, considering the introduction of the pneumococcal vaccine in July 2016, historic data on seasonal pneumonia patterns in Mongolia and the latest Mongolian Multiple Indicator Cluster Survey data on child acute respiratory infection presentation, it is estimated that child under 5 respiratory admission rates will range between 2% and 10% for the summer and winter months, respectively.[21 28 29]

Air quality assessment

As a measure of Ulaanbaatar's air quality over the study period, routinely collected air pollution measurements of $PM_{2.5}$, PM_{10}, carbon monoxide, SO_2, NOx and ozone concentrations (µg/m^3) will be obtained from the 17 air quality monitoring stations run by the GoM as well as one US Embassy air measurement station in Ulaanbaatar. Air quality measurements from these monitoring stations will be aggregated, followed by assessment of mean weekly values. In addition, routinely collected mean daily temperature (°C) and relative humidity (%) measurements will be obtained from Ulaanbaatar Buyant-Ukhaa International Airport and will be included in the analysis as potential confounders.

Outcome measures

The routinely recorded maternal and child health outcomes have been divided into composite outcome groups as shown in table 1. The selection of adverse health outcomes for pregnancy, infancy and children under 5 years old has been based on their association with exposure to air pollution, as discussed further in the first section of the online supplemental materials. Admissions due to child diarrhoea, which is thought to be unaffected by air pollution exposure, has been included to serve as a control outcome measure. Patient characteristics such as maternal age gravidity/parity, known comorbidities and district of residence will be collected to characterise our population.

Research procedure

Data collection

Data from 36 months before and after the introduction of the RCB (5 May 2016 until 15 May 2022) will be collected for this study by trained fieldworkers who are selected for their knowledge and work in the relevant fields (figure 1). Prior to commencing data collection, a pilot session will be undertaken by each fieldworker to assess and ensure accuracy of collected data.

Health outcomes will be manually extracted from the health records held in the archives of the participating hospitals. An electronic health data sheet containing sections on health outcomes stated in table 1 and patient characteristics, such as residence district, existing comorbidities, gravidity/parity and date of delivery, will be used to collect the data.

Health data sheets from each fieldworker will be collated in an encrypted online folder, which will be assessed on a weekly basis for completeness of data. Health outcome data that are readily available at the NSO will be included in a separate encrypted online folder. District-level air quality data will be linked to the health outcomes per district of residence to assess impact of ambient air pollution exposures in a separate, subsequent study. Preliminary analyses will be conducted as per methods stated below on a quarterly basis throughout the data collection period. Full data analysis will be conducted once data collection is completed.

Analysis

Impact model

When using an ITS design, it is good practice to propose an impact model prior to data collection and analysis. Such impact model can demonstrate the assumed effect of the intervention. To accurately determine this assumed impact, five key factors which could influence the impact model and our subsequent assessment of the RCB were identified through literature and qualitative research. These key factors have been graphically depicted in a

Table 1 Maternal and child health outcome measures, definition and data sources

Outcome group	Outcomes	Definition	Data source
One - maternal morbidity	Maternal hypertensive disorders (pre-eclampsia, eclampsia, gestational hypertension)	Hypertensive diseases occurring during pregnancy	Maternity hospitals (1–3), NCMCH
	Gestational diabetes	Diabetes occurring during pregnancy	Maternity hospitals (1–3), NCMCH
Two - perinatal morbidity	Preterm birth	Birth before 37 weeks of gestation	Maternity hospitals (1–3), NCMCH, NSO
	Low birth weight	Neonatal weight <2500 g, regardless of gestational age	Maternity hospitals (1–3), NCMCH, NSO
	Small for gestational age	Neonate weighing <10th percentile of gestational age	Maternity hospitals (1–3), NCMCH, NSO
Three - perinatal mortality	Spontaneous abortion	Fetal death before 20 weeks gestation	Maternity hospitals (1–3), NCMCH, NSO
	Stillbirth	Fetal death after 20 weeks of gestation	Maternity hospitals (1–3), NCMCH
	Neonatal deaths (+age)	Newborn death within 28 days after birth	NCMCH, NSO
Four - child morbidity	Respiratory illnesses requiring hospital admission (pneumonia, bronchitis, bronchiolitis, asthma exacerbation, pulmonary tuberculosis)	Pneumonia—infection of the lung parenchyma Bronchitis—inflammation of the bronchi Bronchiolitis—inflammation of the bronchioles Asthma exacerbation—episode of progressive increased asthma symptoms with decreased expiratory airflow Pulmonary tuberculosis—infection of the lung caused by m. Tuberculosis	NCMCH, NSO
	PICU/NICU admissions	Paediatric intensive care unit (6 months to 17 years) Neonatal intensive care unit (0–6 months)	NCMCH
Five - child mortality	Child death	Death of a child (aged <17 years old); (all cause death)	NCMCH, NSO
Six - control	Diarrhoea (child)	The passage of three or more loose or liquid stools per day	NCMCH, NSO

Maternity hospitals 1–3 — first maternity hospital Urguu, second maternity hospital Khuree and third maternity hospital Amgalan.
NCMCH, National Centre for Maternal and Child Health; NICU, Neonatal Intensive Care Unit; NSO, National Statistics Office; PICU, Paediatric Intensive Care Unit.

factor framework (figure 2). Full details of the information gathered and conclusions made can be found in online supplemental material, which is summarised in figure 2 and table 2.

By identifying these key factors, we were able to propose an evidence-based impact model (figure 3). As shown in figure 3, it is assumed there will be a level (abrupt) and slope (gradual) change in our outcome rates in the postintervention period, compared with the preintervention trend. While we expect there to be a cyclic pattern in the outcomes, due to seasonal variation of pollution levels, this can be accounted for in the model. The slope change is expected to be fairly stable throughout the duration of the study, due to robust enforcement and high uptake of the RCB (online supplemental material). However, identified coinciding events, as shown in Figure 4, are expected to have effects on overall outcome trends and impact of the RCB on these health outcomes.

Descriptive analysis

Initial descriptive analysis will be undertaken, including scatter plots of all outcome data to visualise and identify underlying outcome trends and seasonal patterns. For each outcome, the descriptive analysis will include summary statistics of aggregated (ie, weekly and monthly means) outcome incidence rates and a scatterplot to identify trends, patterns and outliers.[24] Before-and-after comparisons will be conducted using a two-sample t-test to assess the mean difference in outcome data in the preintervention and postintervention periods. This analysis is expected to be confounded by underlying time effects, which we will attempt to allow for using the ITS analysis below.

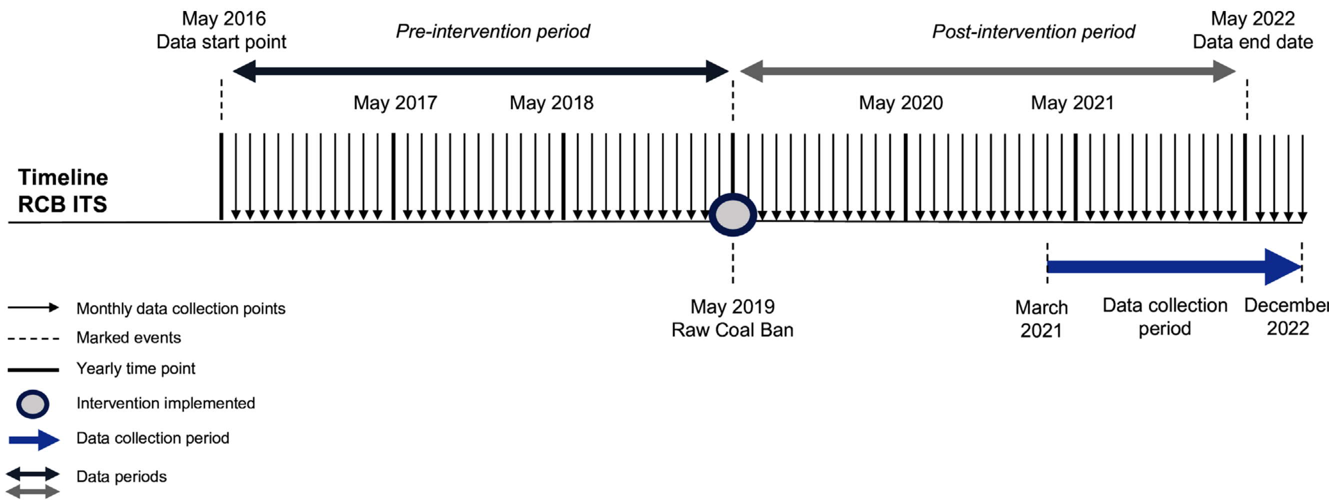

Figure 1 Study timeline, indicating the data collection period and data points, relative to the introduction of the RCB. RCB, raw coal ban; ITS, interrupted time series.

Statistical analysis

An ITS design with segmented regression analysis will be used to address this study's objectives, which will allow to control for previous trend of the weekly outcome data in the preintervention period, and study the dynamics of change over time.[30]

The proposed basic ITS segmented regression model, as presented in figure 3, is expected to consist of a preintervention outcome level at the start of the segment and a slope (gradient of the trend), as well as a postintervention change in level and difference in slope gradient compared with the preintervention period. All statistical analyses will be performed by using STATA software V.17 or R V.4.1.0, accompanied by graphical input from Prism GraphPad software V.9.5.1.

Confounders

The choice of including data from multiple preintervention and postintervention years comes with a risk of potential time-varying confounders, including coinciding cointerventions, the recent COVID-19 pandemic and climate changes. We will be conducting a full policy

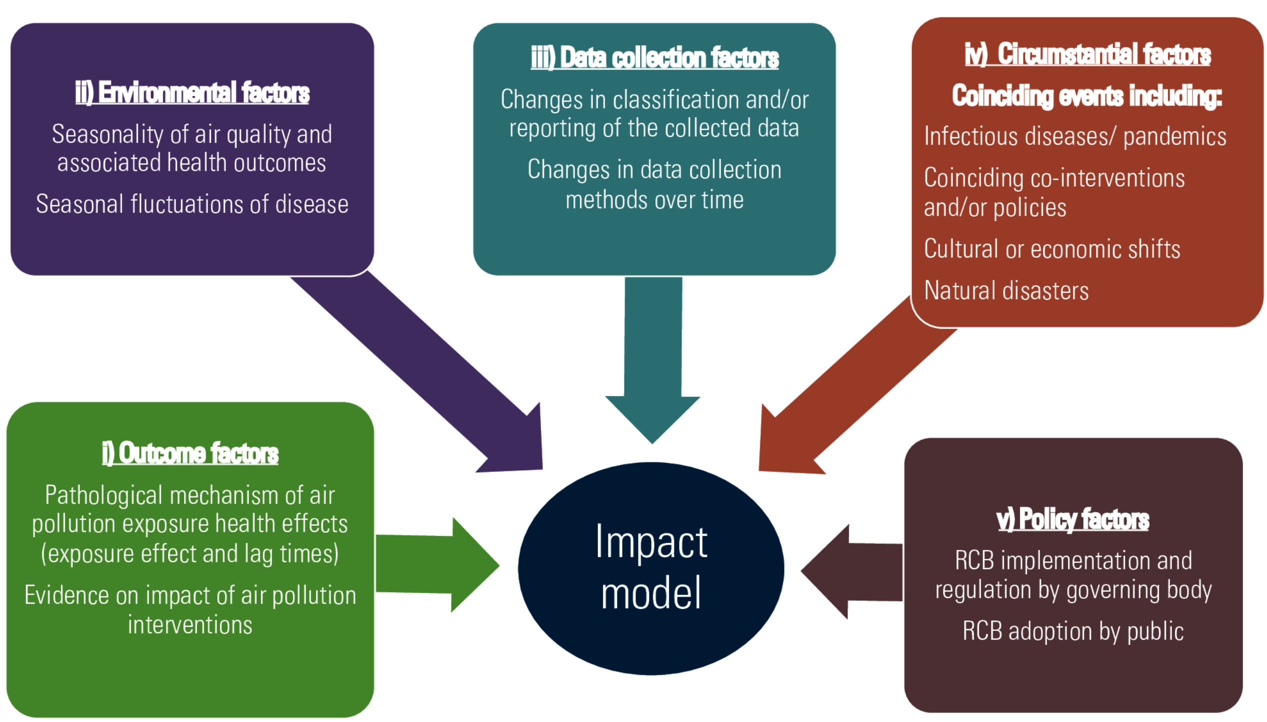

Figure 2 Five factor framework showing the five key factors that were identified to influence the impact model and subsequent assessment of the RCB. RCB, raw coal ban.

Table 2 Summary table of conclusions made for determining the impact model, based on the five factor framework

(1) Health outcome factors	
Factor summary	Impact of air pollution exposure on the selected maternal and neonatal health outcomes vary from short-term to long-term exposure effects throughout all stages of pregnancy. Most of the included outcome measures are suggested to be predominantly affected by long-term air pollution exposure, however, there have been certain health outcomes identified to be (also) affected by short-term air pollution exposure, including hypertensive disorder, stillbirth, spontaneous abortion and child respiratory admissions. These adverse health effects can in turn impact on long-term child morbidity and mortality. Reduced air pollution exposure is expected to lead to a decline in overall deaths due to a significant reduction in risk of cardiopulmonary-related deaths.
Conclusions for impact model	Level and slope change assumed due to both immediate and long-term health effects from air pollution exposure.
(2) Environmental factors	
Factor summary	Cyclic seasonal fluctuation expected in the air pollution-related health outcomes, which can be accounted for in the model. Furthermore, seasonal peaks of infectious diseases such as respiratory and diarrhoeal illnesses to be expected. Potential lag period expected due to the timing of the implementation of the ban.
Conclusions for impact model	Seasonal patterns and potential lag of health outcomes assumed, which will be accounted for in the model.
(3) Data collection factors	
Factor summary	Data collection methods are not expected to be impacted by changes in data classification, interpretation or accuracy of reporting due to clearly defined outcomes, as well as continuous data consistency checking and fieldworker training.
Conclusions for impact model	No assumed changes due to data collection changes.
(4) Circumstantial factors	
Factor summary	Identified coinciding events during the study period include the COVID-19 pandemic and the summer Siberian Forest fires, which both are suggested to impact air pollution exposure and subsequent health effects. Furthermore, the COVID-19 is expected to have longer-term national and individual economic impacts.
Conclusions for impact model	Slope changes assumed as consequence of coinciding events
(5) Policy factors	
Factor summary	RCB policy implementation found to be supported by a robust monitoring system, enforcing uptake and adherence. Consequently, high household uptake of the RCB and use of the alternative briquette fuel, should result in the target of a 50% reduction of air pollution.
Conclusions for impact model	Level change throughout the postintervention period assumed compared with the preintervention period.

RCB, raw coal ban.

review to identify and assess the presence of the coinciding events, which can be controlled for by adding terms to the model that represent these variables.[24]

To control for unknown or unmeasured confounders, the use of a control group is often deemed necessary. The RCB was implemented throughout Ulaanbaatar, leading to the lack of a representative control group that is exposed to comparable pollution levels. As an alternative to a control group, a health outcome that is thought to be unaffected by the intervention will be used as a control series.[24] This indirect control will be modelled using a similar ITS analysis as described below.

Autocorrelation and seasonality

The presence of autocorrelation will be examined through inspection of a plot of residuals and conducting statistical tests such as the Durbin-Watson test, which is deemed suitable due to the length of our data series.[31] On identification, autocorrelation can be adjusted for by including an estimated autocorrelation parameter in our regression model. Given the prior knowledge of Ulaanbaatar's seasonal air pollution situation, it is assumed that there will be a seasonal pattern dominating the data. If through visual inspection of the data a fairly stable cyclic seasonal pattern is evident, monthly parameters can be included into our model to control for confounding effects from such seasonality.[30 32]

After adding autocorrelation parameters, residual autocorrelation will be continuously checked to assess whether the model is appropriate for our data series.

Patient and public involvement

Public involvement will be pursued in the dissemination stages of the study. A multistakeholder meeting will be held to discuss results and formulate comprehensive public information sources on the impact of the RCB on maternal and child health and air pollution in Ulaanbaatar.

ETHICS AND DISSEMINATION

Ethical approval has been obtained via the Ministry of Health, Mongolia (No.445) and University of Birmingham (ERN_21-1403). The evidence gathered in the proposed study will be initially shared with UNICEF Mongolia research team members as part of

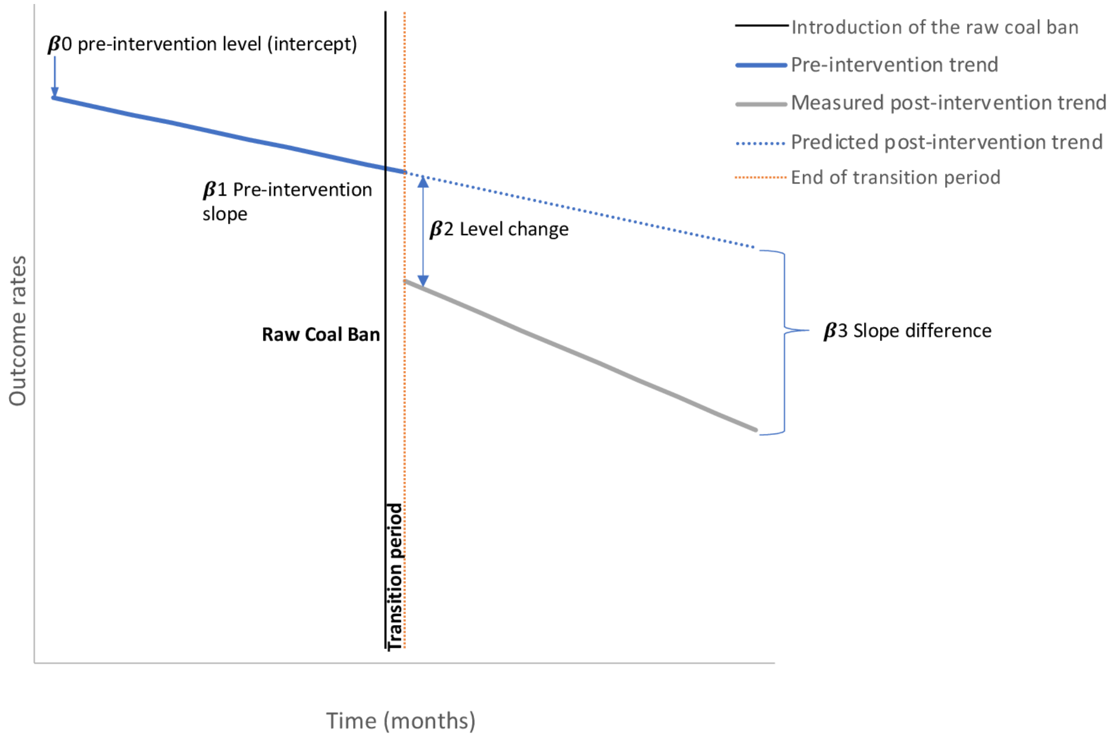

Figure 3 Proposed impact model demonstrating the assumed effect of the RCB prior to data analysis, based on information gathered in the five factor framework (Figure 2) with segmented regression model Yt = β0+β1Tt+ β2Xt+ β3XtTt+ εt. Yt represents a composite outcome over time, T_t the time since commencing the study, X_t represents the variable of the intervention (0 pre-intervention and 1 post-intervention) and X_tT_t represents an interaction term. The baseline level at time 0 is represented by β_0, followed by the trend and the change of outcome over time in the pre-intervention period represented by β_1. The change in outcome level and slope over time in the post-intervention period is represented by β_{2} and β_3, respectively. Graph demonstrates that a level and slope change is expected after implementation of the intervention, with a potential lag (transition) period.

their 'impact of air pollution on maternal and child health' programme. Key findings will be disseminated at the national level, including policy briefing communications with the Mongolian Ministry of Health, the Ministry of Environment and Tourism, as well as other appropriate governmental and academic bodies. Comprehensible summary information containing key messages will be shared in an accessible format on the public level such as through community briefings. Furthermore, it is aimed that the evidence gathered in this study will create a foundation for creating evidence-based future interventions aimed to improve air pollution-related maternal and child health in Ulaanbaatar.

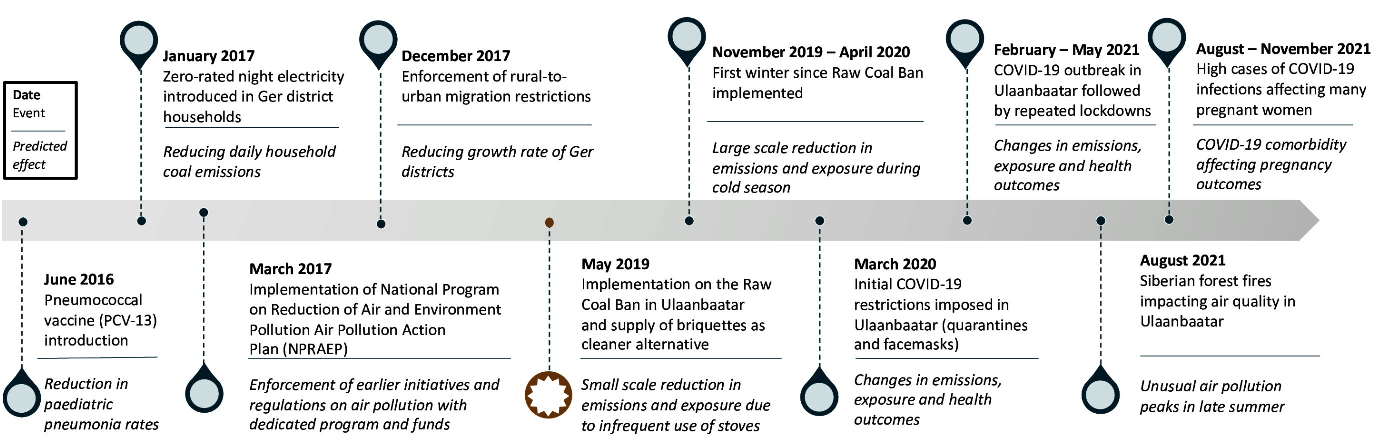

Figure 4 Overview of identified coinciding events during the study period and their predicted effect on the RCB intervention effect. Coinciding events were identified through literature search and stakeholder semi-structured interviews up until December 2021. RCB, raw coal ban

DISCUSSION

This paper describes the protocol of an ITS analysis of a governmental ban on raw coal in Ulaanbaatar, Mongolia, introduced in May 2019. With Mongolia's air quality problem being increasingly recognised and prioritised among national policy-makers in Mongolia, it is expected that more new interventions and policies aimed to reduce air pollution will be introduced over the next decade. The key challenge will be to ensure that lessons learnt from previous mitigation strategies will improve the effectiveness of future actions. Accurately determining the impact of this RCB, as well as determining the facilitators and barriers to its uptake, will, therefore, be crucial for Mongolia's air quality prospects. Assessments of previous interventions, such as the World Bank improved stove intervention in Ulaanbaatar in 2007, identified a lack of knowledge about the intervention itself and its potential health benefits to be the main barrier to stove use behaviour change.[33] Taking such lessons into account for new interventions, such as the RCB, could significantly improve its effectiveness in reducing air pollution and related adverse health.

While no official preinvestigations have been published, early findings on air quality since the RCB introduction have been promising, with PM reductions noted up to 55% compared with previous years.[34] Such reductions could have great implications for air pollution-related health effects but remain unclear due to lack of substantial evidence.

Evidence on the effectiveness of bans on raw coal in other settings has been promising. Intervention assessments in a coal ban zone in northern China showed a decline in PM of up to 60% during peak pollution wintertime.[35] Similarly, a ban on coal sale and distribution in Dublin in 1990 resulted in substantial decrease in air pollution concentrations and related respiratory (15.5%) and cardiovascular (10.3%) death rates within the first year of its introduction.[36] However, no previous studies have investigated the health impacts of this fuel policy intervention in Mongolia, a rapidly developing lower-middle-income country setting.

Our study assesses the effectiveness of the RCB, a natural experimental intervention implemented by the GoM. Before-and-after study designs are commonly used to investigate health interventions, however, they do not take into account the impact of underlying trends, leading to potential trend bias and subsequent incorrect estimation of intervention effect size.[37] To address this, an ITS study methodology, considered the strongest quasi-experimental study evaluations for public health intervention analyses, will be used.[30] By taking the preintervention trends into account, the ITS study design can estimate the independent effect of the intervention.[38] A potential risk with time series is the presence of time-varying confounders and autocorrelation. The presence of potential confounders will be carefully assessed, and those whose weekly means change over time will be added into the model. A limitation of this is the potential risk of ecological bias, which we are conscious of and acknowledge as a limitation to our study design.[39] Autocorrelation, in which two adjacent data points or those further apart, needs to be accounted for to reduce risk of underestimating the standard errors or overestimating the intervention effects.[30] While recent evidence suggests that the restricted maximum likelihood method is preferred for the estimation of the autocorrelation coefficient to reduce risk of biased estimates, this is only recommended for smaller time series with up to 100 data points.[31] We propose using the Durbin-Watson test for detecting the underlying autocorrelation, due to our data series having over 300 time points. By prespecifying and adjusting our model through consideration of our data characteristics, we aim to approach the true intervention effect of this RCB more accurately.

The effectiveness of the RCB to improve ambient air quality will depend critically on (1) the efficacy and efficiency of its implementation, (2) the availability, accessibility and sociocultural acceptance of the fuel alternatives, (3) the impact of unintended or wider negative policy consequences, such as health consequences due to improper use or reduced availability, black markets for coal trading and loss of employment opportunities in coal production and delivery sectors and (4) the relative contribution of non-coal sources to PM pollution at a regional level.

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Contributors SM-H and ED-C initiated the idea for the study. GNT, DW and SM-H developed the study design and objectives. SB, RD, FP and JB developed and gave guidance on the data collection methods. JB, DB, BC and CO initiated and obtained local ethical approvals and gave epidemiological inputs. KH, RT and ED-C developed the statistical analysis approach. SB and JB developed the data management plan. ED-C drafted the initial manuscript and all authors read, edited and approved the final manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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Supplementary materials

Overview of the five key factors identified through literature and qualitative research to influence the impact model and subsequent assessment of the Raw Coal Ban (RCB)

Factor I - Outcome Factors	
Factor assessments	*1. Maternal Morbidity* Exposure to high levels of air pollutants such as PM_{10}, $PM_{2.5}$ and NO during pregnancy have been associated with increased risks of maternal hypertensive disorders, including pre-eclampsia and gestational hypertension [1]. High levels of PM10 and PM2.5 exposure in the first and second trimester, respectively, are suggested to particularly influence hypertensive disorders in later pregnancy[2]. Gestational diabetes mellitus (GDM) has been positively associated with air pollution exposure[3]. Particularly NO and SO_2 in the second trimester have been found to be associated with GDM development. The WHO guidelines used by Mongolian physicians recommends testing all women between 24-28 weeks for gestational diabetes, resulting in either a second or early third trimester diagnosis.
	2. Perinatal Morbidity Preterm birth has been positively associated with air pollution exposure in the first and second trimester. The potential negative effect of pollutants on placentation in early pregnancy as well as activation of inflammation pathways is thoroughly hypothesised[4]. Furthermore, preterm birth has been linked to maternal morbidity, including hypertensive disorders and GDM as discussed above. Low birth weight (LBW) and small for gestational age (SGA): Anthropometric measures at birth have been negatively associated with air pollution exposure throughout the pregnancy[5,6].
	3. Perinatal Mortality Spontaneous abortion has been strongly positively associated with air pollution exposure in Ulaanbaatar[7]. It is suggested that the exposure to air pollution has an immediate effect, and therefore death rates coincide with the seasonal pattern of air pollution fluctuations. Like preterm birth, it has long been hypothesised that air pollution exposure can lead to fetal hypoxia due to reduced tissue oxygenation[8]. Still birth has been strongly associated with air pollution exposure as well[6]. In an interrupted time series study in Brazil, this association seems to have a short lag of less than 5 days[9]. In addition, mechanisms to which intrauterine death is caused by pollution exposure is thought the be similar to spontaneous abortion as explained above. Neonatal death has been associated with air pollution exposure in- and ex- utero[10,11]. The most common causes of neonatal death are linked to respiratory complications, including acute respiratory distress due to prematurity, pneumonia and asphyxia[12].These all could be linked to long-term exposure during pregnancy and associated

	complications (e.g. preterm birth, reduced lung function), as well as short-term exposure in the first month of life (e.g. acute respiratory infections)[4,13,14].
	4. Child Morbidity Respiratory illnesses including pneumonia, bronchitis, bronchiolitis, asthma exacerbation and pulmonary tuberculosis have been linked to both long- and short-term exposure to air pollution[13,15–17]. Furthermore, complications of abovementioned adverse pregnancy outcomes such as preterm birth and low birthweight, which are linked to air pollution exposure, are known contributors to long term child morbidity[18,19]. Respiratory complications are the leading cause of NICU and PICU admissions[20–22]. As stated above, there is a clear link between neonatal deaths, neonatal respiratory disease and child respiratory illnesses and the exposure air pollution exposure in-utero.
	5. Child Mortality Child mortality caused by respiratory infections, represents over 13% of all causes of death under five years old and exposure to air pollution has been shown to be one of the leading causes of these post-neonatal respiratory related deaths[12,14].
	6. Child Diarrhoea (control) To date there is no evidence of child diarrhoea being associated with air pollution exposure. This outcome measure is therefore included as an outcome control group.
Summary	Impact of air pollution exposure on the selected maternal and neonatal health outcomes vary from short- to long-term exposure effects throughout all stages of pregnancy. Most of the included outcome measures are suggested to be predominantly affected by long-term air pollution exposure, however, there have been certain health outcomes identified to be (also) affected by short-term air pollution exposure, including still birth, spontaneous abortion, and child respiratory admissions. These adverse health effects can in turn impact long-term child morbidity and mortality. Reduced air pollution exposure is expected to lead to a decline in overall deaths due to a significant reduction in risk of cardiopulmonary related deaths.
Conclusion	Level and slope change assumed due to both immediate and long-term health effects from air pollution exposure.
Factor II - Environmental Factors	
Factor assessments	Ulaanbaatar's air pollution problem has a seasonal pattern, in which the worst polluted days are in the cold winter months, between October and April, followed by low levels of air pollution in spring and summer. A consequent similar pattern has been shown in air pollution exposure associated health outcomes such as spontaneous abortion and fecundity[7,23]. It is expected that similar seasonal patterns will be seen in certain outcomes in this study. While the ban was introduced in May, a month known for having good air quality, it is not expected to see any significant

	intervention effect until at least November, when the temperature drops, and air pollution and related health events rise. This could cause a potential lag or transition period, which will be addressed in the model. Other seasonal influences include the fluctuations of communicable diseases throughout the year. Regardless of air quality, (viral) respiratory diseases are known to peak during the colder months, when temperatures drop, and people spend more time indoors[24]. This same counts for diarrheal diseases, while in Mongolia these peaks have been shown to present itself earlier in the year too[25].
Summary	Cyclic seasonal fluctuation expected in the air pollution related health outcomes, which can be accounted for. Furthermore, seasonal peaks of infectious diseases such as respiratory and diarrheal illnesses to be expected. Potential lag period expected from the timing of the implementation of the ban.
Conclusion	Seasonal patterns of health outcomes assumed which will be accounted for in the model.
Factor III - Data Collection Factors	
Factor assessments	By using routinely collected data over a prolonged period, there is a certain degree of uncertainty regarding the comparability of the presentation of the data over the years due to potential changes in data classification, interpretation, or accuracy of reporting. Examples include re-classification of certain medical outcomes and method of measuring/reporting of air quality. To account for this, we have clearly defined our outcomes and will conduct frequent checks for missing or inconsistent data throughout the data collection and analysis phases. Data collection fieldworkers are trained, tested and checked on their data collection methods throughout the duration on the study. It is therefore not assumed that such technical data factors would influence our impact model.
Summary	Data collection methods not expected to be impacted by changes in data classification, interpretation, or accuracy of reporting due to clearly defined outcomes, as well as continuous data consistency checking and fieldworker training.
Conclusion	No assumed changes due to data collection changes.
Factor IV - Circumstantial Factors	
Factor assessments	We conducted an initial policy assessment to identify any coinciding events such as cointerventions from 2016 to date, that could affect the estimation of the true intervention impact of the raw coal ban. This policy assessment was conducted using literature search and semi-structured interviews with key stakeholders. From our assessment several coinciding events were identified, as shown in Figure 4, which have the potential of affecting the data due to changes in air pollution emissions and/or exposure. Furthermore, due to recurrent COVID-19 restrictions and infections, as well as the summer 2021 Siberian Forest fires, there is likely to be marked changes in both emissions and exposures at certain timepoints. A high rise in COVID-19 infection and hospitalisation rates amongst (mainly unvaccinated) pregnant women in autumn 2021, is expected to impact our data on pregnancy outcomes including preterm birth and low birth

	weight rates[26]. To what extent these events impact our results remains unclear and will become evident from our analysis.
Summary	Identified coinciding events during the study period include the COVID-19 and the summer 2021 Siberian Forest fires which both are suggested to impact air pollution exposure and subsequent health effects. Furthermore, the COVID-19 is expected to have longer-term national and individual economic impacts and indirect effects.
Conclusion	Slope changes assumed as consequence of coinciding events.
Factor V - Policy Factors	
Factor assessments	Policy implementation: The raw coal ban was put into force on the 15th of May 2019, under the direction of Ulaanbaatar's mayor, who oversees adherence through the Ulaanbaatar Inspection Department and the Police Department. The Ministry of Environment and Travel, Ministry of Energy, Ministry of Finance, Ministry of Law and the Mayor Office have been put in charge of implementing the policy. Furthermore, monitoring and supporting roles are delegated to the General Agency of Specialized Investigation along with civilian policing groups to enforce uptake and adherence. Not adhering to the ban by using or supplying raw coal has been penalised with significant fines (300,000 - 10,000,000MNT / $100 - $3500), with regular checks being conducted throughout the Ger district. Furthermore, there are frequent city border checks to ensure no raw coal in being imported into the city from the main mining sites such as Nailakh. The 1 million tonnes of raw coal used each winter has been replaced by cleaner refined coal briquettes, aiming to improve Ulaanbaatar's air quality by 50%.
	Policy adoption: Unpublished findings* from our mixed-methods household survey study showed that the uptake of the ban in the first two years of its implementation was high (>95%), and the air quality was generally perceived to be better. While accessibility of the improved fuels (briquettes) during the initial stages of the RCB implementation was raised as a concern, partially due to introduction of a rationing system to prevent shortages during the pandemic, our preliminary findings showed that the majority (73%) of households have not experienced reduced accessibility to fuel since introduction of the ban. Furthermore, heavy governmental investment in briquette production and supply suggests accessibility over the study period will only improve.
Summary	RCB policy implementation found to be supported by a robust monitoring system, enforcing uptake and adherence. Consequently, high household uptake of the RCB and use of the alternative briquette fuel, should result in the target of a 50% reduction of air pollution.
Conclusion	Level change in the post-intervention period assumed compared to the pre-intervention period.

*available upon request

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