STUDY PROTOCOL

Evaluating the life-course health impact of a city-wide system approach to improve air quality in Bradford, UK: A quasi-experimental study with implementation and process evaluation

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Abbreviated title: Born in Bradford Breathes

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ACRONYMS

ANPR	Automatic Number Plate Recognition
ARIMA	Auto Regressive Integrated Moving Average
AURN	Automatic Urban and Rural Network
BCAP	Bradford Clean Air Plan
BiB	Born in Bradford
CAZ	Clean Air Zone
CHC	Connected Health Cities
Comm Grp	Community Reference Group
DEFRA	Department for Environment, Food and Rural Affairs
DFT	Department for Transport
GP	General Practice
HGV	Heavy Goods Vehicle
ICD	International Classification of Disease
ITS	Interrupted Time Series
JAQU	Joint Air Quality Unit
LEZ	Low Emission Zone
LGV	Light Goods Vehicle
M	Month
Mgt Grp	Study Management Group
MRC	Medical Research Council
NO_2	Nitrogen dioxide
PM	Particulate Matter
QALY	Quality Adjusted Life Year
Sch Grp	Schools Reference Group
SES	Socio-economic status
SME	Small/ Medium Enterprise
SOP	Standard Operation Procedure
STEM	Science, Technology, Engineering, Mathematics
SSC	Independent study steering group
UoL	University of Leeds
UoY	University of York
WHO	World Health Organisation
WP	Work-package

Contents

1 Abstract

BACKGROUND: Air quality is a major public health threat linked to poor birth outcomes, respiratory and cardiovascular disease, and premature mortality. Deprived groups, children and the elderly are disproportionately affected. Air quality-related illness costs the NHS and wider economy £20 billion/year. Due to illegal levels, the UK Government has issued directives to 28 local authorities to quickly reduce pollution, with charging 'Clean Air Zones' (CAZ), where polluting vehicles are charged to enter, a key component. However, evidence about the effectiveness of CAZs to improve health is scarce. Bradford will implement a CAZ as part of the Bradford Clean Air Plan (B-CAP) in 2021 to reduce pollution, providing a natural experiment.

AIM: To evaluate the effectiveness, cost-effectiveness, inequality impacts and processes involved in implementation of the Bradford Clean Air Plan (including its CAZ) and learn lessons relevant to other local and national efforts to lower pollution. Objectives are to: assess 1) implementation, acceptability, fidelity (Workpackage[WP]1A), 2) change mechanisms (WP1B), and impacts on: 3) air quality (WP2), 4) health effects in children, adults and older adults (WP3A), 5) health inequalities (WP3B) and 6) value for money (WP4).

RESEARCH QUESTIONS: Does the B-CAP improve: life-course health outcomes; air quality; inequalities? Does the B-CAP represent value for money? What are barriers to implementation and are there unintended/adverse consequences?

METHODS: WP1A: 20 interviews with decision makers; 10 public focus groups and documentary analysis of key policies/reports will assess implementation barriers, acceptability and adverse/unanticipated consequences. WP1B: A population survey (n=4000) will assess changes in travel behaviour/attitudes 1 year post-implementation (defined as point at which charging CAZ goes 'live'). WP2: Routine air quality measurements will be supplemented with data from low-cost, validated pollution sensors in 12 schools by pupils trained as citizen scientists (4 inside, 4 bordering and 4 distal to CAZ boundary, n=240 pupils). Pupils will carry sensors for 3 separate months in the year pre, and again in the year post-implementation. We will explore whether reductions in pollution vary by CAZ proximity. WP3A: Using a longitudinal routine health dataset of >500,000 Bradford residents we will conduct a quasi-experimental interrupted time series analysis comparing trends (3 years prior vs 3 years post) in respiratory health (assessed via emergency/GP attendances) with >90% power to detect a 5% reduction at 3 years. Results will be stratified by age (0-17 years; 18-64, 65+). Secondary outcomes include cardiovascular health and birth outcomes. WP3B: We will use the richly-characterised Born in Bradford cohort (13,500 children) to explore health inequalities in respiratory health using detailed socio-economic data. WP4 will adopt a multi-sectoral perspective to determine value for money.

TIMELINE: 60 months[M]: Process and interim analyses (1 year post CAZ implementation) by M37. 3 year follow-up and health economic evaluation by M60.

IMPACT/DISSEMINATION: The UK Government Joint Air Quality Unit has indicated its strong support, enabling policy links. For researchers, policy and decision makers we will produce academic papers, policy briefings and hold dissemination events. For communities, we will prepare lay summaries and publicise these widely, via our established social media channels, local media links, and engagement events. We will develop school citizen science curriculum materials to inspire young researchers.

2 Background and scientific rationale

We have a rare opportunity to conduct an efficient quasi-experimental evaluation of a city-wide air quality intervention (Bradford Clean Air Plan: B-CAP), which includes implementation of a charging Clean Air Zone (CAZ) to determine its impact on air quality, health outcomes and inequalities across the life-course. Based on the UK Government's clean air strategy[1] and air quality plan,[2] CAZs represent a fundamental policy shift to tighten emission standards, accelerating the switch to cleaner vehicles, combined with multi-faceted support activities spanning transport planning and public health, to control traffic levels and reduce emissions by around 25%.

2.1 The problem

Air pollution is one of the biggest contributors to mortality and morbidity globally.[3] Research (including from BiB [4, 5]) has linked poor air quality with a range of health outcomes including poor birth outcomes;[6] cardiovascular events and mortality;[7, 8] respiratory illness;[8] lung cancer;[9] cognitive development and neurological disorders.[10] In Bradford, 33% of childhood asthma cases are linked to poor air quality.[4] Emergency hospital attendances and mortality spike during periods of acute air pollution.[11-13] In the UK, 64,000 deaths are attributable to outdoor air pollution each year, [14] with a greater burden of air quality related illness apparent in young people and the elderly.[15] The costs to the NHS of air quality related illnesses between 2017-2025 is estimated to be £5.56 billion,[15] with the wider economic cost estimated to be £20 billion/year.[16]

The UK is currently breaching legal limits of key pollutants such as Nitrogen Dioxide ([NO_2], annual mean of 40ug/m3)[17] and regularly exceeds World Health Organisation guidance (WHO) for Particulate Matter(PM).[18] Sixty per cent of the UK population live in areas which exceed air quality guidelines,[19] and one third of children are exposed to unsafe pollution levels.[20] The burden of exposure is disproportionately borne by those of lower socio-economic status (SES), [21, 22] and evidence indicates that health effects may be amplified by SES acting as a moderator between exposure and outcomes [23-25], thus increasing inequalities.

2.2 Clean air zone (CAZ)

CAZs have been identified as potentially effective in reducing air pollution [26, 27] thus improving health.[28, 29] The UK Government has issued ministerial directives to 28 local authorities to rapidly improve air quality to legal limits, including consideration of implementing a CAZ. To date, 10 have confirmed plans to implement a CAZ; a number likely to increase as other local authorities further develop their air quality plans. In Bradford, Government projections suggest that without intervention it will not meet compliance with the legal limit for NO_2 until 2027.[2] Thus, in response to a ministerial directive, **Bradford council will implement its air quality plan (which includes a CAZ) to quickly reduce pollution. It anticipated this will be implemented in 2021**. We will evaluate the implementation and impact of the B-CAP on health outcomes and health inequalities.

2.3 Existing evidence

The National Institute for Health and Care Excellence and Public Health England have recommended implementation of CAZs to improve health, but note that further research exploring their effectiveness is required.[27] Systematic reviews highlight a lack of rigorous evaluation of CAZs or other similar initiatives on health outcomes.[28, 30] There have been few evaluations of interventions such as CAZs on air quality or health outcomes. Their impact on relationships between acute pollution episodes and short-term health outcomes has not been explored and little is known about whether these interventions can generate lifetime health and health inequality impacts and cost-savings.[29] In the majority of studies, modelled reductions in air quality (e.g. from projected vehicle emissions and air pollution dispersion models) are linked with assumed improvements in health [28-30]. Results from these complex causal modelling chains are highly uncertain and do not account for important real-world factors (for example, from elevated emissions of air pollutants from modern diesel vehicles, as exposed in the “dieselgate scandal”). Other weaknesses include lack of statistical power, no prospective follow up with baseline health data and lack of controls.[31]

A recently published Cochrane review [32] containing studies up until 2016 identified only 5 studies linking interventions to reduce emissions from vehicular sources with health outcomes. Findings were mixed, and all evidence was rated as having low certainty according to GRADE guidelines.[33] Three found positive effects: Yorifuji [34] found a 5.9% reduction in cardiovascular mortality and a 10% reduction in respiratory mortality associated with mandatory standards for diesel vehicles in Tokyo up to 12 years post implementation (reduction in PM of 3.4%). Also in Japan, Hasunuma [35] found a 17.4% reduction in respiratory symptoms in children (aged 3 and under) from implementing vehicular standards for NO_2/PM (compared to 3.5% for children in control sites, reduction in NO_2 22%); El-Zein [36] found an immediate reduction in respiratory hospitalisations for children under 14 associated with a ban on diesel vehicles in Beirut, Lebanon. More recently, Russell et al [37] found that implementation of pollution-control policies in the 5-county Atlanta metropolitan area (USA) which resulted in a decrease in NO_2 of 24 ug/m3, led to a reduction of 5.9% of respiratory disease emergency department visits. In the Guanzhou region of China, Zhang et al [38] found restrictions on emissions for the Asian Games resulted in a reduction of NO_2 levels by 8.7 ug/m3, which decreased cardiovascular hospital admissions by 19.3% and respiratory admissions by 14.9%.

There is only one UK-based study examining the impact of the London Low Emission Zone (LEZ, implemented in 2008) on health outcomes. [39] In this annual cross-sectional study, Mudway et al [39] found that the London LEZ showed modest improvements in NO_2 (~1ug/m3), but no impact on children’s lung capacity, probably due to the small improvements in air quality. No comparator was used and data were only collected after LEZ implementation. The LEZ was less ambitious than the Government’s proposed CAZ policy, targeting only lower tailpipe emissions of PM, with limited impact on NO_2.[40] London has recently switched on an ‘ultra-low emission zone’ (a CAZ where all non-compliant vehicles are charged to enter). There is an ongoing evaluation of the impact of this upon lung function using a parallel controlled cohort study of primary school children in inner London and Luton which is due to report in January 2024. [41] However, to our knowledge there are no evaluations of these types of interventions outside London.

Our rigorous evaluation is designed to fill a key knowledge gap and provide important evidence on the impact of the recent UK Air Quality Plan policy initiative on health, economic and inequality outcomes. Our embedded implementation and process evaluation will generate rich learning on barriers and enablers to implementation relevant to other urban areas planning and implementing a CAZ approach. Our findings will enable the modelling of potential health impacts of a CAZ approach within other cities in the UK and internationally.

3 Planned intervention- the Bradford air quality plan including clean air zone

Bradford District has been identified by the UK government as being one of 28 areas in England where the average annual concentrations of NO_2 exceed the statutory limit of 40ug/m3 at a number of locations across the district; without intervention, these areas will not achieve compliance until 2027.[42] As a result, Bradford Council has been mandated by central government to bring about compliance in the shortest possible time through major policy options including interventions such as a Clean Air Zone. It is expected that these will instigate desired behavioural responses towards a reduction in most polluting vehicles being driven in the district and an increase in public transport use, and active travel.

Bradford was awarded funding by the UK Government's JAQU to develop a comprehensive **air quality plan outlining activities which will quickly reduce pollution to compliant levels.** The plan was submitted on the 15th November 2019 and was informed by Government guidance, extensive modelling, consultation with business (e.g. bus and taxi companies), communities (including bespoke work with 'seldom heard' and 'underserved' communities Rashid et al) and elected members. The activities outlined within the plan will be funded by the Government's clean air fund and implementation fund (total of £475 million available nationally), and **will be implemented in 2021**, following a period of public consultation. Below is a description of the intervention according to TIDIER guidelines.[43]

Name: Bradford Air Quality Plan (B-CAP)

Why: As part of its Strategic Business Plan, and in order to ensure compliance with legal limits, Bradford Council is required to consider at least one charging CAZ which requires drivers of the most polluting vehicles (below Euro 4 petrol and Euro 6 diesel standards) to pay a daily charge to drive a non-compliant vehicle in the CAZ charging zone. **The CAZ boundary is shown in Figure 1;** it encompasses an area which contains ~20% of the Bradford population, primarily the most deprived inner city wards but including less deprived wards on the outskirts of the city. Rigorous modelling to determine pollution levels within this boundary (informed by routine monitoring and traffic fleet data) has identified at least 16 core link roads spread throughout this area which exceed legal limits. Based on these data, **the required reduction in NO_2 to achieve legal limits (40ug/m3) ranges from 1-18ug/m3.** Thus, at a minimum, the activities included within Bradford's air quality plan have been estimated to achieve up to an 18 ug/m3 reduction in NO_2 (based on 2018 baseline data). However, it is hoped that the ambitious nature of the plan will mean air quality is improved beyond these limits by harnessing the power of the 'system' (e.g. transport, planning, and public health) to work together to further improve outcomes.

What: A **charging clean air zone class 'C'** (targeting non-compliant taxis, buses, heavy goods vehicles [HGVs], and light goods vehicles [LGVs]) Daily charges will be: £12.50 for taxis, £9 for LGVs and £50 for HGVs. Exemptions will be provided for local small/medium enterprises (SMEs), schools and charities. The Bradford ambition is for the CAZ to be supported by a range of other activities/components including: **Electric bus routes** in key parts of the city with road space allocation to **prioritise buses and reduce journey times**; **grants to retrofit polluting buses** to CAZ standards; introduction of **clean air standards for all Taxis** registered in Bradford so only compliant vehicles can operate; **grants and incentive schemes** to encourage i) taxi drivers to upgrade to minimum CAZ standards (hackney carriages), petrol/hybrid (private hire vehicles), or electric (both), ii) HGV, LGV, Coach and minibus owners to upgrade to minimum CAZ standard; new **park and ride** facilities for up to 1000 vehicles /day; installation of **alternative energy centre** providing cost effective green refuelling/recharging facilities; **travel planning** with businesses to promote car sharing, active travel and public transport use amongst employees); and an engagement programme to encourage a **reduction in polluting heating sources** with the CAZ boundary.

Who: Implemented by local authority and independent contractors.

How: Non-compliant vehicles identified during entry to the CAZ via automatic number plate recognition will be charged. Grants will be made available for buses and HGVs to retrofit emission control devices, and incentives for taxi drivers to purchase compliant vehicles.

Where: Zone encompassing areas with illegal levels of pollution: including city centre and key North West road corridor) (see Figure 1)

When and how much: Implemented around summer 2021, to continue (at least) until legal limits are reached.

A logic model summarising the proposed intervention and their hypothesised impacts on outcomes can be found in Figure 2.

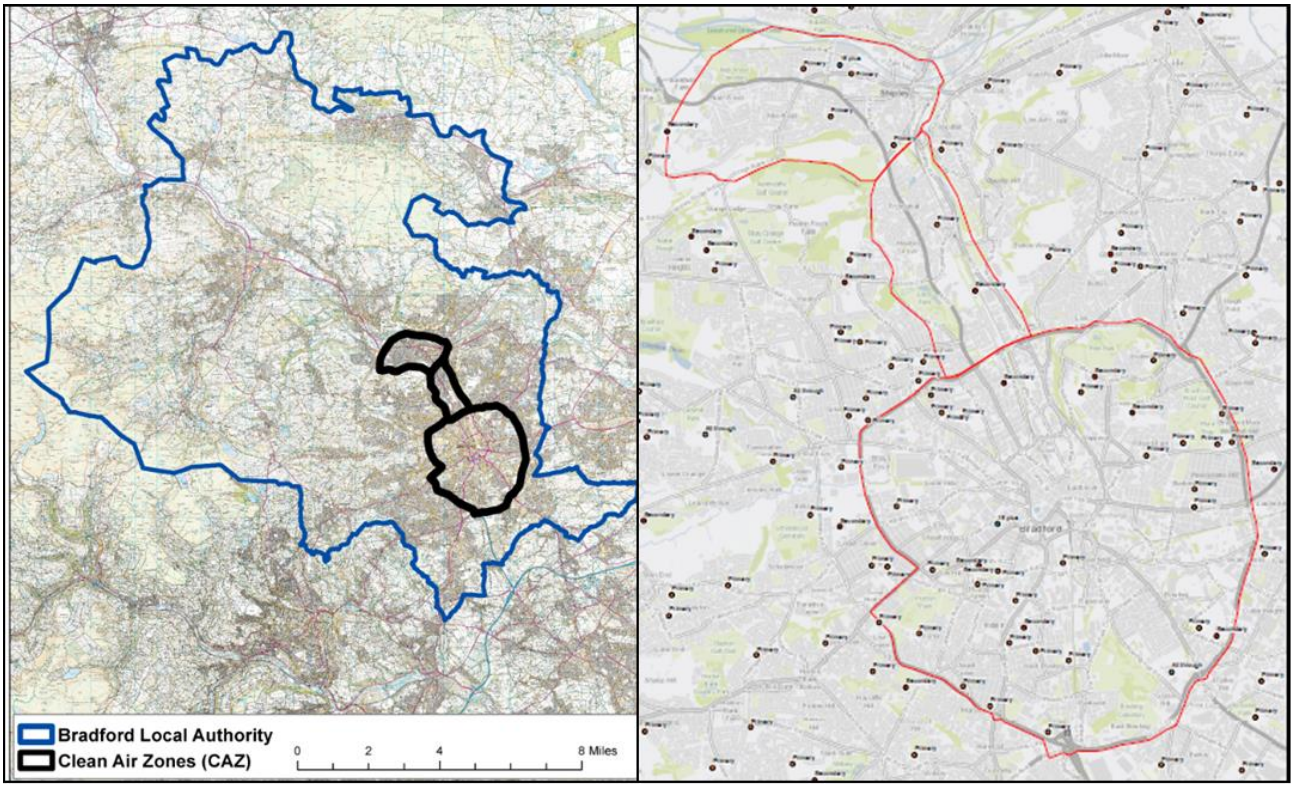

Figure 1: Indicative CAZ Boundary in relation to Bradford District (Left Panel); Snap shot of schools located within and around CAZ (Right Panel)

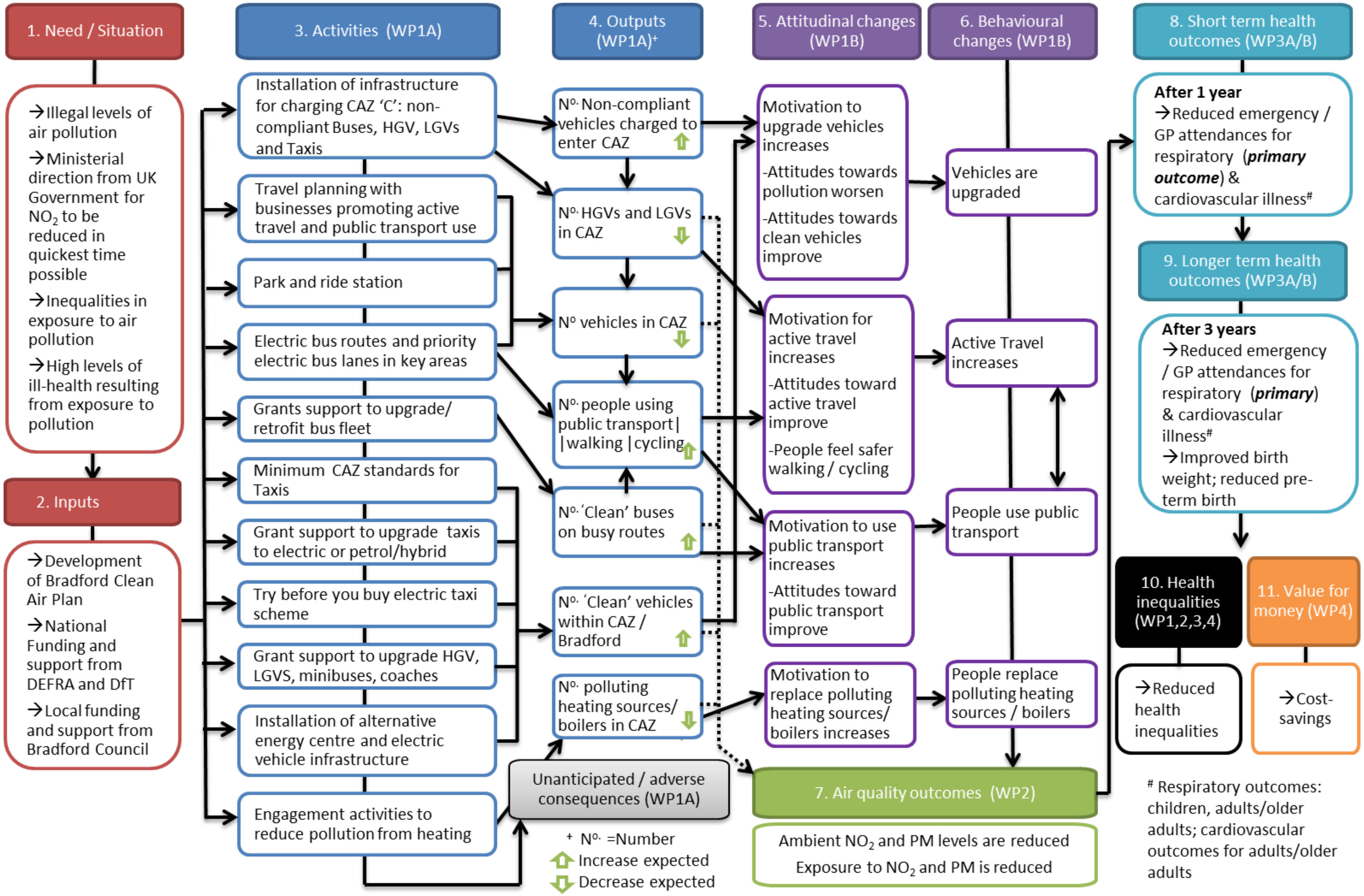

Figure 2: Logic model of the Bradford Clean Air Plan

Notes: WP: Work package; HGV: Heavy Good Vehicle; LGV: Light Goods Vehicle; NO2: Nitrogen dioxide; PM: Particulate matter

4 Project aims and objectives

We aim to assess the impact of the B-CAP on attitudinal, behavioural, air pollution and health outcomes, and its cost-effectiveness, using a multi-outcome, multi-sector approach. We also aim to explore the factors influencing any impact (or lack of) and explore unintended or unanticipated outcomes. The impact of the B-CAP on health inequalities amongst different socio-economic and ethnic groups will be assessed across all outcomes.

Research Questions:

1. What are the key barriers and enablers to implementation of the B-CAP (including acceptability), and are there unintended consequences of the B-CAP for different stakeholder groups (e.g., increased health and economic inequalities)?
2. Does the B-CAP affect travel choice behaviour and attitudes amongst Bradford residents at 12 months post implementation?
3. Does the B-CAP reduce exposure to pollution amongst primary school age children up to 12 months post implementation?
4. What is the impact of the B-CAP 3 years post-implementation on:
    a. **respiratory health** (primary outcome, as assessed by weekly counts of respiratory disease related emergency hospital or General Practice [GP] attendance) of children (aged <18), adults (aged 18-64) and older adults (aged 65+)
    b. **cardiovascular health** (as assessed by weekly counts of cardiovascular disease related emergency hospital/GP attendance) of adults and older adults;
    c. **birth outcomes** such as low birth weight and preterm birth (assessed by monthly counts)
5. How does the B-CAP impact on health inequalities up to three years post implementation?
6. What is the value for money of the B-CAP three years post-implementation and longer term?

5 Research plan and methods

5.1 Design

Our evaluation is based on the MRC guidance for the evaluation and process evaluation of complex interventions[44] and is structured around 4 core work-packages (WP) to assess **implementation**, **mechanisms of impact**, **health outcomes** and **economic outcomes** (see Figure 2 and detailed flow diagram appended). We will explore how **context** interacts with and influences intervention delivery and outcomes, and the impact of the intervention on **health inequalities**. Our quasi-experimental approach will capitalise on a natural experiment within the city (implementation of the B-CAP) and exploit a unique research infrastructure including the connected health cities data set of >500,000 Bradford residents (for which there is existing ethical approval: East Midlands – Derby NHS Research Ethics Committee 17/EM/0254) and detailed questionnaire and longitudinal health assessments of >12,500 families participating in the representative BiB birth cohort study (ethical approvals: baseline 07/1302/112 and follow up 16/YH/0320, both from Bradford and Leeds NHS Research Ethics Committee).

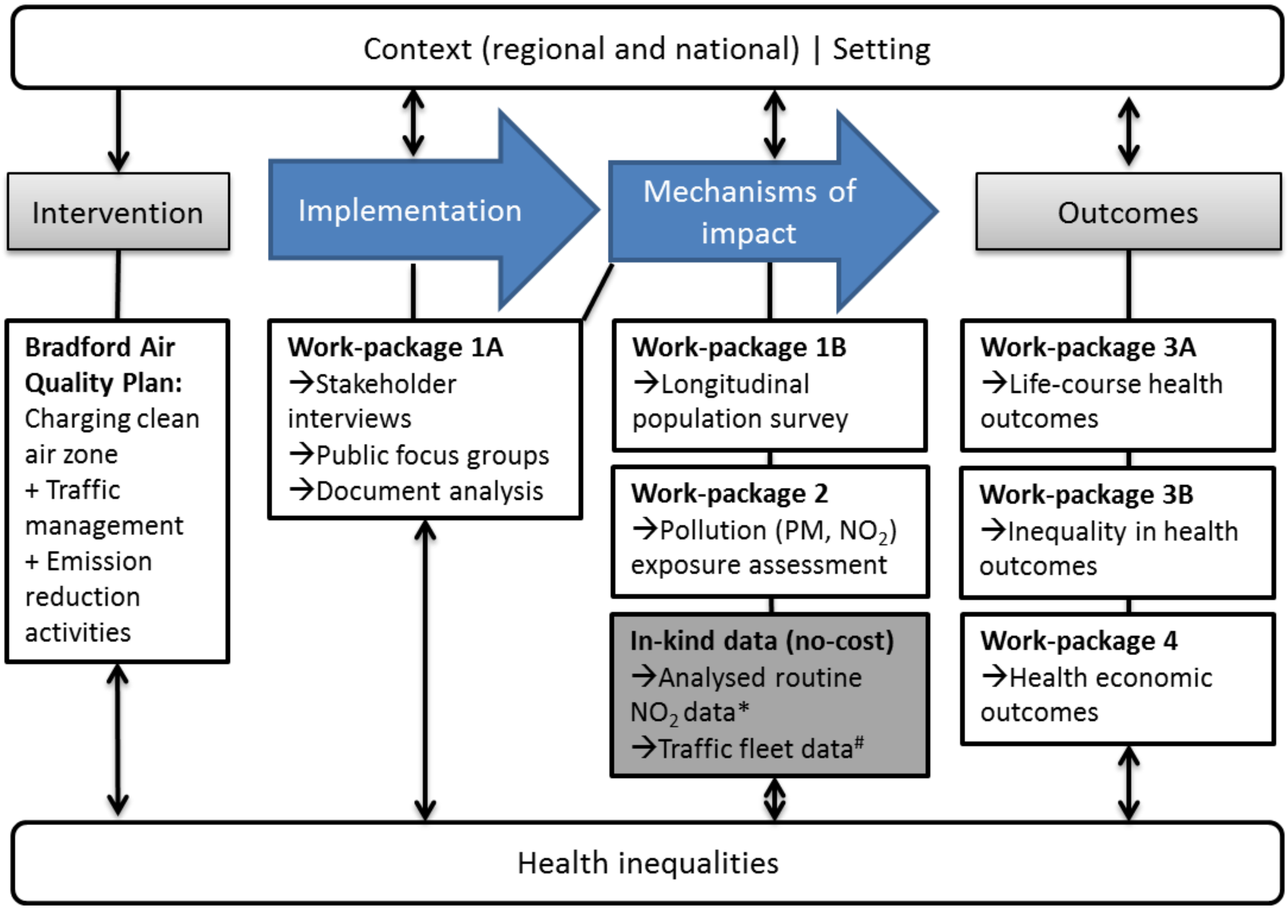

Figure 3. Outline of conceptual framework (adapted from MRC Guidance for Process Evaluation of Complex interventions)[44] NB *: Analysed data provided via DEFRA national evaluation; # Traffic fleet data from Bradford Council Automatic Number Plate Recognition system

5.1.1 Work package (WP) 1

Here we will employ mixed methods to conduct a thorough **process evaluation**.[44] It will draw on recent advances in conceptualising adaptations to intervention processes[45], transferability[46] and explore relationships between context, implementation and setting.[47] It will help us interpret why the B-CAP has (or has not) affected outcomes and inequalities and allow us to understand unanticipated or adverse outcomes. **In WP1A** we will employ qualitative methods including **semi-structured interviews and 'systems' workshops** with key stakeholders to explore **barriers and enablers** to B-CAP implementation, including adaptations and the influence of contextual factors. This analysis will be supplemented by **documentary analysis** of relevant regional and national policy documents, along with local documents (e.g. minutes and reports) related to implementation. **Focus groups** with key community members (across a range of socio-economic groups including 'seldom heard' groups, families, and taxi drivers) will explore **acceptability** of the B-CAP. **In WP1B** we will aim to identify **mechanisms** of any intervention effect by exploring the impact of the B-CAP on population **attitudes** (e.g. towards air quality) and **behaviours** (e.g. reducing car travel; upgrading vehicles) using a population survey nested within the representative BiB cohort study.

5.1.1.1 Process and implementation evaluation

At the outset of the project we will construct a comprehensive **'systems' map** to guide our data collection process. This will involve working with members of the Bradford Air Quality Programme Board to map out key partners, organisations and systems which may impact on, or be affected by implementation of the B-CAP. In WP1A, we will gather qualitative data to inform an **implementation and fidelity** evaluation to build a picture of the degree to which the intervention was delivered as intended, acceptability and unanticipated or adverse events. In WP1B we will gather quantitative data via a **longitudinal population survey** to explore **mechanisms of change**: specifically whether the intervention has the expected changes in behaviours and attitudes up to one year post implementation. We will supplement this bespoke data collection with available information collected via the Bradford council ANPR survey assessing vehicle fleets (proportion of compliant vehicles) travelling within Bradford, and the CAZ boundary. All data sources will allow us to test the assumptions and mechanisms in our logic model (and thus, our implementation pathways).

5.1.1.1.1 Sampling and data collection methods

In WP1A core components of data collection will include i) documentary evidence, ii) semi-structured interviews with stakeholders, iii) focus groups with members of the public. We will collate relevant **documentary evidence** which will allow us to record in detail how the intervention was implemented (for example, air quality board reports and minutes, council scrutiny reports and minutes), and the relevant regional and national policy context (for example, policy briefings, government reports). **Semi-structured qualitative interviews** will be conducted pre- implementation of the CAZ with stakeholders involved in the development of the intervention and again at 12 month post-implementation with key stakeholders identified from our systems map (from businesses, including small to medium enterprises [SME], travel sector, local authority, and voluntary sector) to explore barriers and facilitators to implementation, and reasons for intervention adaption. We will use purposive sampling methods to recruit participants from the local authority (primarily the Bradford Air Quality Programme Board, responsible for intervention development and implementation), local business (Bradford Chamber of Commerce) and transport (bus and taxi) operators. We will recruit to data saturation but anticipate conducting 20 interviews at each time point. Systems workshops with stakeholders who have strategic insight of implementation and system issues will be conducted at 2 and 3 years post-implementation to identify key barriers and enablers.

Public engagement reach and responsiveness will be assessed via **focus groups** to explore the degree to which intervention implementation has impacted beneficiaries and to explore the potential mediating process through which air quality interventions impact on health outcomes. Participants will include members of the public, including school staff/teachers, parents/children commuters within and outside the CAZ boundary. Building on our strong community links we will work with local voluntary sector organisations and schools to identify and recruit a diverse (age, ethnicity, SES) representative range of participants. A discussion guide will be developed covering issues related to acceptance, attitude, impact, engagement, reach and responsiveness. Informed consent will be taken prior to interviews / focus groups which will be audio-recorded and then transcribed. Expenses and refreshments for participants will be provided.

In WP1B we will use the BiB cohort as a platform for our longitudinal survey, in addition to surveying members of the general public. Benefits of using the BiB cohort include the detailed longitudinal information available on health and wellbeing for parents and children, existing consent to contact participants, and validated address and email contact details. The survey will measure changes in **travel choice behaviour and attitudes** and participants' views of the intended and unintended impacts of the B-CAP components on health and travel behaviour. The survey also includes key questions in relation to peoples experiences of the COVID-19 pandemic and subsequent local and national lockdown restrictions. Specifically, this will include questions about household and family, health and wellbeing, financial circumstances, changes to transport and travel behaviours and their priorities for healthy and happy children. From October 2021 we will no longer be collecting data on the impact of the pandemic and a shorter version of the survey will remain open for the general public.

It will be administered immediately pre, and up to 12-month post implementation of the charging CAZ element of the B-CAP. All BiB families still living within Bradford district will be eligible (~10,000, 80% of total cohort). We will offer the survey in a variety of formats including paper based, online, and face to face. Multilingual researchers will facilitate completion in Urdu, and Mirpuri. A pilot of online survey completion within the BiB cohort is planned in January 2020 to inform our recruitment strategy. The survey will be promoted to eligible families using a variety of well-established recruitment methods, including direct communication (letters in school book bags, post) and wider promotion (social media, website, and newsletters). Responses will be monitored, and additional multilingual fieldworker resource will be targeted to harder to reach groups to ensure representativeness. Based on our experience within BiB we estimate a 40% response rate, to achieve 4000 responses at both time points. Our survey development has been informed by 10 focus groups conducted with ethnically diverse community groups across the district (n=87) and incorporates items from existing surveys (for example, the national travel survey[57]). As a result of the Covid-19 pandemic, we have asked our BiB cohort to complete some urgent questionnaires on the impact of this at two time points between March – December 2020. We are therefore conscious that our response rate may be lower than expected due to participant over burden. In this event we hope to open the survey out to the wider population of Bradford. We aim to advertise through council channels with a link to an online survey. All information collected as part of this process will be held by BiB. We will ask non-cohort participants to provide some basic demographic information such as age group, ethnicity and gender to aid analysis. We will also ask for voluntary contact details if they are happy to provide them and follow-up with participants 12 months post implementation. These options will be to provide a mobile phone number, postal address or email address.

5.1.1.1.2 Key outcomes

Key outcomes assessed in WP1 will include: i**ntervention fidelity, adaptations, barriers and enablers to implementation, acceptability, adverse/unintended consequences, travel mode behaviour and attitudes** (assessed at 1 year follow up). Using data collected via Bradford Council ANPR survey (see Figure 3) we will also assess **proportion of 'compliant' vehicles in CAZ** at one year follow-up.

5.1.1.1.3 Analysis methods

In WP1A we will explore the **implementation and fidelity** of the intervention and determine the extent to which any adaptations affect the functioning principles (described in the logic model) of interventions or their components. For example, assessing categories of 'what' (e.g. reduction in numbers of non-compliant vehicles); 'how' (e.g. provision of addition public transport infrastructure; incentives schemes to replace vehicles); 'to whom' (families/children; business); 'by whom' (e.g. council, contractors, public representatives), and whether any (dis)benefits of the intervention are spread equally amongst different socio-economic groups. Qualitative data from the stakeholder interviews and public focus groups will be analysed separately using thematic analysis.[58] Stakeholder interviews will focus on identifying barriers and facilitators to intervention implementation; the COM-B model [59] will be used as a conceptual model to categorise identified barriers and facilitators. Process implementation data (e.g. documentation forms, meeting minutes) will be reviewed by the project management team, and intervention components categorised into adaptation levels (implemented, not implemented, modified). These will be tabulated, scored and presented descriptively. Documents collected to inform contextual influences will also be analysed using thematic analysis. All forms of implementation and adaptation evaluation data will be used to provide a picture of which (and how) adaptations impacted on which outcomes in relation to the intervention descriptors. Data from our **population survey (WP1B)** will support an understanding of the mechanisms of any change and will compare travel/air quality attitudes and behaviour pre and post implementation using McNemars test, paired t-test and Wilcoxon signed rank sum test, stratified by participant characteristics such as ethnicity and socio-economic status. We will be able to examine changes for respondents living within and outside CAZ boundaries to explore whether any changes in behaviour or attitudes differ according to proximity to the CAZ boundary. **We will combine insights from WP1A and WP1B** with relevant data from Bradford Council (e.g. the ANPR survey) to critically review the proposed logic model (appended); including developing a 'dark' logic model [60] outlining key barriers to implementation and threats to the intervention logic to explain any observed unanticipated or adverse events.

5.1.2 Work package 2

Here we will explore **mechanisms** of impact of the B-CAP on **air quality** using routinely collected air quality monitoring data, supplemented by citizen science collected air quality data around schools. A recent pilot study found that 59% of children's exposure to pollution occurs during the school day, or on the commute to school.[48] To explore changes in children's exposure **we will train school pupils and teachers to act as 'citizen scientists' to implement monitoring protocols using state-of-the-art validated mobile and static air quality sensors**. The data collected by these citizen scientists will measure the exposure experienced by children in the region, allowing identification of the areas/times when peak exposure occurs and the fraction of time when exposure is high. Static PM monitors and NO_2 diffusion tubes will be placed in 12 schools (spanning a range of socio-economic situations) to continuously sample for the year prior to the B-CAP and a year post implementation. Using a repeated measures panel design we will assess children's exposure levels during the school day and commuting period simultaneously in 1 x 2 week periods in the year prior to implementation; and 3 x 2 week periods in the year post implementation. Via Co-applicant Tate, we are able to add significant added value to our analyses by leveraging the extensive routine monitoring data, analysis protocols and outputs which will be undertaken as part of the DEFRA national evaluation (which uses a before-and-after design) to determine the impact of Bradford's B-CAP on levels of NO_2 along with other control sites across the UK.

5.1.2.1 Air quality

We will explore the impact of the B-CAP on air quality across the district using routinely collected air quality information collected by Bradford council and analysed by the DEFRA national evaluation. This will be supplemented by additional school based citizen science monitoring to determine changes in personal exposure to pollution as a result of the CAZ.

5.1.2.1.1 Sampling and data collection methods

Routine data: Council led routinely-collected hourly data of NO_2 from seven continuous real-time monitoring stations (with three also measuring PM_{10} and $PM_{2.5}$) will be extracted over the study period, supplemented by 40 NO_2 Palmes diffusion tubes. Data will be collated for three years prior, and three years post implementation. **Citizen science monitoring:** We will recruit 12 schools to take part in citizen science mobile air sensing comprising over a 24-month period (encompassing the year prior, and the year post CAZ implementation). This will involve installation of static pollution sensors in key school locations continuously recording PM and NO_2 (extended observation period); and 'intensive observation periods' where mobile sensors are carried by children during their school week and commute to school. Four schools will be located within the CAZ boundary, geographically separated to provide maximum coverage of the zone; these will be matched with 4 schools located just outside the CAZ boundary (to explore any potential ‘displacement’ of pollution caused by drivers taking alternative routes to avoid the CAZ), and 4 schools distal (>2km) from the CAZ boundary. Figure 1 (right panel) illustrates the spread of primary schools in and around the CAZ boundary. Schools will be matched on key criteria including area level SES, size, ethnicity and proximity to road. This will allow us to examine any distance related dose-response impacts of the CAZ on pollution exposure amongst school children.

Pilot: As a result of the pandemic and subsequent national and local lockdowns in Bradford, the recruitment of schools and citizen scientists has been unavoidably delayed. The intervention (BCAP) has also been impacted and implementation work is now due to begin in January 2021 and become operational in January 2022. Although we have recruited all 12 schools, due to repeated school closures and strict Covid-19 compliance procedures in schools, we have been unable to visit all the schools for child participant (N=240) recruitment and have only managed to recruit child participants at one school. We have therefore decided to utilise this time to conduct pilot citizen science work. This will allow us to test the useability of the sensors and any issues that may arise from the uploading of data and data management. Recruitment of child participants will commence when schools re-open to pupils and allow access to visitors. Currently we are anticipating this to be in the second half of the winter term (Feb 2021).

Equipment: In order to assess PM we plan to use the commercially available In order to assess PM we plan to use the commercially available Atmotube sensors (see https://atmotube.com/products/atmotube-pro?view=en). These small, portable sensors will be supplemented with a smart phone for GPS tracking. A web dashboard to allow easy visualisation of the data is already under development (via the University of Leeds). Data collected from sensors will be uploaded to the web dashboard and lesson plans in science, maths and computing will be built around the analysis of the measured data and will form a key dissemination output. NO_2 will be assessed using the same type of standard Palmes NO_2 diffusion tubes as used by Bradford council.

Continuous static monitoring: Within in each school we will work with pupils to build and install three static PM monitors: (two inside e.g. classroom, dining hall) and one outside the school (e.g. playground). These will run continuously taking measurements every minute. We will validate sensors using council real-time monitoring stations to ensure accuracy. In addition, we will install three outdoor NO_2 diffusion tube (e.g. playground, school gates) which will be changed monthly.

Personal exposure monitoring: Pupil citizen scientists will be trained to assemble and carry the PM sensors in a small rucksack during their school day (including their commute to and from school) for a total of three x two week periods (corresponding to school terms) in an intensive measurement period in the 3 months prior to B-CAP implementation and the 12 months post implementation (4 intensive observational measurement periods in total). We estimate from our previous analysis of roadside and background air quality trends [62] that 3 distributed months of monitoring prior and another 3 distributed months post implementation, with supporting meteorological data (wind speed/direction, temperature, relative humidity), is sufficient to capture the majority of conditions and allow quantification of the change in exposure due to the B-CAP. We have chosen multiple pollution measurement periods combined with the continuous static data to account for day-to-day variations in the levels of background air pollution concentration (primarily due to meteorological conditions) in order to estimate changes in children’s exposure due to the B-CAP. Within each school we will recruit a minimum 20 children from Years 5 and 6 (aged 9-11, total n=240) to carry the sensors. Children will be nominated by school teachers to ensure coverage of a range of locations around the school, and equal numbers of boys/girls, and coverage of different ethnic groups. Inclusion criteria will include: parent provided informed consent, ability to wear and operate mobile sensor device. Our pilot work suggests it is not feasible to ask children to wear devices for more than one week at a time; thus, in order to obtain all 20 children per school worth of data collection we will allocate eligible pupils to one of two data collections teams (week 1, week 2, week 3, week 4); this order will be retained for all data collection periods (i.e. individual children will measure during the same week in year 1 and year 2). Within each school, 5 pupils per week will wear the monitors (e.g. a total of 60 children per week across 12 schools, for four weeks). Children will be asked to carry the sensor for one week, including their journeys to and from school. They place it in the same room as them when stationary (for example in lessons). Children will be encouraged to engage in normal activity throughout the week. They will complete a short diary to record method of travel to school, and locations visited each day. Detailed instructions and training will be given to pupils and parents.

5.1.2.1.2 Key outcomes

Within WP2, key outcomes will assess whether the B-CAP impacts on air quality. They will include **routinely monitored air pollution** (assessed via DEFRA national evaluation at 1 year and 3 years follow up) and **mobile-sensed personal exposure to air pollution** (assessed up to one-year follow-up).

5.1.2.1.3 Analysis methods

Routine air quality: Routine data will analysed by the DEFRA national evaluation team at no cost to the current proposal and will allow an analysis of trends in air quality across the district to be analysed over time. The DEFRA national evaluation will be examining 28 local authority areas (including Bradford) who are developing air quality plans and associated control sites. The analysis will explore the impact of the plans on pollution over and above underlying trends in air quality, traffic demand, transport use and the evolution of the vehicle fleet. The approach estimates the time-varying background levels of air quality from the Automatic Urban and Rural Network (AURN) of continuous monitoring stations for any given time point, and subtracts these from locally measured air quality data at roadside locations so that the contribution and trends associated with local traffic and the implementation of the B-CAP can be identified (see Figure 4). As air pollution levels vary with fluctuations in emissions and dispersing air-flows, the underlying changes can only be established by 'de-weathering' and 'de-seasoning' local data.[63] Then any abrupt or gradual changes in these trends around the intervention date of the B-CAP can be estimated using change point detection methods.[64]

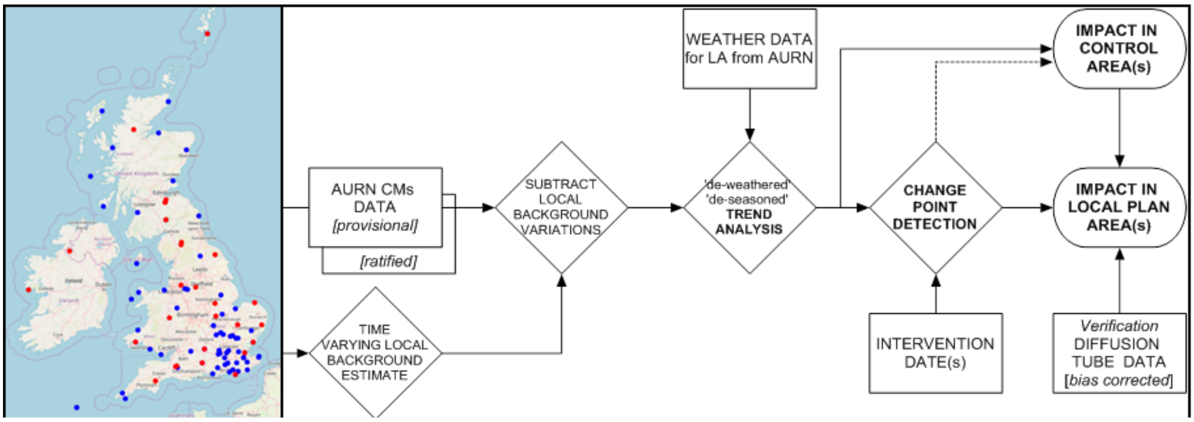

Figure 4: Location of AURN continuous monitoring (CM) sites across UK (left panel), and workflow for processing NO_2 routine monitoring data (right panel)

The DEFRA evaluation methods for processing data will be adapted to deal with the additional data collected across our 12 schools within our intensive observation period (mobile sensing with n=240 citizen scientists) and extended observation periods (continuous monitoring from static sensors). For both, data from sensors will be processed to isolate only data measured outdoors i.e. ambient levels not indoors or in a vehicle. Using processes identified above we will subtract background pollutant levels and remove weather and seasonal influences. This will allow us to isolate the contribution of local traffic emissions (and other sources) to overall exposure, coupled to this the indoor and external sensors will allow us to further apportion exposure regimes.

The **personal exposure** of school citizen scientists (n=240) before and after the introduction of the B-CAP will be mapped onto a 500m x 500m grid centred on each school. Any difference in levels, over the under-lying trends (as determined by the DEFRA evaluation project), will be attributed as impacts of the B-CAP. If the intervention is successful, it is expected that any differences would be greatest for the schools located within the CAZ boundary; however as the CAZ may influence overall traffic volume and traffic flow the benefits may extend beyond the CAZ boundary. Our study design allows us to explore any dose-response relationships with schools located on CAZ boundaries and distal to the CAZ boundary. We will explore differences using a 2 (pre/post) x 3 (location: inside, bordering or distal to CAZ) design using the Friedman test. Data from personal sensors will also be used to create an 'exposure index' along key transit routes to and from schools, allowing us to explore impact of the B-CAP on exposure during the school commute.

For the extended observational period (static monitoring) we will generate an understanding of pollutant distribution in the area, we will use data interpolation between the sites alongside the annual pollutant profiles close to the project schools. This extended period will have an initial duration of a minimum of 24 months centred on the introduction of the B-CAP, although we will explore feasibility of maintaining sensors and rolling out data collection beyond this time.

5.1.3 Work package 3

Here we will assess the extent to which implementation of the B-CAP impacts on **health outcomes**, in **a quasi-experimental interrupted time series design** using our CHC and BiB data sets. We will compare trends of health outcomes collected three years pre, and three years post implementation. Using the CHC dataset, **in WP3A we will explore changes in a range of health outcomes across the life-course up to three years post implementation**. We will explore outcomes overall and separately for children (at birth: pre-term birth, birth weight; and 0-17 years: respiratory health), adults (18 – 64 years, respiratory and cardiovascular health) and older adults (65 years +, respiratory and cardiovascular health). To explore distributional health (inequality) impacts of the CAZ we will stratify using available demographic characteristics including gender, ethnicity and deprivation level (linked to lower super output level). Drawing on the PROGRESS framework for health equity[49], and our extensive experience in exploring health inequalities within the BiB cohort, **in WP3B we will investigate in detail the impact of the B-CAP on health inequalities,** considering a wide range of characteristics, focusing on respiratory health outcomes for 13,500 BiB children.

5.1.3.1 Life course health outcomes

Our primary analyses will use interrupted time series analysis (ITS) to explore the impact of the B-CAP on health outcomes (respiratory and cardiovascular health, and birth outcomes) at three years post implementation using our CHC and BiB datasets.

5.1.3.1.1 Sample size and power calculations

In order to explore power of our ITS to detect changes in health outcomes we have consulted a range of epidemiological studies and systematic reviews, along with identification of relevant intervention studies for effect sizes (see section 2.3). Our own research has found that a 10ug/m3 increase in NO_2 is associated with a 9% increase in the odds of low birthweight while a 5ug/m3 increase in PM2.5 is associated with an 18% increase in odds of low birth weight.[5] A recent systematic review found a small, but significant 2% increase in the odds of low birth weight associated with an increase in exposure of 37ug/m3 NO_2 across pregnancy from 14 studies; odds increased to 7% when assessing by each specific trimester.[65] For other health outcomes, systematic reviews have shown: a 10ug/m3 increase in NO_2 to be associated with increases in respiratory disease hospital admissions ranging between 0.57%-3.5%, and a 0.66% increase in admissions for cardiovascular admissions, with stronger effects among children and the elderly [66-70]. Recent intervention studies are reviewed in detail in section 2.3, but offer no consistent results.

It is clear that further evidence is needed to determine the likely impact of interventions targeting vehicular emissions on health. There are, however, no existing evaluations on which to base effect size assumptions. The UK Government's proposed CAZ strategy is considerably more ambitious than previous schemes such as the London LEZ. The London LEZ went live in 2008 and aimed, through charging, to discourage the use of heavy-duty diesel vehicles older than 8 years (or retrofitted to necessary specifications) and lower levels of particulate matter (PM_{10}). Due to other sources of PM_{10} including diesel light-goods vehicles and cars, impacts were small. CAZs are targeted at encouraging the replacement of vehicles with the newest engine and exhaust after-treatment systems, that the automotive industry now has to prove, are cleaner on-the-road (the Euro 6 vehicle emission standards and Real-Driving Emission legislation). In real urban driving conditions these vehicles can emit ten-fold fewer air pollutants (NO_2, NO_X, PM_{10} and ultra-fine particles) than their predecessors. The UK is the first European state to implement such a strict Clean Air Zone (the London Ultra-LEZ, April 2019). **Based on the evidence reviewed and working on the assumption the B-CAP will reduce NO_2 by between 12-18ug/m3 we have estimated a 5% reduction in health outcomes (emergency / GP attendances and incidence related to both respiratory and cardiovascular outcomes); and a 2% reduction in adverse birth outcomes.** A 5% reduction in emergency attendances relation to respiratory and / or cardiovascular illness would likely have substantial cost-savings for the NHS.[71]

We have reviewed methods to inform power calculations; there are no accepted guidelines for calculating power in ITS designs.[72, 73] Power is dependent on a variety of factors including the length of the time series (with some suggesting 100 observation points required for correct model identification),[74] the balance of time points before and after the intervention, the expected effect size, the extent of autocorrelation between the data points, and sample size per time point. Power increases in a balanced ITS design; in WP3 our proposed study would increase the power by ensuring roughly equal number of data points for the 3 years pre- and 3 years post-implementation. We illustrate the potential power of our analyses for our primary outcome, respiratory health (measured as emergency/GP admissions): in pilot analysis of a subsample of our CHC data set (N=316,585, assessed between Jan 2016-Dec 2018) we observed an average of 380 respiratory attendances per week suggesting adequate counts per observation period. Using weekly counts will give us a total of 312 observation points over a six year period. **Guidance from simulations of Winquist et al [73] suggests we will have >90% power to detect a 2% reduction in admissions.** For our secondary outcomes (cardiovascular/birth) we will assess counts either weekly or monthly depending on prevalence. Using monthly events a balanced design would give us 72 evenly distributed observations points We will explore increasing the baseline intervention trend period by 28 months (e.g. 5 years pre-implementation) to ensure we can maintain 100 observation points (which is acceptable if there are no other major changes in pre-intervention trends in that time period). [72] In WP3B we will focus only on respiratory attendances within the BiB cohort using similar methods. For these analyses we will have fewer events per observation period and so will perform analyses using either weekly or monthly counts.

5.1.3.1.2 Health outcomes measures

We have selected a range of health outcomes to explore, informed by epidemiological evidence. Our primary health outcome is respiratory health, with secondary outcomes of cardiovascular health and birth outcomes as outlined in Table 1. We will explore **health inequalities** in detail for respiratory health amongst children using the BiB data set.

Table 1. Description of health outcomes

Health Outcomes	Relevant ICD-10 codes	Length of follow up	Life-course stage
PRIMARY: Respiratory health: emergency / GP attendances, assessed weekly	Respiratory infection (J05.0, J10-J16, J18, J20, J21); bronchitis (J40 – J42); asthma (J45); COPD (J43-J34)	1 year 3 years	Children Adults Older adults
SECONDARY: Cardiovascular health: Emergency / GP attendances, assessed weekly/monthly	Angina/MI (I20-I22, I24, I25); dysrhythmia/conduction disturbance (I44-I49); heart failure (I50); stroke (haemorrhage or infarction; I60-I64))	1 year 3 years	Adults Older adults
SECONDARY: Birth outcomes, assessed monthly	Pre-term birth (<37 weeks gestation: O60.1, 060.3, P07.2, P07.3) and low birth weight (<2.5 kg: P07.0, P07.1)	3 years	Children

5.1.3.1.3 Sampling and data collection methods

Data extraction algorithms for health outcomes will be compiled using WHO International Classification of Disease (ICD) 10 and READ codes and applied to our CHC and BiB data set (see Table 1). Relevant Read codes will be identified by mapping them to ICD-10 codes using the NHS Digital Technology Reference data Update Distribution. Within our CHC data set, we will extract a range of other characteristics recorded routinely in health records including gender, age, and ethnicity to characterise outcomes along social gradients. Data will be linked to Lower Super Output area. Within the BiB cohort, in addition to linked routine data, we have detailed ongoing assessments of health, wellbeing, cognitive development and socio-economic circumstances currently underway amongst children aged 7-11,[75] along with monthly geocoded address data. This current wave of data collection will complete in December 2020 (prior to implementation). This detailed baseline information will be available at no cost to the study team and will allow detailed subgroup analysis to be performed in WP3B to explore the impact of the B-CAP on health inequalities using dimensions such as SES (education, index of multiple deprivation, financial security and employment status) and ethnicity.

5.1.3.1.4 Analysis methods

In WP3A we aim to explore the impact of the B-CAP on primary and secondary health outcomes across the life-course using our CHC data set of >500,000 individuals. We will use an ITS analysis with a Poisson link function to test for changes in the regression lines of weekly/monthly events of health outcomes using longitudinal data from 3 years pre to 3 years post B-CAP implementation for our three population groups (children, adults and older adults). An ITS will also be created for a non-equivalent outcome of finger wounds as a comparison. We will provide an interim analysis at one year post implementation for our primary health outcome (respiratory health). Data will be assessed for autocorrelation and over-dispersion using ARIMA methods and adjusted for seasonality. Subgroup analyses will explore variations by ethnicity and deprivation level. We hypothesize that implementation of the B-CAP will lead to a larger decrease in hospitalizations for those of the lowest deprivation quintiles and we will explore whether or not this effect is modified by ethnicity. Sensitivity analyses will be conducted to test the impact of varying model assumptions. For example, although we hypothesise that there will be a gradual reduction (slope) in our health outcome, we will also explore whether there have been more abrupt step changes. Further, we will run models with different lag periods.

For WP3B, we will conduct **detailed analyses on health inequalities** using data from the BiB cohort, which has individual, in addition to area level, information on socioeconomic status. We will replicate analysis on respiratory outcomes looking at both combined respiratory morbidities and separately at asthma/wheeze, exploring multi-dimensional measures of socio-economic status,[76] ethnicity, deprivation, employment, religion, education and social capital using the PROGRESS framework as a guide to selecting relevant indicators.[49]. The population survey conducted as part of WP1 will provide additional information about whether the B-CAP resulted in changes to travel behaviour, leading to different levels of exposure, and could be included as a covariate in models along with variables collected as part of the cohort such as time spent outdoors or distance and use of nearby green spaces.

5.1.4 Work package 4

Following guidance on health economic evaluations alongside natural experiments,[50] and our recent work,[51] we will perform a **multi-sectoral health economic evaluation** to determine value for money of the B-CAP considering **healthcare resource use and costs, and quality adjusted life years (QALY)**. Our evaluation will explicitly consider the costs and benefits for a range of decision makers (for example, health care, private economy and local authorities) and sectors (e.g. business, health), along with different SES groups to capture distributional effects (e.g. burden of paying charge) which may impact on inequalities.

5.1.4.1 Health economic evaluation

The health economic evaluation will determine the **value for money of the B-CAP, including any distributional impacts.** This will consider the cost of delivering the interventions in the **B-CAP**, and any cost-offsets, for example due to reduced hospital admissions. The economic evaluation will take **a multi-sectoral perspective**, informed by guidance for conducting economic evaluations within quasi-experiments [50] and our previously published framework [51]. This framework sets out the series of assessments to be made, considering the fact that the B-CAP will have implications for different sectors (NHS, local authority, individuals and private businesses) and will involve different decision makers.

5.1.4.1.1 Sampling and data collection methods

Work-package 4 will use data collected from WP1A (intervention costs) and WP3 (health outcomes).

5.1.4.1.2 Key outcomes

Key economic outcomes include **healthcare resource use and costs**, **quality adjusted life years**, **distributional effects** (all at 3 years follow up).

5.1.4.1.3 Analysis

We will consider the relevant costs, opportunity costs and benefits for each decision maker/sector involved. Potential sources of double counting will be explored and adjusted for. We will then summarise the impacts on each sector, for example, the impact on health and health care costs from an NHS perspective. An aggregate approach across all sectors will also be considered with costs and benefits brought together to estimate the societal benefit of CAZ, which can be expressed as Net Benefit (benefits net of any opportunity costs). Costs (including opportunity costs) and outcomes from healthcare, the local authority and the wider economy, will be considered. Different time horizons will be considered for the analysis to account for budget cycles, differences by sector, i.e. cost may have to be justified over a short time period for some sectors, including local authorities. A decision model will be developed, extrapolating the changes in short term outcomes to longer term costs and consequences. We will use data on the immediate health impacts and health care costs from the CHC dataset and build on the ITS analysis conducted in WP3A. For changes in short term health outcomes, for example cardiovascular, respiratory disease and incidence of pre-term births, models will be extrapolated over the longer (life) time, to determine **quality adjusted life years (QALY)**. The overall cost of the B-CAP will be estimated, and we will show how much of this cost falls on local authorities, and how much falls in the wider economy where they cascade to individuals and private companies (e.g. cost of charge for non-compliant vehicle). The costs of the B-CAP to the local authority and the wider economy, will be assumed to continue for as long as the intervention is applied. **Wider societal benefits** will be considered by exploring any impacts on productivity and individuals' private consumption related to health status, i.e. a health event incurs a productivity loss and associated cost to the economy in terms of lost wages and may reduce an individual's private expenditure.[77]

The analysis of CHC data will also allow us to consider the change in health across different socioeconomic groups (defined by the Index of Multiple Deprivation of the population of the area in which people live at Lower Layer Super Output Area). **Distributional cost-effectiveness analysis [78]** will be used to evaluate the impact the B-CAP has on the **socio-economic distribution of health**, reflecting both the direct impact of the B-CAP on the health of different socioeconomic groups and the impact on heath in terms of forgone health from opportunity costs resulting from any costs associated with the B-CAP. The value for money from the B-CAP can be evaluated considering both goals of improving total population health (net benefit in terms of QALYs for the population of Bradford) and reducing inequalities (e.g. reducing the gap in health outcomes between the most versus the least deprived groups in Bradford, or between ethnic groups).

5.1.5 Added value from local authority and DEFRA evaluation

We are able to add considerable value to our process and mechanism evaluation (work-packages 1 and 2) by combining our bespoke data collection with analysis from the DEFRA national evaluation (led by Co-applicant Tate) to explore the impact of the B-CAP on routinely collected air quality and traffic flow data. In addition, we have access to detailed traffic fleet data (type of vehicles operating within CAZ, and compliance with Euro standards) collected by Bradford Council traffic fleets, collected via Automatic Number Plate Recognition systems (ANPR) which will provide objective indicators of change in traffic fleets as a result of the B-CAP.

5.1.6 Narrative synthesis of findings

Evaluation of complex, system-wide interventions such as the B-CAP requires a comprehensive evaluation strategy. Our conceptual model (Figure 3) recognises the links and interactions between all work-packages. For example, in order to understand the impact of the B-CAP on **health inequalities** we will combine insights from qualitative research (WP1A), survey (WP1B), air quality assessment (WP2), health outcomes (WP3) and our health economic analysis (WP4). In order to explore bidirectional influences of **context and setting** we will consider our findings in light of policy changes, new information (for example, national trends in air quality, vehicle ownership) and information from the DEFRA national evaluation over the duration of the study. We will synthesise findings from each work-package to develop a broader and comprehensive analysis which will help us to develop recommendations to inform policy.

5.2 Setting/ context

Our study is located in Bradford, an urban, multicultural city in the North of England, UK. Bradford is the 6th largest metropolitan district in the UK with a population of >530,000. It has a multi-ethnic population with 67% identifying as White British and 20% as Pakistani in the last census.[52] It is a deprived city, with 40% of Bradford residents living in areas that rank in the most deprived quintile (20%) of local areas in England [53]. It has high levels of ill health, e.g., higher than average mortality from cardiovascular disease under 75 years (102.2 per 100,000), low birth weight babies (3.6%),[54] and 22% incidence of wheezing disorders amongst children.[55]

5.3 Control/ comparator Group

Our primary analysis of intervention effectiveness on health outcomes will be conducted using **Interrupted Time Series (ITS)** analyses in WP3. In this quasi-experimental design, our comparator group will be longitudinal health outcome trends amongst Bradford residents from three years prior to B-CAP implementation; these will be compared with intervention trends up to three years post implementation. We will also explore the effects of the B-CAP on a non-equivalent control outcome extracted from our CHC dataset, such as finger wounds,[37] that is not expected to be affected by the intervention. In our implementation work-package (WP1B) and air quality work-package (WP2) we will compare travel mode behaviour and attitudes and mobile sensed measures of air quality up to 1 year pre implementation. The National DEFRA evaluation (led by Tate) will use an ITS design to explore the impact of similar air quality plans (including CAZs) on routinely collected air quality in 28 intervention areas (including Bradford) and associated control sites. We will be able to use this control data to contextualise the influence (if any) of the B-CAP on air quality in Bradford.

5.4 Study population

For our primary analysis (WP3A), we plan to take **a life-course approach using the entire city population** as our evaluation test-bed. Using our CHC data set of linked routine health and education data from over 500,000 Bradford residents, we will stratify the Bradford population into three groups (children: at birth and 0-17 years; adults: 18-64 years; and older adults (65 years +). Key health outcomes will be extracted from this dataset to provide a comprehensive analysis of any effect of the B-CAP on population health outcomes.

We will add considerable value to the evaluation by using the **BiB cohort of 12,500 Bradford families and 13,500 children** for whom we have longitudinal detailed health and wellbeing assessments (including routine data) and rich socio-economic and ethnicity information.[56] This cohort will allow us to provide more detailed insights into the effect of the B-CAP on health inequalities, and to interrogate our proposed logic model. BiB is a representative research-active cohort of families with children born in the city between 2007-2011 (~60% of the eligible population at time of recruitment). Approximately 85% of the cohort is still resident within Bradford. Fifty percent of mothers in the cohort are of South Asian origin. All of the parents in the cohort are of working age. Routine linked health data is available for 99% of parents and children (which also allows geocoded address information to be captured monthly from primary care records), and education data is available for 85% of children. In addition to these large datasets, other elements of the evaluation will focus on bespoke data collection with key groups including decision makers and stakeholders who have been involved in implementation of the B-CAP plans; and with members of the public, schools and families living in and around the CAZ boundaries.

5.5 Assessment and follow-up

We have included a range of outcome measures that are likely to have shorter (emergency/GP attendances related to respiratory and cardiovascular disease), and longer term effects (birth outcomes). The B-CAP is mandated to improve air quality to compliant levels in *as quick a time as possible*. Based on modelling, the likely impact of measures included within the CAZ, compliance is due to be achieved 1 year post implementation, with gradual ongoing improvements over time. However, research has shown there is no 'safe' level of pollution for health, thus any improvements in air quality are likely to have an impact on health, regardless of whether they are above, or below legal limits.[5] Evidence has shown an immediate temporal relationship between increases in pollution and hospital attendances [67] thus we would expect to see an immediate reduction in emergency and GP attendances related to respiratory (adults and children) and cardiovascular (adults only) events provided the B-CAP is successfully implemented. Our other outcomes (birth outcomes) are likely to show an effect in the longer term. We have chosen **three years as our primary follow-up period to measure effectiveness (with an interim reporting period at one year)** period in order to provide timely evidence for decision makers, including other local authorities on the health impacts of CAZ approaches to improving air quality. As our primary analysis relies on routine data we have **the unique opportunity to revisit our study populations beyond the lifetime of the planned rsearch to provide even longer term follow-ups of the health outcomes outlined in Table 1. W**e have chosen a one year follow up for our process and evaluation outcomes to ensure timely capture of challenges related to implementation, and identification of the proximal effects by which the intervention might have an impact on outcomes.

5.6 Unanticipated outcomes

During our stakeholder and public consultations we have identified concerns about **potential adverse outcomes.** For example, there is a perceived risk of displacement of pollution to the borders of the CAZ as non-compliant vehicle operators choose to take different routes to avoid a charge. There is also the potential for increasing inequalities by economically disadvantaging poorer individuals/families (and taxi drivers in particular) who are more likely to have non-compliant vehicles. There are likely to be a range of other **unanticipated outcomes** which we plan to fully document and record as part of our process evaluation, using information from our semi-structured interviews with stakeholders, documentary analysis of documents related to implementation and focus groups with members of the general public. This period of data collection will be completed by one year post implementation and a summary of unanticipated outcomes will be presented at the Bradford Air Quality Programme Board.

5.7 Scalability and translation

The implementation of charging clean air zones is a core component of Government policy to deal with levels of NO_2 exceeding legal limits and will be implemented in a number of regions across the UK. Using standardised frameworks of intervention implementation, context and transferability.[45-47] our process evaluation will document key factors of both the context and setting which contribute to success (or failure) of these initiatives to improve health and provide cost savings. We will update our intervention logic model to take into account any additional observed factors in order to allow other areas to learn about key context or setting specific barriers and enablers which may have a bearing on successful implementation or transferability. Based on our learning we will provide guidance to other local authorities planning to implement a CAZ approach.

5.8 Socioeconomic position and inequalities

We will explore in detail the impact of the B-CAP on health inequalities experienced by different socio-economic and ethnic groups across all work-packages. Where we will be collecting new data (WP1/2) we will ensure that recruitment strategies are optimised to ensure representativeness of our sample, including access to seldom heard/underserved groups and ethnic minority groups by using our experienced team of multi-lingual community researchers within BiB. Our rich Born in Bradford dataset, combined with our mixed methods process evaluation, will allow us to explore differential health and economic impacts according to ethnicity, deprivation, employment, religion, education and social capital following the PROGRESS framework.[49] Given the potential widespread adoption of charging CAZs, according to government policy, discovering the impact of these initiatives on health inequalities will be crucial to ensure equity of impact amongst different groups.

6 Dissemination, outputs and anticipated impact

We will develop bespoke dissemination, knowledge exchange and impact plans for our key stakeholder groups. For National (DEFRA; Public Health England; NICE; Local Government; Clean Air Groups; Active Travel groups) and regional (local authorities, schools) stakeholders, we will produce **policy and parliamentary briefing notes, plain English summaries and hold dissemination events**. We will develop **implementation guidance** for other local authorities, highlighting successful implementation strategies using the 'Context and Implementation of Complex Interventions' framework as a guide,[47] and issues relating to transferability.[46] For academic audiences, we will publish our findings in **high impact open access journals** and present at relevant national and international conferences.

We have an exciting opportunity to **disseminate our findings creatively to families and children.** Building on our citizen science air quality monitoring, we will work closely with teachers to develop **school based curriculum materials** which will allow pupils to assemble bespoke low cost air quality monitors using the Raspberry Pi microcomputers and use these to develop and evaluate their own local initiatives to improve air quality. Our curriculum materials, which will be developed in close partnership with co-applicants Thorpe (head of Science, St Stephen's School) and Pringle (atmospheric scientist and engagement fellow, University of Leeds) will provide pupils with a range of hands-on research experience including coding, comparing data from multiple sensors (accuracy), measuring, formulating research questions, designing interventions, evaluating interventions, and reporting results. We will develop a web data dashboard allowing citizen scientists to view their air quality measurements on an interactive map, and compare with other areas. **We hope to use these materials as a springboard to engage pupils, particularly from disadvantaged backgrounds, to engage in science, technology, engineering and mathematics (STEM) learning.** We will hold engagement events with parents and teachers from participating schools outside of intensive measurement periods to raise awareness of issues related to air quality.

We are **committed to sharing our learning as widely as possible** using a variety of channels. Air quality is one of the most pressing health issues faced by our country, and public interest in this issue is rising. However, qualitative research conducted as part of our grant development has highlighted that for some communities air quality is a 'hidden' issue and the links between pollution and health are poorly understood in some seldom heard / underserved groups. We will use a range of communication channels to inform both engaged and non-engaged audiences of our work. At a national level **we will engage closely with our media partners** (including BBC Radio 4, The Guardian) to promote relevant press coverage of key findings. We will produce a range of **blogs and video summaries** and disseminate these widely using our established social medial channels (Twitter, Facebook, and YouTube). For local communities, we will hold a range of **engagement events** in community venues (schools, libraries, mosques, community centres) to give a summary of our findings. We will also promote our school curriculum materials widely using established links with the Centre for Applied Education Research (http://caerbradford.org/), and the Department for Education. Via co-applicants Jones and Tate, we have access to the **JAQU advisory group** (including 12 local authorities), **UN Environment**, and **Walk21** (leading international charter for walking) linking directly to national and international decision makers (see support letters); we will use these channels to promote our findings and implementation guides.

Our research has potential for great impact. The UK Government have committed over £475 million to tackle air quality, primarily through encouraging adoption of charging CAZs across the UK. However, as yet there is no evidence exploring the impact of these types of initiatives on health. **Our project is uniquely placed to explore the impact of this element of Government policy to tackle the effect of air quality on health**. **It is therefore likely to have great impact on the continued adoption (or cessation) of this policy**. Our research will be the first to quantify the impact of these types of policy on population health using a rigorous quasi experimental design. Our findings will allow those implementing similar initiatives to model the health impact within their own areas, and our health economic evaluation will enable informed decisions about value for money of such schemes. We also anticipate that our research will have impact for communities, increasing knowledge about the effects of air quality, providing strategies to reduce air pollution exposures, helping to reduce health inequalities, and promoting wellbeing. Our school-based curriculum materials will help to empower children living in disadvantaged areas, and inspire them in STEM related learning.

7 Project timetable

This is a 60 month project with a proposed start date of 1st July 2020. To provide timely evidence for decision makers, we have designed our evaluation to include an interim reporting point 1 year post implementation which will include key health outcomes, and full results of implementation and process evaluation, delivered by month(M)37. A Gantt timetable can be seen in Table 2.

7.1 Timescales

Ethics for WP1 and 2 will be obtained pre-award. **WP1A**: Document collation (policy, meetings) (Month[M]1-24), Stakeholder interviews (M24-26), Public focus groups (M24-26), Qualitative analyses (M25-30); **WP1B**: Questionnaire development and piloting (M1-6), Baseline population survey (M9-12), Follow up population survey (M22-25), Analysis (M26-29); **WP2**: Pilot (ongoing), Constructing and calibrating sensors; database development (M1-3), Web interface development (M4-6), Continuous PM and NO_2 monitoring (12 schools) (M1-24), Mobile exposure assessment (n=240) (M3,8,12,15,20,24), Development of curriculum materials (M12-24); **WP3A/B**: Data preparation and analysis (interim) (M22-36); Data preparation and analysis (final-3 years post implementation); **WP4**: Health economic evaluation (M53-58). **INTERIM REPORT** (M35-37); **FINAL REPORT** (M55-60).

Table 2. Gantt timetable

		Year 1 (Quarters)				Year 2 (Quarters)				Year 3 (Quarters)				Year 4 (Quarters)				Year 5 (Quarters)			
	Pre	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
CAZ prep																					
Implementation																					
Ethics																					
WP1A					*1									+				+			
WP1B											*3,4										
WP2									*2												
WP3A /3B													*5								
INTERIM REPORT														*6							

WP4																					
FINAL REPORT																					***7,8**
Mgt Grp		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
SSC			X		X		X		X		X				X				X		
Com Grp		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Sch Grp			X		X		X		X												

Key: *CAZ Prep: Council Set-up period for implementation of CAZ; Implementation – CAZ implemented in Month 12; Mgt Grp: Study management group meeting; SSC: Independent Study Steering Group Meeting, Com Grp: Community reference group meeting; Sch Grp: Schools reference group meeting. + System workshops. Asterisked numbers related to milestones (see below).*

7.2 Milestones

***1**: Baseline population survey completed, M12; ***2**: School monitoring completed, M24; ***3**: follow-up population survey completed M25; ***4**: Stakeholder interviews and public focus groups completed M26; ***5** interim analysis completed M33; ***6** interim report completed M37; ***7** final health and economic analysis completed M58; ***8** final report submitted M60.

8 Project management and governance

McEachan (Chief Investigator) will oversee the project and lead dissemination supported by a Programme Co-ordinator (to be appointed). An **operational group** comprising of work-package leads and research staff will meet monthly to oversee implementation of the research project. Individual work-package teams will meet more frequently as required and manage day to day activities. A **study management group** comprising all co-applicants will meet quarterly to oversee milestones and risks. A **community advisory panel** (chaired by Mahmood, and supported by Islam) will meet quarterly throughout and a **schools advisory panel** (parents, children, teachers, chaired by Thorpe and supported by Pringle) will meet twice per year (first 2 years) to help co-produce research methods, oversee progress and facilitate dissemination. Mahmood, Islam, Thorpe and Pringle will be key communication links between these groups and the study management group. McEachan and Jones are both representatives on the external Bradford Council Air Quality Programme Board (responsible for developing and implementing the CAZ and associated activities, meeting monthly) and will ensure alignment between research activities and implementation activities. An **independent study steering committee** will be convened to provide independent oversight (advising on methodology, ensuring studies are conducted according to protocol, research conduct and safety) and support the interpretation of findings. The group will meet twice in years 1-2; and yearly thereafter (7 meetings in total). As a low risk study, a Data Management Executive committee is not deemed necessary.

9 Ethics/ regulatory approvals

Ethics approvals for using routine data from both the Born in Bradford (baseline 07/1302/112 and follow up: 16/YH/0320, both from Bradford and Leeds NHS Research Ethics Committee) and Connected Health Cities datasets are already in place (Connected Health Cities Data: East Midlands – Derby NHS Research Ethics Committee 17/EM/0254). Ethical approval for new data collection activities in work-packages has been obtained from Bradford and Leeds NHS Research ethics committee (20/YH/0158). Bradford Teaching Hospitals NHS Foundation Trust will act as study sponsor.

10 Public involvement

We have consulted widely within our communities (2 workshops, total >50 attendees, funded by a PPI research grant), schools (primary and nursery), and 20 local councillors. We have conducted ten focus groups with ethnically diverse community groups living in deprived areas located within the proposed CAZ boundary. We have worked with 10 schools to pilot static air quality monitoring and have conducted citizen science walks using our planned monitors in one further school. Key learning has included: a) deprived communities may not perceive air quality as a health issue, b) communities are worried about unintended consequences (economic/physical) and inequalities; it is felt taxi drivers will be disproportionally affected; c) public transport and cycling infrastructure is not perceived as accessible/affordable d) schools/children are eager to engage with opportunities to monitor air quality and citizen science. We have used these findings to refine elements of WP1 (e.g. identifying stakeholder groups) and WP2 (citizen science exposure assessment). Public and school advisory groups will meet regularly to help co-produce our research.

11 Authorship and acknowledgement

The success of the research depends upon the collaboration of all participants. For this reason, credit for the main results will be given to all those who have collaborated in the research, through authorship and by contribution. Uniform requirements for authorship for manuscripts submitted to journals will guide authorship decisions. These state that authorship credit should be based only on substantial contribution to:

- conception and design, or acquisition of data, or analysis and interpretation of data
- drafting the article or revising it critically for important intellectual content
- final approval of the version to be published
- and that all these conditions must be met (www.icmje.org).

In light of this, the Chief Investigator, mentors and relevant staff will be named as authors in any publication, and an appropriate first author agreed through discussion amongst the Study Management Group (SMG) members. In addition, all collaborators will be listed as contributors for, giving details of their roles in planning, conducting and reporting the research. The BiB BREATHES team should be acknowledged in all publications, as should the NIHR PHR programme (as detailed below). Other key individuals will be included as authors or contributors as appropriate and at the discretion of the SMG. Any disputes relating to authorship will be resolved by the independent study steering group.

The Chair and Independent members of the study steering group will be acknowledged, but will not qualify for full authorship, in order to maintain their independence.

The SMG will agree a publication plan and must be consulted prior to release or publication of any trial data.

Individual collaborators must not publish data concerning their participants which is directly relevant to the questions posed in the research until the main results have been published. Local collaborators may not have access to data until after publication of the main results.

Processes for the drafting, review and submission of abstracts and manuscripts
The agreed first author of abstracts is responsible for circulating these to the other members of the SMG team for review at least 15 days prior to the deadline for submission.

The agreed first author of manuscripts is responsible for ensuring:

- timely circulation of all drafts to all co-authors during manuscript development and prior to submission
- timely (and appropriate) circulation of reviewers' comments to all co-authors
- incorporation of comments into subsequent drafts
- communication with the study steering group and NIHR
-

The first author is responsible for submission of the publication and must keep the BiB BREATHES team and all authors informed of the abstract's or manuscript's status. The SSC will be kept informed of rejections and publications as these occur. On publication, the first author should send copies of the abstract or manuscript to the study management group, the Sponsor and to all other co-authors, and ensure communication with the NIHR PHR programme as per their requirements.

The following funding acknowledgement should be included in **all** publications.

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For publications reporting data from Connected Health and Born in Bradford additional funding acknowledgements should be included. These can be obtained by emailing the BiB Director.

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