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The Queensland Family Cohort: Study Protocol

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Title:
The Queensland Family Cohort: Study Protocol

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Abstract

Introduction: The perinatal – postnatal family environment is associated with childhood outcomes including impacts on physical and mental health and educational attainment. Family longitudinal cohort studies collect in depth data that can capture the influence of an era on family lifestyle, mental health, chronic disease, education and financial stability to enable identification of gaps in society and provide the evidence for changes in Government in policy and practice.

Methods and analysis: The Queensland Family Cohort (QFC) is a prospective, observational, longitudinal study that will recruit 12,500 pregnant families across the state of Queensland, Australia and intends to follow-up families and children for three decades. To identify the immediate and future health requirements of the QLD population; pregnant participants and their partners will be enrolled by 24 weeks gestation and followed-up at 24, 28 and 36 weeks gestation, during delivery, on-ward, 6 weeks post-partum, and then every 12 months where questionnaires, biological samples and physical measures will be collected from parents and children. To examine the impact of environmental exposures on families, data related to environmental pollution, household pollution and employment exposures will be linked to pregnancy and health outcomes. Where feasible data linkage of State and Federal Government databases will be used to follow the participants long term. Biological samples will be stored long term for future discoveries of biomarkers of health and disease.

Ethics and dissemination: Ethical approval has been obtained from the Mater Research Ethics (HREC/16/MHS/113). Findings will be reported to (1) QFC participating families; (2) funding bodies, institutes and hospitals supporting the QFC; (3) federal, state and local governments to inform policy; (4) presented at local, national and international conferences and (5) disseminated by peer-review publications.

Trial registration: n/a

Article Summary

Strengths and limitations of this study:

Strengths

- In-depth data and biological sample collection of physical, social and mental well-being of mother, father/partner, and child at multiple time points
- Survey instruments based on validated tools and routinely collected clinical data
- Recognising the equal importance of the family relationships including same sex relationships on the child so that mothers, fathers or partners are all involved

Limitations

- Cultural consultation for individuals who identify as First Nations People is ongoing
- Cost to maintain cohort, infrastructure, storage of data and biobank is high, with lifelong surveillance of families dependent on philanthropic, state and/or federal support

Background and rationale

The Developmental Origins of Health and Disease (DOHaD) proposes that the intrauterine environment, when impacted by poor maternal nutrition, severe stress or illness, has a detrimental impact on the developing child, both in the short and long term. These prenatal effects can increase the risk of cardiovascular disease, hypertension, obesity, type 2 diabetes, metabolic syndrome and kidney disease [1-3]. However, as the scientific community learns more about how health develops in adulthood, we are also recognising the influences of the paternal environment and the impacts of the intergenerational insults on fetal development [4]. Longitudinal cohort studies that follow participants over time, taking repeated measures, provide compelling data and are powerful research tools to determine associations between a variety of health outcomes and can help drive significant policy change [5].

Although there have been 17 Australian birth cohort studies so far, only 2 have been federally funded; the Longitudinal Study of Australian Children (LSAC) established in 2004 [6], and Footprints in Time: Longitudinal Study of Indigenous Children (LSIC) established in 2008 [7]. While these two cohorts began the innovative approach of linking government administrative data, with basic physical and cognitive information, these children are now aged 15 and 10 years respectively, highlighting a need for more recent data to inform policy. As children were the point of interest for each of these cohorts, important antenatal, postnatal and early life data was not collected from parents, and no biological samples were accrued.

A systematic review of longitudinal birth cohorts in Australia that included measures from one parent and offspring are shown in Table 1. Of these cohorts; almost all were established over 20 years ago, only half of the studies included antenatal measures whilst less than half involved the partner. Of studies that included partners, only 3 studies had biological samples collected from the father. Research involving individuals who identify as First Nations People was minimal and identified only 2 cohorts with specific focus on these groups: the Gudaga cohort in Sydney, New South Wales (NSW) [8] and the Aboriginal Birth Cohort (ABC) in the Northern Territory (NT) [9]. However, since the time of this publication there have been others developed in Australia, including the Gomeroi gaaynggal cohort (NSW) [10], and PANDORA cohort (NT) [11], that are solely focused on the First Nation community.

Of the Australian birth studies, the 2 largest are the Raine Study (Mothers n=2900, Babies n= 2868 and Partners n=2804) and the Mater-University of Queensland Study of Pregnancy (MUSP) (Mothers n=7631, Babies n=7223, Partners n=522) with a retention of 82% and 53% at 14 and 21 years respectively [12, 13].

The Raine Study was established in Western Australia (WA) in 1989 with a total of 2,900 women birthing in Perth enrolled [14]. Infants from the cohort have been followed for 27 years. Collection of data began at 18 weeks' gestation of pregnancy and has included diverse survey topics of participants including, for example; education, toxin exposures, breastfeeding child behaviour, physical activity, mental health from mothers, fathers, offspring as well as biological samples from the same. Although, the investigators of this cohort suggest that this is perhaps the most comprehensive longitudinal study of its kind to date in Australia, there is no doubt that significant societal change has occurred in the 30 years since it began. As such intrauterine and paternal influences during conception and pregnancy are likely to be markedly different.

Only 2 of the studies identified in the systematic review by Townsend et al., [15], originated in Queensland (QLD) - Environments for Healthy Living (EHL) Griffith birth cohort and the MUSP cohort. The larger of the two (MUSP), was established over 35 years ago and continues to follow participants with a focus on sociological and psychological outcomes [16]. While its impacts on QLD health practice and policy have been considerable, since the inception of this cohort, there have been significant societal changes. The MUSP cohort did not recruit partners, and only 4.04% (n=273 from 6,527 recruits) were First Nations People with poor retention rates of this subgroup limiting the capacity of the study to fully appreciate the health needs of First Nation families during the perinatal period [17]. The QLD population has changed significantly since 1980 with a dramatic rise in obesity rates now affecting up to 50% of the population [18], an increase in maternal age at first birth, rising rates of childhood asthma and allergy [19, 20], a significant change in dietary behaviour [21], a rise in immigration and communities with a diverse range of health problems.

The Environments for Healthy Living (EHL) Griffith birth cohort began in Logan, Gold Coast and Tweed regions of South-East QLD and Northern New South Wales (NSW) in 2006 [22]. Unlike many other cohorts in Australia, this cohort included an investigation of social, environmental, neighbourhood and family functioning within its DOHaD-style cohort. Cord blood was also collected. This cohort was designed in partnership with another research consortium in Wales, United Kingdom so that the EHL Wales cohort could provide international comparisons. Data linkages for Medicare Benefits Scheme (MBS), Pharmaceutical Benefits Scheme (PBS) and the child's immunisation history were obtained from the Medicare records. Maternal perinatal history was obtained from health records. The EHL Griffith birth cohort ceased recruitment and follow-up of participants several years ago when funding for the study ceased.

Looking to the future of birth cohorts in QLD, the Mater Hospital in Brisbane is in a strong position to establish such a cohort particularly given it has the highest birth rate in Queensland [23] and provides tertiary and quaternary level health services for both high, and low socioeconomic (SES) populations. Recently, the Queensland Family Cohort (QFC) completed a pilot feasibility study in Brisbane. The protocol for the QFC study was developed through a consultation process with QLD health researchers with expertise in DOHaD methodology. This multi-stage process resulted in a series of 21 research themes for the cohort. Each theme has its own series of questions and the methodologies to answer these have been developed by a collaborative group.

The particular strengths of this cohort design, are its 1) recruitment from entire state of QLD (1.85 million km^2) which has a population of 5.2 million including ~4.3% First Nation community members; 2) detailed collection of physical, social and mental health data of mother, father/partner, and child; 3) biological samples collected at multiple time points from all family members; 4) all survey instruments are based on validated tools and routinely collected clinical data; 5) inclusion of biological samples were agreed by the research collective only after detailed justification by individual researchers; 6) recognising the equal importance of the family relationships on the child so that parents and partners are all involved; 7) inclusive of same sex relationships and single parents; and 8) inclusion of any participant regardless of chronic and acute health conditions.

The data obtained will enable characterisation of all participants' health and social experiences for each family unit enrolled in the study to identify the current trends in health and health behaviours. It will identify immediate and future health requirements of the QLD population which will have a significant impact on health policy and practice and help define preventative interventions required for the health of future generations of Australians. Using this rich data source, we will endeavour to understand the biological mechanisms that may contribute to adverse health outcomes in parents and their children which will drive future interventions in health care that include lifestyle, pharmacological and clinical modifications in practice.

Methods and analysis

Study Design and Setting

The QFC is a prospective, observational, longitudinal study that has been piloted at the Mater Mothers' Hospital (MMH) from 2018-2020 with an aim to continue for three decades. Families will be followed throughout pregnancy, childbirth and infancy via individually funded, separate follow-up studies. Long term follow-up of these participants and their children via data linkage is the aim. Although participant numbers for the pilot study have been attained, the research team continued to recruit into the cohort when COVID-19 pandemic arose in order to further understand implications of COVID-19 on families during the pandemic, albeit with a modified protocol.

Following thorough analysis of the pilot data, additional sites will be added across QLD after 2020, and will be inclusive of metropolitan, rural and remote communities. Additionally, this study will partner with First Nation communities and organisations to modify protocol methods to ensure the inclusion of these community members.

Inclusion criteria

For the pilot phase of the study, pregnant individuals who undertook their antenatal care at the MMH were eligible to participate, however following the pilot project, this will extend into a multisite program across QLD health services. Pregnant individuals who are permanent residents of Australia and reside in QLD, are 12-24 weeks pregnant and their partners, if they have one, were invited to participate in the study. To ensure the cohort is representative of the QLD population, every effort will be made to invite all eligible individuals to participate in the study including those; from non-English speaking backgrounds, under the age of 18 years, with special needs, and First Nation community members. Importantly, this cohort is seeking a true understanding of the breadth of health issues for families, so that participants with any underlying serious or chronic health conditions are also eligible for inclusion in the study.

Exclusion criteria

As this cohort has a significant focus on the health of the family unit, if the pregnant person would like to participate in the cohort, but their partner does not consent, or vice versa, then they will be excluded from the study. If either person is unable to give informed consent, they will be excluded from participating in the study.

Recruitment and Consent

Potential pregnant participants and their partners are approached for participation in the study by suitably qualified experienced research midwives either face-to-face, or via phone.

Alternatively, potential families can also contact the study via publicity generated by social media and marketing campaigns detailing the QFC study. Regardless of the mode used to make initial contact, those interested in participating are provided with the participant information statement prior to obtaining written consent.

Study Regimen

Active data is collected from pregnant participants and their partners throughout their pregnancy, delivery and into early infancy, as shown in Table 2. Active data collection will continue in multiple locations in QLD up to three years gestational age corrected, with lifelong, passive data collection via MBS and PBS data linkage.

During the recent pilot study, data was collected four times during pregnancy (12-24 weeks, 24 weeks, 28 weeks and 36 weeks), at delivery, post-delivery (on the ward), and at 6 weeks post-partum. Table 2 outlines items collected at each of these occasions that were undertaken by the participant unaided, while Table 3 highlights the time and those items collected with the assistance of a research team member. In brief, these were collected as follows: *12-24 weeks* – consent and enrolment forms completed by pregnant participant and their partner; *24 week* – is a study visit for pregnant participant and partner for questionnaires, biological sample collection from both and an ultrasound growth scan; *28 and 36 weeks* – each has a study visit with questionnaires, biological samples and a ultrasound growth scan collected; *delivery* – placenta, cord blood sample collection and chart review; *on-ward visit* – chart review, questionnaire and biological samples collected from mother and baby; *6 weeks post-partum* – breastfeeding assessment, body composition of infant, questionnaires and biological sample collection. Consent for data linkage will be sought for participants from the QFC pilot study.

Study data were collected and managed using Research Electronic Data Capture (REDCap) electronic data capture tools hosted at University of Queensland [24, 25]. REDCap is a secure, web-based software platform designed to support data capture for research studies providing 1) modifiable user rights to protect identifiable data; 2) an intuitive interface for validated data capture; 3) audit trails for tracking data manipulation and export procedures; 4) automated export procedures for seamless data downloads to common statistical packages; and 5) procedures for data integration and interoperability with external sources [26, 27]. Data collected was entered into REDCap by a Research Nurse/Midwife, Research Assistant or another suitably trained member of the research team. Double data entry and cross validation methods were used to ensure validity and quality of data.

The QFC Study has focused on data collection and outcomes from 21 major themes from the QFC Research Collaborative (Figure 1), each with their own series of study questions highlighted in Supplementary Table 1. Data collected across the themes included participant questionnaires and routinely collected clinical data from medical charts (demographics, medication usage, medical history, pathology, medical imaging and other clinical results), as well as intervention data (biological samples, physical and psychological assessments obtained for research purposes only). Data will be collected by experienced and qualified research nurses, midwives and research assistants. Some data will be collected by research trained allied health professionals, including sonographers, dieticians, physiotherapists and psychologists prospectively from patient notes, observation charts, study specific questionnaires and assessments, photographs and videos, and electronic laboratory results by research staff and the principal investigator. Data collection forms will be electronic, except in cases where the participant does not have reliable access to a computer or the internet, or where a participant requests the use of paper forms.

Primary Outcomes

This cohort has primary outcomes to determine:

i) current status of parental physical and mental health and its impact on health of offspring

ii) explore genetic and biological mechanisms that drive chronic disease risk in pregnancy, in childhood and in later life and

iii) understand the influence of the environment and climate change on the health of future generations.

Assessments

The associated measures, assessments and sample collections for the cohort are listed in Tables 2 and 3. All questionnaires for the study have been either used in routine clinical care or previously validated and references are included within the Tables where appropriate. Secondary outcomes specific to the individual themes are listed in Supplementary Table 1.

Sample Size

A sample size of 12,500 QLD families was chosen so that some of the rarer complications of pregnancy can be interrogated with sufficient statistical power. For example, delivery of small-for-gestational infants occurs in approximately 6.7% QLD deliveries and a stillbirth delivery occurs in approximately 0.6% of QLD deliveries, thus warranting a large cohort size [28].

Statistical analysis

Missing outcome data will not be imputed in the primary analysis, as the key assumption of missing at random is not likely to hold in the analysis population. Sensitivity analyses will be conducted, however, using multiple imputations method to explore the potential impact of missing data on outcomes. The characteristics of those participants with missing data will be compared between two treatment groups (healthy vs unhealthy outcomes). Baseline characteristics of babies and their parents will be summarised for each site as well as overall using descriptive statistics. Continuous variables will be reported as numbers of observed and missing values, mean, standard deviation, median and range. Categorical variables will be described as frequencies and percentages.

Data Availability Statement

Data from the QFC Study will be made available in the future for collaborative research questions. Such requests must be authorised by the Principal Investigators, the QFC Research Governance Committee and the appropriate Human Research Ethics Committees and Human Research Governance Safety Entities.

Patient and Public Involvement

The protocol for the pilot study was developed with extensive engagement within the QFC Research Collaborative community and a community engagement group including consumers (individuals aged 18-65). This group highlighted that understanding mental health and social support networks were essential for a vulnerable population such as pregnant women (and their families). Accordingly, both mental and physical wellbeing are strong components within the QFC study design (Table 2). In addition, the QFC Research Collaborative compromised of research academics and clinicians (Figure 1), identified the clinical data, biological samples and questionnaires necessary for taking a snapshot of a reproductive age population that would also capture the consumers suggestions raised in the community engagement group.

The QFC team are currently working in partnership with the First Nation communities of QLD to determine how to best to ensure that this protocol is truly inclusive of their community members. At the time of writing, the research team have developed the terms of reference to establish a new consumer panel who are either expecting a baby; have young children or QFC participants, who will further refine the protocol design from their previous experience and preferences, for the future QFC study. The QFC team will ensure that this group includes partners, and First Nation families. QFC Participants were not involved in the recruitment of the study but have provided information in the form of feedback surveys to further refine the

study protocol. Lay reports will be made available to interested participants in the form of a newsletter sent to them via email and via formal invitation to a seminar day where researchers will describe individual findings.

Sources of bias

One of the significant sources of bias is related to consent. Under the ethics approval given for the study, the research team can only approach potential participants to join study if they have indicated that they are willing to be involved in 'any research that is undertaken by Mater Health' when they complete their antenatal enrolment forms. If the potential participant leaves this blank or indicates no, they cannot be contacted. This is likely to mean that those joining the study are coming from a pool of potential participants that are likely to be better educated and of higher socio-economic status [29]. Although all potential participants were approached and followed-up, selection bias may have been introduced for potential participants who were linguistically diverse and failed to respond to follow-up attempts [30, 31]. Like many other cohort studies, this protocol relies on the collection of self-reported data from participants. This is an inherent source of bias in self-collected data [32].

Ethics and regulatory aspects

Ethics

The QFC study has been approved by the Mater Misericordia Limited Human Research Ethics and Governance Safety Committee (HREC/16/MHS/113).

Participant Safety

All risks to the participants in the study will be mitigated by ensuring all recruitment and data collection is managed by appropriately trained and experienced research staff which have had training in empathetic, cross-cultural communication. Recruitment staff will be research nurses and midwives with extensive experience in research and clinical practice. Data will be stored in a secure setting and data linkage software will be adequately protected to maintain security and privacy.

Study Governance

The QFC study is overseen by the principal investigators and the QFC Research Governance Management Committee. This committee meet every 2 months to: 1) continue to develop the strategic directions and priorities for the protocol; 2) review all sub-study applications to the cohort prior to their submission to ethics; and 3) review all unexpected findings from the analysis under an ethically defensible plan with the QFC Clinical Advisory Panel [33]. Each

QFC research theme has a theme leader who report annually and develop the individual research hypotheses within their theme. New research questions require a sub-study application that outlines what data requirements the applicant requires for analysis. When approved by the QFC Research Governance Management Committee, the sub-study application and reference letter from the QFC Research Governance Committee is attached as supporting documents to a new Human Research Ethics application, where approval is sought. Most recently, the QFC Research Governance Management Committee has identified that a community-based Consumer Advisory Committee would be of benefit to the long-term development of the cohort as it continues into the future. The terms of reference for this group have been developed and its establishment is planned for late 2020.

Unexpected findings during examinations

If analysed data from the study were to reveal findings that bear on the wellbeing of participants, their relatives or their community, whether anticipated or incidental to the scope of the research, the QLD Research Governance Committee team are formally notified. The QLD Research Governance Committee will create a panel of experts to cross-check research findings for accuracy (QFC Clinical Advisory Panel). Only those confirmed research findings that are clinically actionable, where there are established therapeutic or preventative interventions or other available actions, such as lifestyle changes or reproductive decisions, that have the potential to change the clinical course of the disease or improve the individual's and/or their genetic relative's quality of life are to be considered to be returnable to the participant. This panel will, in conjunction with representatives from the QLD Research Governance Committee, identify and recontact the participant initially via letter, and then by telephone [33].

Dissemination

The findings from the analysis of cohort data will be disseminated in a variety of ways including abstracts, posters and presentations at conferences, and published manuscripts in peer-reviewed journals. These will also be reported to federal, state and local governments to inform policy and reports made to funding bodies, institutes and hospitals that participated in and supported the cohort study. Members of the study team will have publishing and authorship rights in accordance with NHMRC Australian Code for the Responsible Conduct of Research, the International Committee of Medical Journal Editors requirements for authorship, and as described in research agreements.

Discussion

The QFC is of enormous significance to Australia, particularly to the state of QLD. The only previous longitudinal cohort established in QLD was initiated over 30 years ago [12], and whilst its contributions continue to impact on policy, this cohort sampled only within metropolitan Brisbane and failed to include rural and remote QLD communities. Since its inception, there have been significant societal changes including an increasing burden of chronic disease in adulthood, thus impacting the health outcomes of pregnancy and infancy. Additionally, the impact of other influences such as home environment [34], social determinants of health [35] and the role of fathers [4] on the child are becoming better understood, and the QFC is one of the few Australian cohorts that includes direct sampling of partners. This work will lead to identification of immediate and future health requirements of Australian families, and a solid body of evidence with which to develop well-defined intervention studies to improve health.

The unique outcomes of the QFC will include: 1) deep analysis of maternal and paternal health during antenatal and postpartum periods; 2) examination of perinatal outcomes; 3) life-course analysis of maternal, paternal and infant health outcomes; 4) analysis of biological samples to understand biological mechanisms driving health outcomes; 5) development of rich data that characterises health, social, environmental and educational experiences of family members that can lead to improve understanding of health and disease for all family members during this period. To our knowledge, there is no other cohort within Australia and very few internationally, where all these five points are incorporated into a single study cohort.

The QFC pilot study has so far demonstrated the ability to recruit pregnant participants from private and public sectors, including specialised clinics such as diabetes and refugee clinics. Participating families had individual members born in 53 different countries including Australia, with the maternal age of conception spanning 24 years. Further, our families have identified as single (pregnant participant only), cis-gender and gender diverse. Overall, there has been a 6% withdrawal rate by 6 weeks post-partum. This suggests while still ongoing, the QFC study has the ability to cover the entire range of socioeconomic and cultural groups within the QLD population.

Like many longitudinal cohort studies [15], a significant limitation of the project is the cost of establishing and maintaining a cohort over a number of decades, storing its biological samples and the costs of analysis. To overcome these limitations, the principal investigator has developed this as a multi-institutional initiative that encompasses the entire state, with each institute contributing financially or in-kind towards the cohort (Figure 1). Additionally, the

study protocol has not yet completed cultural consultation with the First Nations communities although it is in process with in-principal agreements from First Nation organisations as the first outcome achieved. At this point in the study, it is worth noting that the piloted participating families have been recruited in the metropolitan community of Brisbane and its findings when reported may not be widely applicable in rural and remote communities. In conclusion, despite the limitations, analysis of data arising from this cohort will influence policy and practice for health care that is based on the current health of QLD families, and provide further understanding of the impact of current health of family members on the health of the next generation.

Figure 1: The QFC Research Collaborative. Each large sphere (navy blue) represents one of the 21 research themes that compromise the QFC research collaborative. Each number represents an individual researcher (149 researchers to date). Each small sphere represents the affiliation of that particular researcher (51 collaborating institutes/universities). These affiliations are as follows:

ACU (Faculty of Health Sciences); ACU (Institute for Learning Science and Teacher Education); ACU; UQ (Faculty of Health and Behavioural Sciences); Child Health Research Centre; Griffith University; James Cook University (Australian Institute of Tropical Health & Medicine); James Cook University (Department of Medicine); Mater Health; Mater Health Pathology (consultant microbiologist); Mater Health; Princess Alexander Hospital; Mater Health; Queensland Children's Hospital; Mater Research - UQ; Mater Health; Mater Research; Carbal Medical Services; Mater Research -UQ; Menzies Health Institute Queensland, Griffith University (Griffith Health); Metro South Health, QUT (Faculty of Health); Metro South Health; Princess Alexander Hospital; Monash University (Faculty of Medicine, Nursing and Health Sciences); NSW Department of Planning, Industry and Environment; Pathology Queensland; QIMR Berghofer; QUT (Faculty of Health); QUT (Faculty of Health); Child Health Research Centre; QUT (Faculty of Science and Engineering); QUT (Faculty of Science and Engineering); Child Health Research Centre; QUT (Faculty of Health); UQ (Centre of Clinical Research); QUT; University of Georgia; South Australian Health and Medical Research Institute; Sun Yat- Sen University; University of Newcastle; University of Southampton; UQ (Institute for Social Science Research; Faculty of Humanities and Social Sciences); UQ (Centre of Clinical Research); UQ (Diamantina Institute); UQ (Diamantina Institute); Dermatology Research Centre; UQ (Discipline of General Practice; Primary Care Clinical Unit);

 UQ (Faculty of Business, Economics & Law);  UQ (Faculty of Engineering, Architecture & Information Technology);  UQ (Faculty of Health and Behavioural Sciences);  UQ (Faculty of Health and Behavioural Sciences); Bond University (Faculty of Health Sciences & Medicine); Mater Health;  UQ (Faculty of Medicine);  UQ (Faculty of Medicine) Child Health Research Centre;  UQ (Faculty of Medicine); Centre for Health Services Research;  UQ (Faculty of Medicine); Mater Research-UQ;  UQ (Faculty of Medicine); Perinatal Research Centre;  UQ (Faculty of Science); UQ (Centre of Clinical Research);  UQ (Institute for Molecular Bioscience);  UQ (Institute for Social Science Research);  UQ (Queensland Brain Institute);  Wesley Hospital Monash IVF; Wesley Hospital Monash IVF; University of Melbourne.

Tables

Table 1: Longitudinal birth cohorts in Australia where measures from one parent and the child were recorded. (Completed (C), Ongoing (O) and Emerging (E)).

Decade cohort began	Cohort Name	Status	Australian State or Territory	References
1970's	Port Pirie Cohort Study	O	SA	[36]
	Adelaide Nutrition Study	C	SA	[37]
	Brunswick Family Study	C	VIC	[38]
1980's	Mater- University of QLD Study of Pregnancy	O	QLD	[12]
	The Raine Study	O	WA	[14]
	Aboriginal Birth Cohort	O	NT	[39]
	Adelaide Respiratory Cohort	C	SA	[40]
	Nepean Study/ Nepean Kids Growing up Study	C	NSW	[40]
1990's	Generation One cohort	O	SA	[41]
	Tasmanian Infant Health Study	O	TAS	[42]
2000's	Environments for health living Griffith Birth Cohort study	C	QLD/ NSW	[22]
	Peri/Postnatal Epigenetic Study	O	VIC	[43]
	Triple B Study: Bumps, Babies and Beyond	O	NSW	[44]
	Watch Study	O	NSW	[45]
	Gudaga Study	O	NSW	[46]
	Gomeroi gaaynggal	C	NSW	[47]
2010's	Splash	E	VIC	[48]
	VicGen	E	VIC	[49]
	ORIGINS	E	WA	[50]
	Pregnancy and Neonatal Diabetes Outcomes in Remote Australia (PANDORA)	E	NT	[51]

Timepoint	Pregnant Participant		Partner		Baby	
	Questionnaires	Measures/Samples	Questionnaires	Measures/Samples	Questionnaires	Measures/Samples
Enrolment	Asthma Control Questionnaire (ACQ)[52] Adult Sleep Pattern Questionnaire (ASPQ)[53-56] Cultural background Feeding your baby[57] Obstetric History Physical Activity[58-62] Residential Housing Questionnaire (RHQ)[63] -nasal Outcome Test (22 items questionnaire) (SNOT-22)[64]	none	ACQ ASPQ Cultural background Feeding your baby Physical Activity RHQ SNOT-22	none	none	none
24 Week Gestation	ACQ Assessment of Quality of Life Questionnaire (AQoL-6D)[65] ASPQ Bristol Stool Chart[66] Constipation score [67] Couples Satisfaction Index (CSI)[68] Depression Anxiety Stress Scale (DASS-21)[69] DSM-5 Self-Rated Level 1 Cross-Cutting Symptom Measure -	Hair Sample Microba Swab Saliva Sample Stool Sample Toenail Sample Urine Sample Vaginal Swab	ACQ AQoL-6D ASPQ Bristol Stool Chart Constipation score CSI DASS-21 DSM 5 CCSM EQ-5D-5L Full AES FFQ 2010 MSPSS Photograph of Medication Physical Activity RHQ	Hair Sample Microba Swab Saliva Sample Stool Sample Toenail Sample Urine Sample	none	none

	Adult (DSM 5 CCSM)[70] EuroQol 5-dimenstion Questionnaire (EQ-5D-5L)[71] Full Australian Eating Survey Food Frequency Questionnaire (AES FFQ 2010) [72] Musculoskeletal Function Questionnaire (MSK Questions)[73, 74] Multidimensional Scale of Perceived Social Support (MSPSS)[75] Photograph of Medication Physical Activity RHQ SNOT-22 Social Readjustment Rating Scale (SRRS)[76]		SNOT-22 SRRS			
28 Week Gestation	ACQ ASPQ Photograph of Medication (if changed from last appointment) Physical Activity SNOT-22	Microba Swab Saliva Sample Stool Sample Urine Sample	none	none	none	none
36 Week Gestation	ACQ ASPQ Constipation score	Saliva Sample Urine Sample Vaginal Swab	none	none	none	none

	Intention to breastfeed questionnaire [57] MSK Questions Photograph of Medication (if changed from last appointment) Physical Activity SNOT-22					
Delivery	none	none	none	none	none	none
On-Ward	Breastfeeding questionnaire [57]	Colostrum/Breast Milk Sample	none	none	Skin-to-skin contact Nutrition	Meconium Sample Urine Sample
6 Weeks Post-partum	ACQ AQoL ASPQ Breastfeeding experience [57] Bristol Stool Chart Constipation score Childcare CSI DASS-21 DSM 5 CCSM Edinburgh Postnatal Depression Scale (EPDS)[77] EQ-5D-5L Full AES FFQ 2010 MSK Questions MSPSS Photograph of Medication (if changed	Breast Milk Sample Hair Sample Microba Swab Saliva Sample Stool Sample Toenail Sample Urine Sample	none	none	Infant Sleep Diary * Nutrition [57] Infant Medication	Hair Sample Stool Sample Toenail Sample Urine Sample

	from last appointment)
	Physical Activity
	RHQ
	SNOT-22
	SRRS

Table 2 Questionnaires, measures and biological samples completed by participants within the QFC cohort unaided. The appropriate references are included for validated tools. Those without references are tools used routinely in clinical care. *Collection measures planned for the future.

Timepoint	Pregnant Participant		Partner		Baby	
	Surveys/Histories	Measures/Samples	Surveys/Histories	Measures/Samples	Surveys/Histories	Measures/Samples
Enrolment	Contact Details Demographics Education History Employment History Family History Malignant melanoma risk Medical History	Bioimpedance Blood Pressure Heart rate Height Skin fold thickness Weight	Contact Details Demographics Education History Employment History Family History Malignant melanoma risk Medical History	Height Waist Circumference Weight	none	none
24 Week Gestation	Alcohol Consumption Medication and Lifestyle Substances Smoking Status	Blood Sample Breast Skin Swab Cheek Swab Bioimpedance Blood Pressure Heart rate Skin fold thickness Weight Gestational Weight Gain (GWG)	Alcohol Consumption Medication and Lifestyle Substances Smoking Status	Bioimpedance Blood Pressure Blood Sample Cheek Swab Heart rate Skin fold thickness Skin Swab Waist Circumference Weight WG	none	Fetal Kidney Scan Fetal Growth Scan Uterine artery Doppler, US for Placental elastography Neonatal Intensive Care Unit (NICU) body measures in preterm infants
28 Week Gestation	Alcohol Consumption Medication and Lifestyle Substances Smoking Status Pregnancy Complications Glucose Tolerance Tests	Bioimpedance Blood Pressure Blood Sample Heart rate Saliva Sample Skin fold thickness Weight GWG	none	none	none	Fetal Kidney Scan Fetal Growth Scan Uterine artery Doppler Placental elastography NICU body measures in preterm infants
36 Week Gestation	Alcohol Consumption	Bioimpedance Blood Pressure	none	none	none	Fetal Kidney Scan Fetal Growth Scan

	Medication and Lifestyle Substances Smoking Status	Blood Sample Cheek Swab Heart rate Saliva Sample Skin fold thickness Weight GWG				Uterine artery Doppler Placental elastography NICU body measures in preterm infants
Delivery	Medication used during labour and delivery Delivery details including complications	none	none	none	Medication used during labour and delivery Delivery Details Length of NICU Stay	Abdominal Circumference Weight Cheek Swab Cord Blood or Guthrie cord blood spot Guthrie heel prick Head Circumference Middle Upper Arm Circumference Placenta dimensions, stereology, histology, weight Placenta photograph
On-Ward	Medication prescribed on ward and at discharge,	Blood pressure	none	none	Peapod Photograph/Video of baby's mouth, tongue, feeding Anthropometry Medication prescribed on ward and at discharge	Microba Swab Skin Swab
6 Weeks Post-partum	Alcohol Consumption	Breast Skin Swab Cheek Swab	none	none	Photographs of rash#	Abdominal Circumference

	Medication and Lifestyle Substances Smoking Status	Video of feeding Medical Complications (first 6 weeks of life) Peapod	Cheek Swab Head Circumference Microba Swab Middle Upper Arm Circumference Skin Swab

Table 3 Surveys, histories, measures and biological samples completed by participants with the assistance of a research team member. #Asthma/Dermatitis related

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Authors' contributions:

DJB and KMR jointly wrote the manuscript, DJB, KMR, SK, VC, designed the QFC protocol, CT, TH, JJM, , FF, MO responsible for recruitment and retention of participants for QFC cohort, DJB, VC, CF, JMS, JJM, CT, MO, TH, designed the Redcap system for QFC data management, EC, CE, DF, SK designed ultrasound data collection, EC, CE collected ultrasound data from QFC participants, DJB, CF, JMS, designed FreezerPro system for management of QFC participants, DJB, KMR, CT, AP, GdZ, KM, SK, VC are members of QFC Governance committee, CF, JMS, JJM, CT, MO, TH, EC, CE, DF, AP, GdZ, KM, SK all reviewed and edited of manuscript on behalf of the Queensland Family Cohort Research Collaborative. All members of the QLD Family Cohort Research Collaboration were involved in establishing the aims and the design of the cohort study.

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No competing interests

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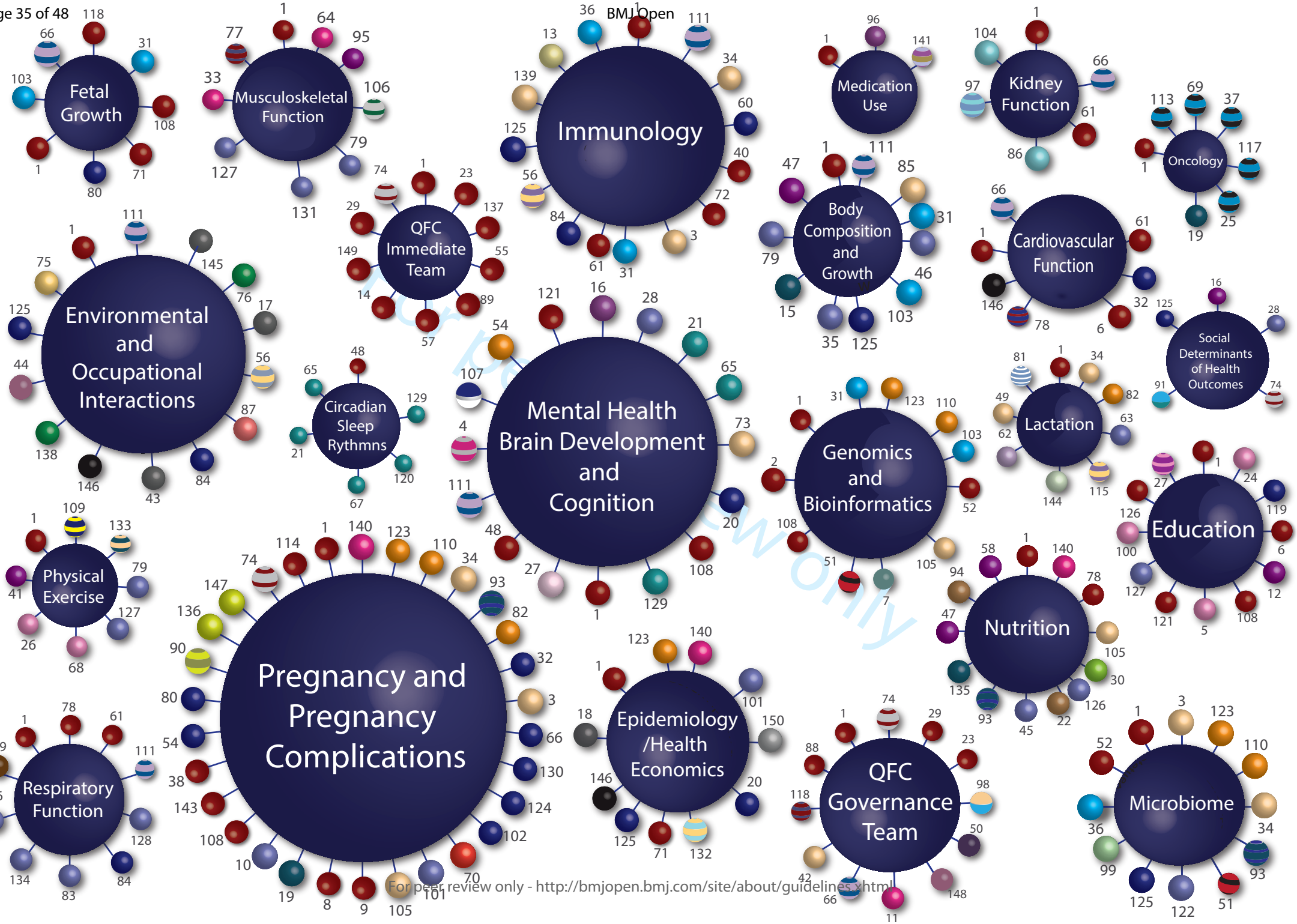

Theme	Major Research Question	Primary Exposure Measures Collected		Collaborations
		Histories/Surveys/Questionnaires	Measures/Biological Samples	
Cardiovascular function	▯ Characterisation of the cardiovascular systems of our reproductive population and its relationship to fetal growth and child cardiovascular function ▯ The relationship between maternal cardiovascular system and placental circulation and fetal cardiac output (fetal distress, tachycardia, congenital heart defects) ▯ The relationship between maternal cardiovascular system and placental circulation and fetal kidney development	▯ Delivery Details ▯ Demographics ▯ Family History ▯ Medical History ▯ Medication and Lifestyle ▯ Medication chart review for medication during labour and delivery ▯ Pregnancy Complications	▯ Blood pressure ▯ Cord blood ▯ Heart rate ▯ Height ▯ Placenta and Placenta Measures ▯ Skinfold thickness ▯ Ultrasound data ▯ Urine ▯ Weight, BMI ▯ PeaPod	▯ Fetal Growth ▯ Kidney Function ▯ Medication Usage ▯ Neonatal/Child Body Composition and Growth ▯ Pregnancy and Pregnancy and Complications
Education	▯ What are the educational achievements of the parents and attitudes to linguistics? ▯ How does maternal-baby interaction influence early oracy? ▯ What is the impact of the parents' social and family networks on child literacy? ▯ Tracking the relationship between child health and academic achievement through data linkage ▯ Impact of preterm delivery on linguistics, oracy and academic attainment	▯ Childcare ▯ Department of Education* and NAPLAN data linkage* ▯ Education history ▯ Pregnancy Complications ▯ Reading for Enjoyment ▯ Reading for Occupation	none	▯ Epidemiology and Health Economics ▯ Pregnancy and Pregnancy Complications ▯ Social Determinants of Health Outcomes

	y Impact of childcare on oracy and literacy			
Environmental and Occupational Interactions	y Examine impact of environmental exposures on microbiome y Are there similarities between the impact of environmental exposures on families in Australia relative to families in China? y What is the impact of air quality on pregnancy outcomes and respiratory health? y Gestational elemental exposures and its impact of pre and postnatal growth and development	y Adult Sleep Patterns y Alcohol Consumption y Australian Eating Survey Food Frequency y Breastfeeding Questionnaires y Delivery Details y Demographics y Depression Anxiety Stress Scale y Education History y Employment History y Indoor/Outdoor air sample y Medical History y Medication and Lifestyle y Medication chart review for medication during labour and delivery y Postcode / Geocode y Pregnancy Complications y Residential Housing Questionnaire y Smoking Status Assessment of Quality of Life questionnaire	y Baby Measures y Blood y Breast milk y Hair y Toenail y Urine	y Immunology y Lactation y Medication Usage y Microbiome y Nutrition y Pregnancy and Pregnancy Complications y Respiratory
Epidemiology and Health Economics	y How does health utility change throughout pregnancy and post-partum? y Is there inequality of opportunity in parental mental health outcomes and use of mental health and other health services?	y Alcohol Consumption y Cultural background y Demographics y Education history y Employment history y European Quality of Life 5-Dimension y Medical History	none	y Education y Medication Usage y Mental Health and Cognitive Development y Pregnancy and Pregnancy Complications

	y What are the payment mechanisms for health services for parents? Does travel impede their use of services? y Does alcohol and substance abuse change health care utilisation during pregnancy?	y Medication Treatment* y PBS/MBS data linkage* y Postcode / Geocode y Pregnancy Complications		y Social Determinants of Health Outcomes
Fetal growth	y Characterise the variables contributing to idiopathic growth restriction and large for gestational age y How does fetal growth influence other early life characteristics (education, physical and mental health, social behaviour)	y Delivery Details y Department of Education* and NAPLAN data linkage* y Medical History y Pregnancy Complications	y Baby Measures y Cord blood y Middle Cerebral Artery Doppler/Placental Artery Doppler y Peapod y Placenta and Placenta measures y Ultrasound data	y Education y Neonatal/Child Body Composition and Growth y Pregnancy and Pregnancy Complications
Genomics and Bioinformatics	y The relationship between the genome, complex traits and disease, mental health, maternal and fetal health, pregnancy outcomes, and development y The impact of the mitochondrial genome on pregnancy outcomes y The interaction of the genome with the microbiome y The role of and prevalence of somatic and de novo genomic variation y Twin studies	y Medical History y Family History y Demographics y Pregnancy Complications	y Blood y Cheek swab y Cord blood y Heel prick y Microba swab y Placenta: dimensions, samples y Stool	y Mental Health and Cognitive Development y Microbiome y Pregnancy and Pregnancy Complications
Immunology	y The in utero and early life contributions to childhood allergy,	y Asthma control questionnaire y Sino-Nasal Outcome test y Medical History	y Blood y Cord blood y Microba swab	y Medication Usage y Microbiome

	autoimmunity and disease development ȳ The influence of the maternal microbiome on childhood allergy, autoimmunity susceptibility and disease development ȳ The impact of maternal and childhood infection on child health and development ȳ The relationship between child microbiome and disease ȳ How extrinsic and intrinsic factors influence the development of the immune system	ȳ Medication and Lifestyle ȳ Medication chart review for medication during labour and delivery ȳ Pregnancy Complications	ȳ Saliva ȳ Stool ȳ Urine ȳ Vaginal swab	ȳ Pregnancy and Pregnancy complications ȳ Respiratory
Kidney Function	ȳ What genetics factors contribute to kidney disease and kidney disease risk? Can these mutations be reversed to prevent kidney disease? ȳ What pregnancy related events compromise fetal kidney development? ȳ How does prematurity affect kidney development? ȳ What are the population-based characteristics of kidney function? ȳ Determinant of infant kidney size and function	ȳ Alcohol Consumption ȳ Australian Eating Survey Food Frequency ȳ Delivery Details ȳ Demographics ȳ Medical History ȳ Medication and Lifestyle ȳ Medication chart review for medication during labour and delivery ȳ Pregnancy Complications	ȳ Baby Measures ȳ Blood ȳ Blood Pressure ȳ Height ȳ PeaPod ȳ Ultrasound data ȳ Urine ȳ Weigh, BMI	ȳ Cardiovascular Function ȳ Fetal Growth ȳ Medication Usage ȳ Neonatal/Child Body Composition and Growth ȳ Nutrition ȳ Pregnancy and Pregnancy Complications
Lactation	ȳ Characterisation of breastfeeding habits in current population and parents views on breastfeeding	ȳ Alcohol Consumption ȳ Australian Eating Survey Food Frequency ȳ Baby Nutrition ȳ Breastfeeding questionnaires	ȳ Baby Measures ȳ Breast milk ȳ Colostrum ȳ Height	ȳ Microbiome ȳ Nutrition ȳ Pregnancy and Pregnancy Complications

	y Identification of factors that inhibit breastfeeding in first 6 weeks postpartum y Identifying the impact of mastitis on breastfeeding continuation y Determining the impact of BMI on breastfeeding continuation y Impact of tongue tie on breastfeeding success	y Delivery Details y Demographics y Intention to breastfeed y Pregnancy Complications y Skin-skin contact y Time to first breastfeed	y Photographs of mouth and tongue y Skin swab y Vaginal swab y Videos of feeding y Weight, BMI	y Social Determinants and Health Outcomes
Medication Usage	y To evaluate medication (prescription and non-prescription) usage patterns in mothers, partners and their children. y To assess health outcomes (beneficial or adverse) and wellbeing of mothers, partners and their children in relation to medication use	y Delivery Details y Demographics y Medication and Lifestyle y Medication chart review for medication during labour and delivery y Medication Treatment* y Pregnancy Complications	y Baby Measures	y Immunology y Mental Health and Cognitive Development y Pregnancy and Pregnancy Complications
Mental Health, Brain Development and Cognition	y The relationship between maternal mental health and wellbeing and its impact on pregnancy and child neurodevelopmental outcomes y The relationship between mental health status of partners and its impact on maternal mental health and wellbeing, pregnancy outcomes and child development y Interaction and dependencies between mental and physical health	y Assessment of Quality of Life questionnaire y Bayley Scales of Infant and Toddler Development* y Child Behaviour and Neurodevelopment*$ y Couple Satisfaction Index y Depression Anxiety Stress Scale y Edinburgh Post-natal Depression Scale y European Quality of Life 5-Dimension y Medical History y Medication and Lifestyle	y Blood y Cheek swab y Cord blood y Urine y Weight, BMI	y Fetal Growth y Immunology y Medication Usage y Physical Exercise y Pregnancy and Pregnancy Complications y Social Determinants of Health Outcomes

			y Medication chart review for medication during labour and delivery y Medication Treatment* y Multidimensional Scale of Perceived Social Support y DSM-5 Self-Rated Level 1 Cross-Cutting Symptom Measure - Adult y Social Readjustment Rating Scale		
Microbiome	y To examine the interaction between mother, father and baby microbiome (normal microbiome) y To examine the impact of pregnancy and pregnancy complications on maternal and neonatal microbiome (infection, preterm birth, pre-eclampsia, hyperemesis gravidarum) y To examine the role of nutrition, feeding and supplement usage in microbiome development and stability (method of feeding, vitamin/mineral supplementation) y To examine the impact of medical interventions pre- and post-conception on the microbiome (IVF, medications) y The characteristics of the vaginal microbiome in complicated pregnancies	y Bristol stool chart y Constipation score y Demographics y Family History y Hyperemesis Questions y Medical History y Medication and Lifestyle y Medication chart review for medication during labour and delivery y Pregnancy Complications	y Cheek swab y Cord blood y Microba swab y Placenta and Placenta Measures y Skin swab y Stool y Urine y Vaginal swab	y Immunology y Lactation y Medication Usage y Pregnancy and Pregnancy Complications

Musculoskeletal function	ý Is obstructive defaecation associated with mode of delivery during childbirth? ý What is the prevalence, severity and impact of foot pain during pregnancy and postpartum and is predictive of peri-or post-natal prolapse? ý Is physical activity in the ante- and post-natal period related to the prevalence of Pregnancy- related Low back pain, pelvic girdle pain and Stress Urinary Incontinence?	ý Adult Sleep Patterns ý Bristol stool chart ý Constipation score ý Demographics ý Employment History ý Medical History ý Musculoskeletal function ý Physical Activity ý Pregnancy Complications ý Pregnancy History ý Residential Housing Questionnaire ý Smoking Status	ý Height ý Weight, BMI ý Blood	ý Pregnancy and Pregnancy Complications ý Physical Exercise
Neonatal/Child Body Composition and Growth	ý Is infant body composition related to later health and disease? ý Characterisation of body composition from in utero to early life ý Genetic factors that contribute to obesity in childhood ý Impact of preterm delivery on body composition ý What is the contribution of early life nutrient to body composition over time	ý Baby Nutrition* ý Breastfeeding questionnaires ý Demographics ý Feeding your baby ý Medical History ý Medication and Lifestyle ý Pregnancy Complications ý PBS/MBS data linkage*	ý Baby measures ý Cheek swab ý Cord blood ý Guthrie Heel Prick ý NICU body measures for preterm infants ý PeaPod ý Ultrasound data	ý Cardiovascular Function ý Fetal Growth ý Genomics and Bioinformatics ý Medicine Usage ý Nutrition ý Pregnancy and Pregnancy Complications
Nutrition	ý How does maternal dietary intake, micronutrient supplement intake, and gestational weight gain change during pregnancy and the early postpartum period, and how does this compare with guidelines?	ý Alcohol consumption ý Australian Eating Survey Food Frequency ý Breastfeeding Questionnaires ý Delivery Details ý Demographics ý Medical History	ý Baby measures ý Bioimpedance ý Blood ý Height ý Skin fold thickness ý Waist circumference ý Weight, BMI	ý Education ý Medication Usage ý Mental Health and Cognitive Development ý Microbiome

	y What is the relationship between dietary intake and gestational weight gain across pregnancy? y What is the relationship between maternal and paternal characteristics and (i) dietary and (ii) gestational weight gain guideline attainment? y What maternal characteristics mediate the relationship between dietary intake/micronutrient supplement intake and nutrient status during pregnancy and the early postpartum period, and how does this affect birth outcomes? y What is the relationship between maternal dietary intake/micronutrient supplementation and her gut microbiome, and how does this affect birth outcomes?	y Medication and Lifestyle y Pregnancy Complications	y Placenta and Placenta Measures y Stool y PeaPod	y Neonatal/Child Body Composition and Growth y Pregnancy and Pregnancy Complications
Oncology	y Pregnancy and melanoma risk y Breast cancer and breastfeeding y Origins of childhood cancer y Lifestyle factors and risk of cancer y Ovarian cancer and pregnancy y Identification of risk factors for melanoma during pregnancy and beyond	y Alcohol consumption y Australian Eating Survey Food Frequency y Baby Nutrition* y Breastfeeding Questionnaires y Demographics y Exposure Measurements (Water, Sun, Chemicals, Pesticides)* y Family History y Malignant melanoma risk y Medical History	y Breastmilk y Blood y Placenta y Saliva	y Genomics and Bioinformatics y Lactation y Medication Usage y Nutrition y Pregnancy and Pregnancy Complications

		y Medical Scans (x-ray, PET, CAT)* y Medication and Lifestyle y Medication Treatment* y Pregnancy Complications		
Physical Exercise	y Activity changes with pregnancy y The effect of exercise during pregnancy on domains of early childhood development y How does activity in Australian women now compare to the Australian women's longitudinal study data of aged matched women from the 1990s y The role of movement across the day on maternal mental health y Effect on physical activity on placental thickness	y Alcohol Consumption y Australian Eating Survey Food Frequency y Demographics y Family History y Medical History y Medication and Lifestyle y Physical Activity y Smoking Status	y Baby Measures y Blood y Cord blood y Height y Placenta y Placenta and Placenta Measures y Saliva y Weight, BMI	y Education y Medication Usage y Mental Health and Cognitive Development y Nutrition y Pregnancy and Pregnancy Complications y Social Determinants and Health Outcomes
Pregnancy and Pregnancy Complications	y What are the pregnancy related risk factors, placenta function and outcomes associated with PE, PTD, GD, IUGR? y Placental micronutrient environment and its relationship to maternal nutrition y The impact of endocrine disruptors on thyroid function and placental TSH pathways y Link between genetics and pregnancy complications	y Alcohol Consumption y Asthma Control Questionnaire y Australian Eating Survey Food Frequency y Delivery Details y Demographics y Family History y Hyperemesis questions y Medical History y Pregnancy Complications	y Baby Measures y Blood y Cheek swab y Cord Blood y Guthrie blood spot y Placenta and Placenta Measures y Ultrasound Data y Vaginal swab	y Fetal Growth y Genomics and Bioinformatics y Microbiome y Neonatal/Child Body Composition y Nutrition

	y Placental iron transfer and iron bioavailability in infants of asthmatic mothers y The role of eicosanoids in mid-late gestation			
Respiratory	y What is the prevalence of asthma in the reproductive age population? y Does maternal asthma worsen with pregnancy and is it related to environmental pollutants? y What pregnancy related variables influence the development of asthma in childhood? y How does rhinitis in pregnancy influence neonatal outcome?	y Alcohol Consumption y Asthma Control Questionnaire y Delivery Details y Demographics y Exacerbation Questionnaire y Family History y Medical History y Medication and Lifestyle y Physical Activity y Pregnancy Complications y Sino-nasal Outcome Test y Smoking Status	y Blood y Height y Photographs of Rash y Weight, BMI	y Immunology y Medication Usage y Pregnancy and Pregnancy Complications
Sleep and Circadian Rhythms	y Impact of parental sleep and stress on parental physical, social and mental health y Impact of pregnancy on sleep patterns and sleep disturbance y Relationship between early identification of snoring and sleep disturbance with pregnancy complications: gestational diabetes, pre-eclampsia, fetal growth restriction, preterm delivery, autism y Impact of parental and child sleep on child development and physical health outcomes	y Adult Sleep Patterns y Australian Eating Survey Food Frequency y Couple Satisfaction Index y Delivery Details y Demographics y Depression Anxiety Stress Scale y Edinburgh Post-natal Depression Scale y European Quality of Life 5-Dimension y Infant sleep diary y Medical History y Medication and Lifestyle	y Baby Measures y Height y Weight, BMI y Bioimpedance y NICU body measures in preterm infants y Peapod	y Education y Mental Health and Cognitive Development y Medication Usage y Pregnancy and Pregnancy Complications

	y Relationship between environmental and biological factors with parental and child sleep	y Multidimensional Scale of Perceived Social Support y Physical Activity y DSM-5 Self-Rated Level 1 Cross-Cutting Symptom Measure - Adult y Social Readjustment Rating Scale y Pregnancy Complications		
Social Determinants of Health Outcomes	y Impact of social disadvantage on maternal, paternal health in Qld y Does parental social determinants of health (housing, education, employment) impact on pregnancy and birth outcomes? y Social networks and their impact on child development y Social disadvantage and its impact on child nutrition, cognitive development and subsequent child educational outcomes y What are the characteristics of individuals who are resilient in the face of early life adversity? y How does developmental trauma and early adversity among individuals affect long-term trajectories	y Childcare y Demographics y Depression Anxiety Stress Scale y Edinburgh Post-natal Depression Scale y Education History y Employment History y European Quality of Life 5-Dimension y Family history y Multidimensional Scale of Perceived Social Support y Physical Activity y DSM-5 Self-Rated Level 1 Cross-Cutting Symptom Measure - Adult y PBS/MBS Data Linkage* y Residential housing questionnaire y Social Readjustment Rating Scale	none	y Education y Epidemiology and Health Economics y Genomics y Mental Health and Cognitive Development y Nutrition y Pregnancy and Pregnancy complications

Supplementary Table 1: Secondary Outcomes according to the 21 themes that make the QFC Research Collaborative. Research measures and samples used to address the secondary outcomes and the collaborations involved in addressing these questions. *Collection measures planned for the future $Age appropriate measures to be collected in the future.

STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1 3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5
Objectives	3	State specific objectives, including any prespecified hypotheses	7
Methods			
Study design	4	Present key elements of study design early in the paper	8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	8-9
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up (*b*) For matched studies, give matching criteria and number of exposed and unexposed	8-9
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	20-25
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	20-25
Bias	9	Describe any efforts to address potential sources of bias	11
Study size	10	Explain how the study size was arrived at	10
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	20-25
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding (*b*) Describe any methods used to examine subgroups and interactions (*c*) Explain how missing data were addressed (*d*) If applicable, explain how loss to follow-up was addressed (*e*) Describe any sensitivity analyses	11
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	n/a
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time (eg, average and total amount)	n/a
Outcome data	15*	Report numbers of outcome events or summary measures over time	n/a

Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (*b*) Report category boundaries when continuous variables were categorized (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	n/a
Discussion			
Key results	18	Summarise key results with reference to study objectives	14
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	15
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	14
Generalisability	21	Discuss the generalisability (external validity) of the study results	14
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	29

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.

BMJ Open

The Queensland Family Cohort: Study Protocol

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Title:
The Queensland Family Cohort: Study Protocol

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Abstract

Introduction: The perinatal – postnatal family environment is associated with childhood outcomes including impacts on physical and mental health and educational attainment. Family longitudinal cohort studies collect in depth data that can capture the influence of an era on family lifestyle, mental health, chronic disease, education and financial stability to enable identification of gaps in society and provide the evidence for changes in Government in policy and practice.

Methods and analysis: The Queensland Family Cohort (QFC) is a prospective, observational, longitudinal study that will recruit 12,500 pregnant families across the state of Queensland, Australia and intends to follow-up families and children for three decades. To identify the immediate and future health requirements of the QLD population; pregnant participants and their partners will be enrolled by 24 weeks gestation and followed-up at 24, 28 and 36 weeks gestation, during delivery, on-ward, 6 weeks post-partum, and then every 12 months where questionnaires, biological samples and physical measures will be collected from parents and children. To examine the impact of environmental exposures on families, data related to environmental pollution, household pollution and employment exposures will be linked to pregnancy and health outcomes. Where feasible, data linkage of State and Federal Government databases will be used to follow the participants long term. Biological samples will be stored long term for future discoveries of biomarkers of health and disease.

Ethics and dissemination: Ethical approval has been obtained from the Mater Research Ethics (HREC/16/MHS/113). Findings will be reported to (1) QFC participating families; (2) funding bodies, institutes and hospitals supporting the QFC; (3) federal, state and local governments to inform policy; (4) presented at local, national and international conferences and (5) disseminated by peer-review publications.

Trial registration: n/a

Article Summary

Strengths and limitations of this study:

Strengths

- In-depth data and biological sample collection of physical, social and mental well-being of mother, father/partner, and child at multiple time points
- Survey instruments based on validated tools and routinely collected clinical data
- Recognising the equal importance of the family relationships (including same sex relationships) on the child so that mothers, fathers or partners are all involved

Limitations

- Cultural consultation for individuals who identify as First Nations People is ongoing
- Cost to maintain cohort, infrastructure, storage of data and biobank is high, with lifelong surveillance of families dependent on philanthropic, state and/or federal support

Background and rationale

The Developmental Origins of Health and Disease (DOHaD) proposes that the intrauterine environment, when impacted by poor maternal nutrition, severe stress or illness, has a detrimental impact on the developing child, both in the short and long term. These prenatal effects can increase the risk of cardiovascular disease, hypertension, obesity, type 2 diabetes, metabolic syndrome and kidney disease [1-3]. However, as the scientific community learns more about how health develops in adulthood, we are also recognising the influences of the paternal environment and the impacts of the intergenerational insults on fetal development [4]. Longitudinal cohort studies that follow participants over time, taking repeated measures, provide compelling data and are powerful research tools to determine associations between a variety of health outcomes and can help drive significant policy change [5].

Although there have been 17 Australian birth cohort studies so far, only 2 have been federally funded; the Longitudinal Study of Australian Children (LSAC) established in 2004 [6], and Footprints in Time: Longitudinal Study of Indigenous Children (LSIC) established in 2008 [7]. While these two cohorts began the innovative approach of linking government administrative data, with basic physical and cognitive information, these children are now aged 15 and 10 years respectively, highlighting a need for more recent data to inform policy. As children were the point of interest for each of these cohorts, important antenatal, postnatal and early life data were not collected from parents, and no biological samples were accrued.

A systematic review of longitudinal birth cohorts in Australia that included measures from one parent and offspring are shown in Table 1. Of these cohorts; almost all were established over 20 years ago, only half of the studies included antenatal measures, whilst less than half involved the partner. Of studies that included partners, only 3 studies had biological samples collected from the father. Research involving individuals who identify as First Nations People was minimal and identified only 2 cohorts with specific focus on these groups: the Gudaga cohort in Sydney, New South Wales (NSW) [8] and the Aboriginal Birth Cohort (ABC) in the Northern Territory (NT) [9]. However, since the time of this publication there have been others developed in Australia, including the Gomeroi gaaynggal cohort (NSW) [10], and PANDORA cohort (NT) [11], that are solely focused on the First Nation community.

Of the Australian birth studies, the 2 largest are the Raine Study (Mothers n=2900, Babies n= 2868, and Partners n=2804) and the Mater-University of Queensland Study of Pregnancy (MUSP) (Mothers n=7631, Babies n=7223, and Partners n=522) with a retention of 82% and 53% at 14 and 21 years respectively [12, 13].

The Raine Study was established in Western Australia (WA) in 1989 with a total of 2,900 women birthing in Perth enrolled [14]. Infants from the cohort have been followed for 27 years. Collection of data began at 18 weeks' gestation of pregnancy and has included diverse survey topics of participants including; education, toxin exposures, breastfeeding child behaviour, physical activity, mental health from mothers, fathers, offspring, as well as biological samples from the same. Although the investigators of this cohort suggest that this is perhaps the most comprehensive longitudinal study of its kind to date in Australia, there is no doubt that significant societal change has occurred in the 30 years since it began. As such, intrauterine and paternal influences during conception and pregnancy are likely to be markedly different.

Only 2 of the studies identified in the systematic review by Townsend et al., [15], originated in Queensland (QLD) - Environments for Healthy Living (EHL) Griffith birth cohort and the MUSP cohort. The larger of the two (MUSP), was established over 35 years ago and continues to follow participants with a focus on sociological and psychological outcomes [16]. While its impacts on QLD health practice and policy have been considerable, since the inception of this cohort, there have been significant societal changes. The MUSP cohort did not recruit partners, and only 4.04% (n=273 from 6,527 recruits) were First Nations People with poor retention rates of this subgroup limiting the capacity of the study to fully appreciate the health needs of First Nation families during the perinatal period [17]. The QLD population has changed significantly since 1980 with a dramatic rise in obesity rates now affecting up to 50% of the population [18], an increase in maternal age at first birth, rising rates of childhood asthma and allergy [19, 20], a significant change in dietary behaviour [21], a rise in immigration and communities with a diverse range of health problems.

The Environments for Healthy Living (EHL) Griffith birth cohort began in Logan, Gold Coast and Tweed regions of South-East QLD and Northern New South Wales (NSW) in 2006 [22]. Unlike many other cohorts in Australia, this cohort included an investigation of social, environmental, neighbourhood and family functioning within its DOHaD-style cohort. Cord blood was also collected. This cohort was designed in partnership with another research consortium in Wales, United Kingdom so that the EHL Wales cohort could provide international comparisons. Data linkages for Medicare Benefits Scheme (MBS), Pharmaceutical Benefits Scheme (PBS) and the child's immunisation history were obtained from the Medicare records. Maternal perinatal history was obtained from health records. The EHL Griffith birth cohort ceased recruitment and follow-up of participants several years ago when funding for the study ceased.

Looking to the future of birth cohorts in QLD, the Mater Hospital in Brisbane is in a strong position to establish such a cohort particularly given it has the highest birth rate in Queensland [23] and provides tertiary and quaternary level health services for both high, and low socioeconomic (SES) populations. Recently, the Queensland Family Cohort (QFC) completed a pilot feasibility study in Brisbane. The protocol for the QFC study was developed through a consultation process with QLD health researchers with expertise in DOHaD methodology. This multi-stage process resulted in a series of 21 research themes for the cohort. Each theme has its own series of questions and the methodologies to answer these have been developed by a collaborative group.

The particular strengths of this cohort design, are its 1) recruitment from entire state of QLD (1.85 million km^2), which has a population of 5.2 million including approximately 4.3% First Nation community members; 2) detailed collection of physical, social and mental health data of mother, father/partner, and child; 3) biological samples collected at multiple time points from all family members; 4) all survey instruments are based on validated tools and routinely collected clinical data; 5) inclusion of biological samples were agreed by the research collective only after detailed justification by individual researchers; 6) recognising the equal importance of the family relationships on the child so that parents and partners are all involved; 7) inclusive of same sex relationships and single parents; and 8) inclusion of any participant regardless of chronic and acute health conditions.

The data obtained will enable characterisation of all participants' health and social experiences for each family unit enrolled in the study to identify the current trends in health and health behaviours. It will identify immediate and future health requirements of the QLD population which will have a significant impact on health policy and practice and help define preventative interventions required for the health of future generations of Australians. Using this rich data source, we will endeavour to understand the biological mechanisms that may contribute to adverse health outcomes in parents and their children. This will drive future interventions in health care that include lifestyle, pharmacological and clinical modifications in practice.

Methods and analysis

Study Design and Setting

The QFC is a prospective, observational, longitudinal study that will be piloted at the Mater Mothers' Hospital (MMH) from 2018-2021 with an aim to continue for three decades. Families will be followed throughout pregnancy, childbirth and infancy via individually funded, separate follow-up studies. Long term follow-up of these participants and their children via data linkage is the aim. Although participant numbers for the pilot study have been attained, the research team continued to recruit into the cohort when COVID-19 pandemic arose in order to further understand implications of COVID-19 on families during the pandemic, albeit with a modified protocol.

Following thorough analysis of the pilot data, additional sites will be added across QLD after 2021, and will be inclusive of metropolitan, rural and remote communities. Additionally, this study will partner with First Nation communities and organisations to modify protocol methods to ensure the inclusion of these community members.

Inclusion criteria

For the pilot phase of the study, pregnant individuals who are booked to deliver at the MMH will be eligible to participate. Following the pilot project however, this will extend into a multisite program across QLD health services. Pregnant individuals who are permanent residents of Australia and reside in QLD, are 12-24 weeks pregnant and their partners, if they have one, will be invited to participate in the pilot study. To ensure the cohort is representative of the QLD population, every effort will be made to invite all eligible individuals to participate in the study including those; from non-English speaking backgrounds, under the age of 18 years, with special needs, and First Nation community members. Importantly, this cohort is seeking a true understanding of the breadth of health issues for families, so that participants with any underlying serious or chronic health conditions will be eligible for inclusion in the study.

Exclusion criteria

As this cohort has a significant focus on the health of the family unit, if the pregnant person would like to participate in the cohort, but their partner does not consent, or vice versa, then they will be excluded from the study. If either person is unable to give informed consent, they will be excluded from participating in the study.

Recruitment and Consent

Potential pregnant participants and their partners will be approached for participation in the study by suitably qualified experienced research midwives either face-to-face, via phone or via SMS. Alternatively, potential families can also contact the study via publicity generated by social media and marketing campaigns detailing the QFC study. Regardless of the mode used to make initial contact, those interested in participating will be provided with the participant information statement prior to obtaining written consent.

Study Regimen

Active data is collected from pregnant participants and their partners throughout their pregnancy, delivery and into early infancy, as shown in Table 2. Active data collection will continue in multiple locations in QLD up to three years gestational age corrected, with lifelong, passive data collection via MBS and PBS data linkage.

For the pilot study, data will be collected four times during pregnancy (12-24 weeks, 24 weeks, 28 weeks and 36 weeks), at delivery, post-delivery (on the ward), and at 6 weeks post-partum. Table 2 outlines items collected at each of these occasions that will be undertaken by the participant unaided, while Table 3 highlights the time and those items collected with the assistance of a research team member. In brief, these will be collected as follows: *12-24 weeks* – consent and enrolment forms completed by pregnant participant and their partner; *24 week* – is a study visit for pregnant participant and partner for questionnaires, biological sample collection from both and an ultrasound growth scan; *28 and 36 weeks* – each has a study visit for pregnant participant only with questionnaires, biological samples and a ultrasound growth scan collected; *delivery* – placenta, cord blood sample collection and chart review; *on-ward visit* – chart review, questionnaire and biological samples collected from mother and baby; *6 weeks post-partum* – breastfeeding assessment, body composition of infant, questionnaires and biological sample collection from mother. Consent for data linkage will be sought for participants from the QFC pilot study.

Study data will be collected and managed using Research Electronic Data Capture (REDCap) electronic data capture tools hosted at University of Queensland [24, 25]. REDCap is a secure, web-based software platform designed to support data capture for research studies providing 1) modifiable user rights to protect identifiable data; 2) an intuitive interface for validated data capture; 3) audit trails for tracking data manipulation and export procedures; 4) automated export procedures for seamless data downloads to common statistical packages; and 5) procedures for data integration and interoperability with external sources [26, 27]. Data

collected will be entered into REDCap by a Research Nurse/Midwife, Research Assistant or another suitably trained member of the research team. Double data entry and cross validation methods will be used to ensure validity and quality of data.

The QFC Study has focused on data collection and outcomes from 21 major themes from the QFC Research Collaborative (Figure 1), each with their own series of study questions highlighted in Supplementary Table 1. Data collected across the themes included participant questionnaires and routinely collected clinical data from medical charts (demographics, medication usage, medical history, pathology, medical imaging and other clinical results), as well as intervention data (biological samples, physical and psychological assessments obtained for research purposes only). Data will be collected by experienced and qualified research nurses, midwives and research assistants. Some data will be collected by research trained allied health professionals, including sonographers, dieticians, physiotherapists and psychologists prospectively from patient notes, observation charts, study specific questionnaires and assessments, photographs and videos, and electronic laboratory results by research staff and the principal investigator. Data collection forms will be electronic, except in cases where the participant does not have reliable access to a computer or the internet, or where a participant requests the use of paper forms.

Primary Outcomes

This cohort has three primary outcomes to determine:

i) current status of parental physical and mental health and its impact on health of offspring

ii) explore genetic and biological mechanisms that drive chronic disease risk in pregnancy, in childhood and in later life and

iii) understand the influence of the environment and climate change on the health of future generations.

Assessments

The associated measures, assessments and sample collections for the cohort are listed in Tables 2 and 3. All questionnaires for the study have been either used in routine clinical care or previously validated and references are included within the Tables where appropriate. Secondary outcomes specific to the individual themes are listed in Supplementary Table 1.

Sample Size

A sample size of 12,500 QLD families was chosen so that some of the rarer complications of pregnancy can be interrogated with sufficient statistical power. For example, delivery of small-

for-gestational infants occurs in approximately 6.7% QLD deliveries and a stillbirth delivery occurs in approximately 0.6% of QLD deliveries, thus warranting a large cohort size [28].

Statistical analysis

Missing outcome data will not be imputed in the primary analysis, as the key assumption of missing at random is not likely to hold in the analysis population. Sensitivity analyses will be conducted, however, using the multiple imputations method to explore the potential impact of missing data on outcomes. The characteristics of those participants with missing data will be compared between two treatment groups (healthy vs unhealthy outcomes). Baseline characteristics of babies and their parents will be summarised for each site, as well as overall, using descriptive statistics. Continuous variables will be reported as numbers of observed and missing values, mean, standard deviation, median and range. Categorical variables will be described as frequencies and percentages.

Data Availability Statement

Data from the QFC Study will be made available in the future for collaborative research questions. Such requests must be authorised by the Principal Investigators, the QFC Research Governance Committee and the appropriate Human Research Ethics Committees and Human Research Governance Safety Entities.

Patient and Public Involvement

The protocol for the pilot study was developed with extensive engagement within the QFC Research Collaborative community and a community engagement group including consumers (individuals aged 18-65). This group highlighted that understanding mental health and social support networks were essential for a vulnerable population such as pregnant women (and their families). Accordingly, both mental and physical wellbeing are strong components within the QFC study design (Table 2). In addition, the QFC Research Collaborative compromised of research academics and clinicians (Figure 1), identified the clinical data, biological samples and questionnaires necessary for taking a snapshot of a reproductive age population that would also capture the consumers suggestions raised in the community engagement group.

The QFC team are currently working in partnership with the First Nation communities of QLD to determine how to best ensure that this protocol is truly inclusive of their community members. At the time of writing, the research team developed the terms of reference to establish a new consumer panel who are either expecting a baby; have young children or are QFC pilot participants, who will further refine the protocol design from their previous experience and preferences, for the future multisite QFC study. The QFC team will ensure that this group

includes partners, and First Nation families. QFC pilot Participants were not involved in the recruitment of the study but have provided information in the form of feedback surveys to further refine the study protocol. Lay reports will be made available to interested participants in the form of a newsletter sent to them via email and via formal invitation to a seminar day where researchers will describe individual findings.

Sources of bias

One of the significant sources of bias is related to consent. Under the ethics approval given for the study, the research team can only approach potential participants to join the study if they have indicated that they are willing to be involved in 'any research that is undertaken by Mater Health' when they complete their antenatal enrolment forms. If the potential participant leaves this blank or indicates no, they cannot be contacted. This is likely to mean that those joining the study are coming from a pool of potential participants that may be better educated and of higher socio-economic status [29]. Although all potential pilot participants will be approached and followed-up using phone calls or SMS reminders, selection bias may be introduced for potential participants who are linguistically diverse and may fail to respond to follow-up attempts [30, 31]. Moreover, while we acknowledge that understanding the reason and demographics of families who do not consent to participant in this study would be of benefit, under the ethics approval for the pilot study, we are unable to follow-up or question a participant once they refuse contact. Like many other cohort studies, this protocol relies on the collection of self-reported data from participants. This is an inherent source of bias in self-collected data [32].

Ethics and regulatory aspects

Ethics

The QFC study has been approved by the Mater Misericordia Limited Human Research Ethics and Governance Safety Committee (HREC/16/MHS/113).

Participant Safety

All risks to the participants in the study will be mitigated by ensuring all recruitment and data collection is managed by appropriately trained and experienced research staff which have had training in empathetic, cross-cultural communication. Recruitment staff will be research nurses and midwives with extensive experience in research and clinical practice. Data will be stored in a secure setting and data linkage software will be adequately protected to maintain security and privacy.

Study Governance

The QFC study is overseen by the principal investigators and the QFC Research Governance Management Committee. This committee will meet every 2 months to: 1) continue to develop the strategic directions and priorities for the protocol; 2) review all sub-study applications to the cohort prior to their submission to ethics; and 3) review all unexpected findings from the analysis under an ethically defensible plan with the QFC Clinical Advisory Panel [33]. Each QFC research theme has a theme leader who will report annually and develop the individual research hypotheses within their theme. New research questions require a sub-study application that outlines what data requirements the applicant requires for their application along with their planned analysis. When approved by the QFC Research Governance Management Committee, the sub-study application and reference letter from the QFC Research Governance Committee is attached as supporting documents to a new Human Research Ethics application, where approval is sought. Most recently, the QFC Research Governance Management Committee has identified that a community-based Consumer Advisory Committee would be of benefit to the long-term development of the cohort as it continues into the future. The terms of reference for this group have been developed and its establishment is planned for late 2021.

Unexpected findings during examinations

Participants are advised during the consenting process that if disclosures are required by law, or there are health concerns during routine appointments that require urgent care, that it is the duty of care of the research midwives' to disclose or escalate the issue as appropriate. If analysed data from the study were to reveal findings that bear on the wellbeing of participants, their relatives or their community, whether anticipated or incidental to the scope of the research, the QFC Research Governance Committee team will be formally notified. The QFC Research Governance Committee will create a panel of experts to cross-check research findings for accuracy (QFC Clinical Advisory Panel). Only those confirmed research findings that are clinically actionable, where there are established therapeutic or preventative interventions or other available actions, such as lifestyle changes or reproductive decisions, that have the potential to change the clinical course of the disease or improve the individual's and/or their genetic relative's quality of life, will be considered to be returnable to the participant. This panel will, in conjunction with representatives from the QFC Research Governance Committee, identify and recontact the participant initially via letter, and then by telephone [33].

Dissemination

The findings from the analysis of cohort data will be disseminated in a variety of ways including abstracts, posters and presentations at conferences, and published manuscripts in peer-reviewed journals. These will also be reported to federal, state and local governments to inform policy and reports made to funding bodies, institutes and hospitals that participated in and supported the cohort study. Members of the study team will have publishing and authorship rights in accordance with NHMRC Australian Code for the Responsible Conduct of Research, the International Committee of Medical Journal Editors requirements for authorship, and as described in research agreements.

Discussion

The QFC is of enormous significance to Australia, particularly to the state of QLD. The only previous longitudinal cohort established in QLD was initiated over 30 years ago [12], and whilst its contributions continue to impact on policy, this cohort sampled only within metropolitan Brisbane and failed to include rural and remote QLD communities. Since its inception, there have been significant societal changes including an increasing burden of chronic disease in adulthood, thus impacting the health outcomes of pregnancy and infancy. Additionally, the impact of other influences such as home environment [34], social determinants of health [35] and the role of fathers [4] on the child are becoming better understood, and the QFC is one of the few Australian cohorts that includes direct sampling of partners. This work will lead to identification of immediate and future health requirements of Australian families, and a solid body of evidence with which to develop well-defined intervention studies to improve health.

The unique outcomes of the QFC will include: 1) deep analysis of maternal and paternal health during antenatal and postpartum periods; 2) examination of perinatal outcomes; 3) life-course analysis of maternal, paternal and infant health outcomes; 4) analysis of biological samples to understand biological mechanisms driving health outcomes; 5) development of rich data that characterises health, social, environmental and educational experiences of family members that can lead to improve understanding of health and disease for all family members during this period. To our knowledge, there is no other cohort within Australia and very few internationally, where all these five points are incorporated into a single study cohort.

The QFC pilot study has so far demonstrated the ability to recruit pregnant participants from private and public sectors, including specialised clinics such as diabetes and refugee clinics. Participating families had individual members born in 53 different countries including

Australia, with the maternal age of conception spanning 24 years. Further, our families have identified as single (pregnant participant only), cis-gender and LGBTQIA+ members. Overall, there has been a 10.6% withdrawal rate by 6 weeks post-partum. This suggests while still ongoing, the QFC study has the ability to cover the entire range of socioeconomic and cultural groups within the QLD population.

Like many longitudinal cohort studies [15], a significant limitation of the project is the cost of establishing and maintaining a cohort over a number of decades, storing its biological samples and the costs of analysis. To overcome these limitations, the principal investigator has developed this as a multi-institutional initiative that encompasses the entire state, with each institute contributing financially or in-kind towards the cohort (Figure 1). Additionally, the study protocol has not yet completed cultural consultation with the First Nations communities although it is in process with in-principal agreements from First Nation organisations as the first outcome achieved. At this point in the study, it is worth noting that the piloted participating families have been recruited in the metropolitan community of Brisbane and its findings, when reported, may not be widely applicable in rural and remote communities. In conclusion, despite the limitations, analysis of data arising from this cohort will influence policy and practice for health care that is based on the current health of QLD families, and provide further understanding of the impact of current health of family members on the health of the next generation.

Figure 1 Legend: The QFC Research Collaborative. Each large sphere (navy blue) represents one of the 21 research themes that compromise the QFC research collaborative. Each number represents an individual researcher (149 researchers to date). Each small sphere represents the affiliation of that particular researcher (51 collaborating institutes/universities). These affiliations are as follows: ACU (Faculty of Health Sciences); ACU (Institute for Learning Science and Teacher Education); ACU/UQ (Faculty of Health and Behavioural Sciences); Child Health Research Centre; Griffith University; James Cook University (Australian Institute of Tropical Health & Medicine); James Cook University (Department of Medicine); Mater Health; Mater Health Pathology (consultant microbiologist); Mater Health/Princess Alexander Hospital; Mater Health/ Queensland Children's Hospital; Mater Research – UQ/Mater Health; Mater Research/Carbal Medical Services; Mater Research -UQ; Menzies Health Institute Queensland/Griffith University (Griffith Health); Metro South Health/QUT (Faculty of Health); Metro South Health/Princess Alexander Hospital; Monash University (Faculty of Medicine, Nursing and Health Sciences); NSW Department of Planning, Industry and Environment; Pathology Queensland; QIMR Berghofer; QUT (Faculty of Health); QUT (Faculty of Health)/Child Health Research Centre; QUT (Faculty of Science and Engineering); QUT (Faculty of Science and Engineering)/Child Health Research Centre; QUT (Faculty of Health)/UQ (Centre of Clinical Research); QUT/University of Georgia; South Australian Health and Medical Research Institute; Sun Yat- Sen University; University of Newcastle; University of Southampton; UQ (Institute for Social Science Research; Faculty of Humanities and Social Sciences); UQ (Centre of Clinical Research); UQ (Diamantina Institute); UQ (Diamantina Institute)/Dermatology Research Centre; UQ (Discipline of General Practice; Primary Care Clinical Unit); UQ (Faculty of Business, Economics & Law); UQ (Faculty of Engineering, Architecture & Information Technology); UQ (Faculty of Health and Behavioural Sciences); UQ (Faculty of Health and Behavioural Sciences)/Bond University (Faculty of Health Sciences & Medicine)/Mater Health; UQ (Faculty of Medicine); UQ (Faculty of Medicine)/Child Health Research Centre; UQ (Faculty of Medicine)/Centre for Health Services Research; UQ (Faculty of Medicine)/Mater Research-UQ; UQ (Faculty of Medicine)/Perinatal Research Centre; UQ (Faculty of Science)/UQ (Centre of Clinical Research); UQ (Institute for Molecular Bioscience); UQ (Institute for Social Science Research); UQ (Queensland Brain Institute); Wesley Hospital Monash IVF; Wesley Hospital Monash IVF/University of Melbourne.

Tables

Table 1: Longitudinal birth cohorts in Australia where measures from one parent and the child were recorded. (Completed (C), Ongoing (O) and Emerging (E)).

Decade cohort began	Cohort Name	Status	Australian State or Territory	References
1970's	Port Pirie Cohort Study	O	SA	[36]
	Adelaide Nutrition Study	C	SA	[37]
	Brunswick Family Study	C	VIC	[38]
1980's	Mater- University of QLD Study of Pregnancy	O	QLD	[12]
	The Raine Study	O	WA	[14]
	Aboriginal Birth Cohort	O	NT	[39]
	Adelaide Respiratory Cohort	C	SA	[40]
	Nepean Study/ Nepean Kids Growing up Study	C	NSW	[40]
1990's	Generation One cohort	O	SA	[41]
	Tasmanian Infant Health Study	O	TAS	[42]
2000's	Environments for health living Griffith Birth Cohort study	C	QLD/ NSW	[22]
	Peri/Postnatal Epigenetic Study	O	VIC	[43]
	Triple B Study: Bumps, Babies and Beyond	O	NSW	[44]
	Watch Study	O	NSW	[45]
	Gudaga Study	O	NSW	[46]
	Gomeroi gaaynggal	C	NSW	[47]
2010's	Splash	E	VIC	[48]
	VicGen	E	VIC	[49]
	ORIGINS	E	WA	[50]
	Pregnancy and Neonatal Diabetes Outcomes in Remote Australia (PANDORA)	E	NT	[51]

Table 2 Questionnaires, measures and biological samples completed by participants within the QFC cohort unaided. The appropriate references are included for validated tools. Those without references are tools used routinely in clinical care. *Collection measures planned for the future.

Timepoint	Pregnant Participant		Partner		Baby	
	Questionnaires	**Measures/Samples**	**Questionnaires**	**Measures/Samples**	**Questionnaires**	**Measures/Samples**
Enrolment	Asthma Control Questionnaire (ACQ)[52] Adult Sleep Pattern Questionnaire (ASPQ)[53-56] Cultural background Feeding your baby[57] Obstetric History Physical Activity[58-62] Residential Housing Questionnaire (RHQ)[63] -nasal Outcome Test (22 items questionnaire) (SNOT-22)[64]	none	ACQ ASPQ Cultural background Feeding your baby Physical Activity RHQ SNOT-22	none	none	none
24 Week Gestation	ACQ Assessment of Quality of Life Questionnaire (AQoL-6D)[65] ASPQ Bristol Stool Chart[66] Constipation score [67] Couples Satisfaction Index (CSI)[68]	Hair Sample Microba Swab Saliva Sample Stool Sample Toenail Sample Urine Sample Vaginal Swab	ACQ AQoL-6D ASPQ Bristol Stool Chart Constipation score CSI DASS-21 DSM 5 CCSM EQ-5D-5L Full AES FFQ 2010 MSPSS	Hair Sample Microba Swab Saliva Sample Stool Sample Toenail Sample Urine Sample	none	none

	Depression Anxiety Stress Scale (DASS-21)[69] DSM-5 Self-Rated Level 1 Cross-Cutting Symptom Measure - Adult (DSM 5 CCSM)[70] EuroQol 5-dimenstion Questionnaire (EQ-5D-5L)[71] Full Australian Eating Survey Food Frequency Questionnaire (AES FFQ 2010) [72] Musculoskeletal Function Questionnaire (MSK Questions)[73, 74] Multidimensional Scale of Perceived Social Support (MSPSS)[75] Photograph of Medication Physical Activity RHQ SNOT-22 Social Readjustment Rating Scale (SRRS)[76]		Photograph of Medication Physical Activity RHQ SNOT-22 SRRS			
28 Week Gestation	ACQ ASPQ	Microba Swab Saliva Sample Stool Sample Urine Sample	none	none	none	none

	Photograph of Medication (if changed from last appointment) Physical Activity SNOT-22					
36 Week Gestation	ACQ ASPQ Constipation score Intention to breastfeed questionnaire [57] MSK Questions Photograph of Medication (if changed from last appointment) Physical Activity SNOT-22	Saliva Sample Urine Sample Vaginal Swab	none	none	none	none
Delivery	none	none	none	none	none	none
On-Ward	Breastfeeding questionnaire [57]	Colostrum/Breast Milk Sample	none	none	Skin-to-skin contact Nutrition	Meconium Sample Urine Sample
6 Weeks Post-partum	ACQ AQoL ASPQ Breastfeeding experience [57] Bristol Stool Chart Constipation score Childcare CSI DASS-21 DSM 5 CCSM	Breast Milk Sample Hair Sample Microba Swab Saliva Sample Stool Sample Toenail Sample Urine Sample	none	none	Infant Sleep Diary * Nutrition [57] Infant Medication	Hair Sample Stool Sample Toenail Sample Urine Sample

Edinburgh Postnatal Depression Scale (EPDS)[77]
EQ-5D-5L
Full AES FFQ 2010
MSK Questions
MSPSS
Photograph of Medication (if changed from last appointment)
Physical Activity
RHQ
SNOT-22
SRRS

Table 3 Surveys, histories, measures and biological samples completed by participants with the assistance of a research team member. #Asthma/Dermatitis related

Timepoint	Pregnant Participant		Partner		Baby	
	Surveys/Histories	**Measures/Samples**	**Surveys/Histories**	**Measures/Samples**	**Surveys/Histories**	**Measures/Samples**
Enrolment	Contact Details Demographics Education History Employment History Family History Malignant melanoma risk Medical History	Bioimpedance Blood Pressure Heart rate Height Skin fold thickness Weight	Contact Details Demographics Education History Employment History Family History Malignant melanoma risk Medical History	Height Waist Circumference Weight	none	none
24 Week Gestation	Alcohol Consumption Medication and Lifestyle Substances Smoking Status	Blood Sample Breast Skin Swab Cheek Swab Bioimpedance Blood Pressure Heart rate Skin fold thickness Weight Gestational Weight Gain (GWG)	Alcohol Consumption Medication and Lifestyle Substances Smoking Status	Bioimpedance Blood Pressure Blood Sample Cheek Swab Heart rate Skin fold thickness Skin Swab Waist Circumference Weight WG	none	Fetal Kidney Scan Fetal Growth Scan Uterine artery Doppler, US for Placental elastography Neonatal Intensive Care Unit (NICU) body measures in preterm infants
28 Week Gestation	Alcohol Consumption Medication and Lifestyle Substances Smoking Status	Bioimpedance Blood Pressure Blood Sample Heart rate Saliva Sample Skin fold thickness	none	none	none	Fetal Kidney Scan Fetal Growth Scan Uterine artery Doppler Placental elastography

	Pregnancy Complications Glucose Tolerance Tests	Weight GWG				NICU body measures in preterm infants
36 Week Gestation	Alcohol Consumption Medication and Lifestyle Substances Smoking Status	Bioimpedance Blood Pressure Blood Sample Cheek Swab Heart rate Saliva Sample Skin fold thickness Weight GWG	none	none	none	Fetal Kidney Scan Fetal Growth Scan Uterine artery Doppler Placental elastography NICU body measures in preterm infants
Delivery	Medication used during labour and delivery Delivery details including complications	none	none	none	Medication used during labour and delivery Delivery Details Length of NICU Stay	Abdominal Circumference Weight Cheek Swab Cord Blood or Guthrie cord blood spot Guthrie heel prick Head Circumference Middle Upper Arm Circumference Placenta dimensions, stereology, histology, weight Placenta photograph

On-Ward	Medication prescribed on ward and at discharge,	Blood pressure	none	none	Peapod Photograph/Video of baby's mouth, tongue, feeding Anthropometry Medication prescribed on ward and at discharge	Microba Swab Skin Swab
6 Weeks Post-partum	Alcohol Consumption Medication and Lifestyle Substances Smoking Status	Breast Skin Swab Cheek Swab	none	none	Photographs of rash# Video of feeding Medical Complications (first 6 weeks of life) Peapod	Abdominal Circumference Cheek Swab Head Circumference Microba Swab Middle Upper Arm Circumference Skin Swab

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Authors' contributions:

DB and KR jointly wrote the manuscript; DB, KR, SK, VC designed the QFC protocol; CT, TH, JJM, FF, MO responsible for recruitment and retention of participants for QFC cohort; DB, VC, CF, JS, JJM, CT, MO, TH designed the REDCap system for QFC data management; EC, CE, DF, SK designed ultrasound data collection; EC, CE collected ultrasound data from QFC participants; DB, CF, JS designed FreezerPro system for management of QFC participants; DB, KR, CT, TP, GdZ, KM, SK, VC are members of QFC Governance committee; CF, JS, JJM, CT, MO, TH, EC, CE, DF, TP, GdZ, KM, SK, VC all reviewed and edited of manuscript on behalf of the Queensland Family Cohort Research Collaborative. All members of the QLD Family Cohort Research Collaboration were involved in establishing the aims and the design of the cohort study.

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No competing interests

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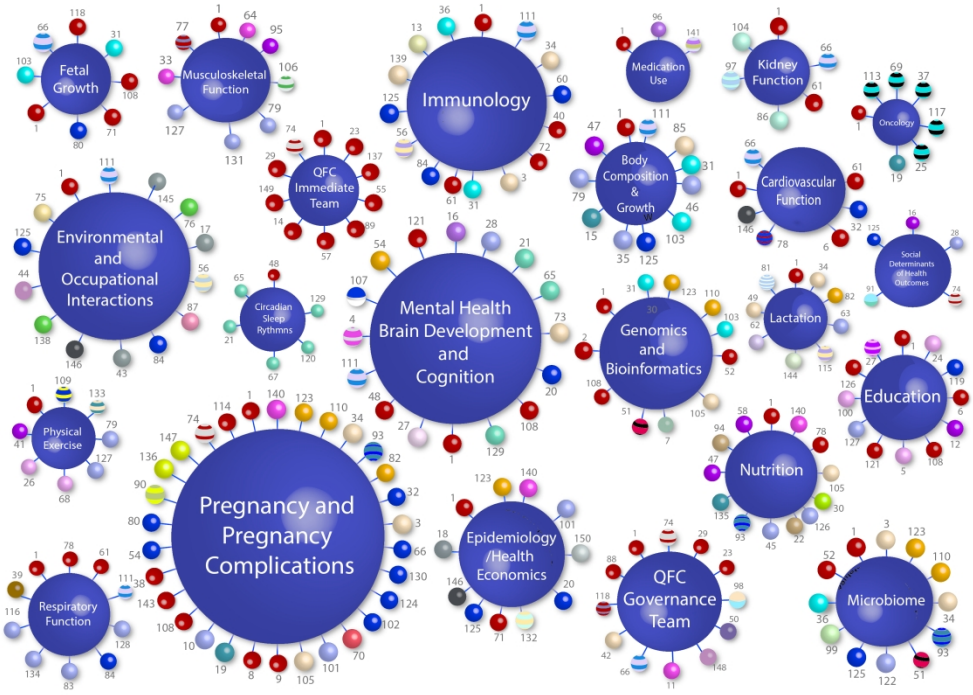

The QFC Research Collaborative. Each large sphere (navy blue) represents one of the 21 research themes that compromise the QFC research collaborative. Each number represents an individual researcher (149 researchers to date). Each small sphere represents the affiliation of that particular researcher (51 collaborating institutes/universities).

295x261mm (300 x 300 DPI)

Supplementary Table 1: Secondary Outcomes according to the 21 themes that make the QFC Research Collaborative. Research measures and samples used to address the secondary outcomes and the collaborations involved in addressing these questions. *Collection measures planned for the future $Age appropriate measures to be collected in the future.

Theme	Major Research Question	Primary Exposure Measures Collected		Collaborations
		Histories/Surveys/Questionnaires	Measures/Biological Samples	
Cardiovascular function	▶ Characterisation of the cardiovascular systems of our reproductive population and its relationship to fetal growth and child cardiovascular function ▶ The relationship between maternal cardiovascular system and placental circulation and fetal cardiac output (fetal distress, tachycardia, congenital heart defects) ▶ The relationship between maternal cardiovascular system and placental circulation and fetal kidney development	▶ Delivery Details ▶ Demographics ▶ Family History ▶ Medical History ▶ Medication and Lifestyle ▶ Medication chart review for medication during labour and delivery ▶ Pregnancy Complications	▶ Blood pressure ▶ Cord blood ▶ Heart rate ▶ Height ▶ Placenta and Placenta Measures ▶ Skinfold thickness ▶ Ultrasound data ▶ Urine ▶ Weight, BMI ▶ PeaPod	▶ Fetal Growth ▶ Kidney Function ▶ Medication Usage ▶ Neonatal/Child Body Composition and Growth ▶ Pregnancy and Pregnancy and Complications
Education	▶ What are the educational achievements of the parents and attitudes to linguistics? ▶ How does maternal-baby interaction influence early oracy? ▶ What is the impact of the parents' social and family networks on child literacy?	▶ Childcare ▶ Department of Education* and NAPLAN data linkage* ▶ Education history ▶ Pregnancy Complications ▶ Reading for Enjoyment ▶ Reading for Occupation	none	▶ Epidemiology and Health Economics ▶ Pregnancy and Pregnancy Complications ▶ Social Determinants of Health Outcomes

	▶ Tracking the relationship between child health and academic achievement through data linkage ▶ Impact of preterm delivery on linguistics, oracy and academic attainment ▶ Impact of childcare on oracy and literacy			
Environmental and Occupational Interactions	▶ Examine impact of environmental exposures on microbiome ▶ Are there similarities between the impact of environmental exposures on families in Australia relative to families in China? ▶ What is the impact of air quality on pregnancy outcomes and respiratory health? ▶ Gestational elemental exposures and its impact of pre and postnatal growth and development	▶ Adult Sleep Patterns ▶ Alcohol Consumption ▶ Australian Eating Survey Food Frequency ▶ Breastfeeding Questionnaires ▶ Delivery Details ▶ Demographics ▶ Depression Anxiety Stress Scale ▶ Education History ▶ Employment History ▶ Indoor/Outdoor air sample ▶ Medical History ▶ Medication and Lifestyle ▶ Medication chart review for medication during labour and delivery ▶ Postcode / Geocode ▶ Pregnancy Complications ▶ Residential Housing Questionnaire	▶ Baby Measures ▶ Blood ▶ Breast milk ▶ Hair ▶ Toenail ▶ Urine	▶ Immunology ▶ Lactation ▶ Medication Usage ▶ Microbiome ▶ Nutrition ▶ Pregnancy and Pregnancy Complications ▶ Respiratory

		▶ Smoking Status Assessment of Quality of Life questionnaire		
Epidemiology and Health Economics	▶ How does health utility change throughout pregnancy and post-partum? ▶ Is there inequality of opportunity in parental mental health outcomes and use of mental health and other health services? ▶ What are the payment mechanisms for health services for parents? Does travel impede their use of services? ▶ Does alcohol and substance abuse change health care utilisation during pregnancy?	▶ Alcohol Consumption ▶ Cultural background ▶ Demographics ▶ Education history ▶ Employment history ▶ European Quality of Life 5-Dimension ▶ Medical History ▶ Medication Treatment* ▶ PBS/MBS data linkage* ▶ Postcode / Geocode ▶ Pregnancy Complications	none	▶ Education ▶ Medication Usage ▶ Mental Health and Cognitive Development ▶ Pregnancy and Pregnancy Complications ▶ Social Determinants of Health Outcomes
Fetal growth	▶ Characterise the variables contributing to idiopathic growth restriction and large for gestational age ▶ How does fetal growth influence other early life characteristics (education, physical and mental health, social behaviour)	▶ Delivery Details ▶ Department of Education* and NAPLAN data linkage* ▶ Medical History ▶ Pregnancy Complications	▶ Baby Measures ▶ Cord blood ▶ Middle Cerebral Artery Doppler/Placental Artery Doppler ▶ Peapod ▶ Placenta and Placenta measures ▶ Ultrasound data	▶ Education ▶ Neonatal/Child Body Composition and Growth ▶ Pregnancy and Pregnancy Complications
Genomics and Bioinformatics	▶ The relationship between the genome, complex traits and disease, mental health, maternal	▶ Medical History ▶ Family History ▶ Demographics	▶ Blood ▶ Cheek swab ▶ Cord blood	▶ Mental Health and Cognitive Development

	and fetal health, pregnancy outcomes, and development ▶ The impact of the mitochondrial genome on pregnancy outcomes ▶ The interaction of the genome with the microbiome ▶ The role of and prevalence of somatic and de novo genomic variation ▶ Twin studies	▶ Pregnancy Complications	▶ Heel prick ▶ Microba swab ▶ Placenta: dimensions, samples ▶ Stool	▶ Microbiome ▶ Pregnancy and Pregnancy Complications
Immunology	▶ The in utero and early life contributions to childhood allergy, autoimmunity and disease development ▶ The influence of the maternal microbiome on childhood allergy, autoimmunity susceptibility and disease development ▶ The impact of maternal and childhood infection on child health and development ▶ The relationship between child microbiome and disease ▶ How extrinsic and intrinsic factors influence the development of the immune system	▶ Asthma control questionnaire ▶ Sino-Nasal Outcome test ▶ Medical History ▶ Medication and Lifestyle ▶ Medication chart review for medication during labour and delivery ▶ Pregnancy Complications	▶ Blood ▶ Cord blood ▶ Microba swab ▶ Saliva ▶ Stool ▶ Urine ▶ Vaginal swab	▶ Medication Usage ▶ Microbiome ▶ Pregnancy and Pregnancy complications ▶ Respiratory
Kidney Function	▶ What genetics factors contribute to kidney disease and kidney disease risk? Can these	▶ Alcohol Consumption ▶ Australian Eating Survey Food Frequency ▶ Delivery Details	▶ Baby Measures ▶ Blood ▶ Blood Pressure ▶ Height	▶ Cardiovascular Function ▶ Fetal Growth ▶ Medication Usage

	mutations be reversed to prevent kidney disease? ▶ What pregnancy related events compromise fetal kidney development? ▶ How does prematurity affect kidney development? ▶ What are the population-based characteristics of kidney function? ▶ Determinant of infant kidney size and function	▶ Demographics ▶ Medical History ▶ Medication and Lifestyle ▶ Medication chart review for medication during labour and delivery ▶ Pregnancy Complications	▶ PeaPod ▶ Ultrasound data ▶ Urine ▶ Weigh, BMI	▶ Neonatal/Child Body Composition and Growth ▶ Nutrition ▶ Pregnancy and Pregnancy Complications
Lactation	▶ Characterisation of breastfeeding habits in current population and parents views on breastfeeding ▶ Identification of factors that inhibit breastfeeding in first 6 weeks postpartum ▶ Identifying the impact of mastitis on breastfeeding continuation ▶ Determining the impact of BMI on breastfeeding continuation ▶ Impact of tongue tie on breastfeeding success	▶ Alcohol Consumption ▶ Australian Eating Survey Food Frequency ▶ Baby Nutrition ▶ Breastfeeding questionnaires ▶ Delivery Details ▶ Demographics ▶ Intention to breastfeed ▶ Pregnancy Complications ▶ Skin-skin contact ▶ Time to first breastfeed	▶ Baby Measures ▶ Breast milk ▶ Colostrum ▶ Height ▶ Photographs of mouth and tongue ▶ Skin swab ▶ Vaginal swab ▶ Videos of feeding ▶ Weight, BMI	▶ Microbiome ▶ Nutrition ▶ Pregnancy and Pregnancy Complications ▶ Social Determinants and Health Outcomes
Medication Usage	▶ To evaluate medication (prescription and non-prescription) usage patterns in mothers, partners and their children.	▶ Delivery Details ▶ Demographics ▶ Medication and Lifestyle ▶ Medication chart review for medication during labour and delivery	▶ Baby Measures	▶ Immunology ▶ Mental Health and Cognitive Development

	▶ To assess health outcomes (beneficial or adverse) and wellbeing of mothers, partners and their children in relation to medication use	▶ Medication Treatment* ▶ Pregnancy Complications		▶ Pregnancy and Pregnancy Complications
Mental Health, Brain Development and Cognition	▶ The relationship between maternal mental health and wellbeing and its impact on pregnancy and child neurodevelopmental outcomes ▶ The relationship between mental health status of partners and its impact on maternal mental health and wellbeing, pregnancy outcomes and child development ▶ Interaction and dependencies between mental and physical health	▶ Assessment of Quality of Life questionnaire ▶ Bayley Scales of Infant and Toddler Development* ▶ Child Behaviour and Neurodevelopment*$ ▶ Couple Satisfaction Index ▶ Depression Anxiety Stress Scale ▶ Edinburgh Post-natal Depression Scale ▶ European Quality of Life 5-Dimension ▶ Medical History ▶ Medication and Lifestyle ▶ Medication chart review for medication during labour and delivery ▶ Medication Treatment* ▶ Multidimensional Scale of Perceived Social Support ▶ DSM-5 Self-Rated Level 1 Cross-Cutting Symptom Measure - Adult ▶ Social Readjustment Rating Scale	▶ Blood ▶ Cheek swab ▶ Cord blood ▶ Urine ▶ Weight, BMI	▶ Fetal Growth ▶ Immunology ▶ Medication Usage ▶ Physical Exercise ▶ Pregnancy and Pregnancy Complications ▶ Social Determinants of Health Outcomes

Microbiome	▶ To examine the interaction between mother, father and baby microbiome (normal microbiome) ▶ To examine the impact of pregnancy and pregnancy complications on maternal and neonatal microbiome (infection, preterm birth, pre-eclampsia, hyperemesis gravidarum) ▶ To examine the role of nutrition, feeding and supplement usage in microbiome development and stability (method of feeding, vitamin/mineral supplementation) ▶ To examine the impact of medical interventions pre- and post-conception on the microbiome (IVF, medications) ▶ The characteristics of the vaginal microbiome in complicated pregnancies	▶ Bristol stool chart ▶ Constipation score ▶ Demographics ▶ Family History ▶ Hyperemesis Questions ▶ Medical History ▶ Medication and Lifestyle ▶ Medication chart review for medication during labour and delivery ▶ Pregnancy Complications	▶ Cheek swab ▶ Cord blood ▶ Microba swab ▶ Placenta and Placenta Measures ▶ Skin swab ▶ Stool ▶ Urine ▶ Vaginal swab	▶ Immunology ▶ Lactation ▶ Medication Usage ▶ Pregnancy and Pregnancy Complications

Musculoskeletal function	▶ Is obstructive defaecation associated with mode of delivery during childbirth? ▶ What is the prevalence, severity and impact of foot pain during pregnancy and postpartum and is predictive of peri-or post-natal prolapse? ▶ Is physical activity in the ante- and post-natal period related to the prevalence of Pregnancy-related Low back pain, pelvic girdle pain and Stress Urinary Incontinence?	▶ Adult Sleep Patterns ▶ Bristol stool chart ▶ Constipation score ▶ Demographics ▶ Employment History ▶ Medical History ▶ Musculoskeletal function ▶ Physical Activity ▶ Pregnancy Complications ▶ Pregnancy History ▶ Residential Housing Questionnaire ▶ Smoking Status	▶ Height ▶ Weight, BMI ▶ Blood	▶ Pregnancy and Pregnancy Complications ▶ Physical Exercise
Neonatal/Child Body Composition and Growth	▶ Is infant body composition related to later health and disease? ▶ Characterisation of body composition from in utero to early life ▶ Genetic factors that contribute to obesity in childhood ▶ Impact of preterm delivery on body composition ▶ What is the contribution of early life nutrient to body composition over time	▶ Baby Nutrition* ▶ Breastfeeding questionnaires ▶ Demographics ▶ Feeding your baby ▶ Medical History ▶ Medication and Lifestyle ▶ Pregnancy Complications ▶ PBS/MBS data linkage*	▶ Baby measures ▶ Cheek swab ▶ Cord blood ▶ Guthrie Heel Prick ▶ NICU body measures for preterm infants ▶ PeaPod ▶ Ultrasound data	▶ Cardiovascular Function ▶ Fetal Growth ▶ Genomics and Bioinformatics ▶ Medicine Usage ▶ Nutrition ▶ Pregnancy and Pregnancy Complications
Nutrition	▶ How does maternal dietary intake, micronutrient supplement intake, and gestational weight gain change	▶ Alcohol consumption ▶ Australian Eating Survey Food Frequency ▶ Breastfeeding Questionnaires	▶ Baby measures ▶ Bioimpedance ▶ Blood ▶ Height	▶ Education ▶ Medication Usage

	during pregnancy and the early postpartum period, and how does this compare with guidelines? ▶ What is the relationship between dietary intake and gestational weight gain across pregnancy? ▶ What is the relationship between maternal and paternal characteristics and (i) dietary and (ii) gestational weight gain guideline attainment? ▶ What maternal characteristics mediate the relationship between dietary intake/micronutrient supplement intake and nutrient status during pregnancy and the early postpartum period, and how does this affect birth outcomes? ▶ What is the relationship between maternal dietary intake/micronutrient supplementation and her gut microbiome, and how does this affect birth outcomes?	▶ Delivery Details ▶ Demographics ▶ Medical History ▶ Medication and Lifestyle ▶ Pregnancy Complications	▶ Skin fold thickness ▶ Waist circumference ▶ Weight, BMI ▶ Placenta and Placenta Measures ▶ Stool ▶ PeaPod	▶ Mental Health and Cognitive Development ▶ Microbiome ▶ Neonatal/Child Body Composition and Growth ▶ Pregnancy and Pregnancy Complications
Oncology	▶ Pregnancy and melanoma risk ▶ Breast cancer and breastfeeding ▶ Origins of childhood cancer ▶ Lifestyle factors and risk of cancer	▶ Alcohol consumption ▶ Australian Eating Survey Food Frequency ▶ Baby Nutrition* ▶ Breastfeeding Questionnaires	▶ Breastmilk ▶ Blood ▶ Placenta ▶ Saliva	▶ Genomics and Bioinformatics ▶ Lactation ▶ Medication Usage ▶ Nutrition

	▶ Ovarian cancer and pregnancy ▶ Identification of risk factors for melanoma during pregnancy and beyond	▶ Demographics ▶ Exposure Measurements (Water, Sun, Chemicals, Pesticides)* ▶ Family History ▶ Malignant melanoma risk ▶ Medical History ▶ Medical Scans (x-ray, PET, CAT)* ▶ Medication and Lifestyle ▶ Medication Treatment* ▶ Pregnancy Complications		▶ Pregnancy and Pregnancy Complications
Physical Exercise	▶ Activity changes with pregnancy ▶ The effect of exercise during pregnancy on domains of early childhood development ▶ How does activity in Australian women now compare to the Australian women's longitudinal study data of aged matched women from the 1990s ▶ The role of movement across the day on maternal mental health ▶ Effect on physical activity on placental thickness	▶ Alcohol Consumption ▶ Australian Eating Survey Food Frequency ▶ Demographics ▶ Family History ▶ Medical History ▶ Medication and Lifestyle ▶ Physical Activity ▶ Smoking Status	▶ Baby Measures ▶ Blood ▶ Cord blood ▶ Height ▶ Placenta ▶ Placenta and Placenta Measures ▶ Saliva ▶ Weight, BMI	▶ Education ▶ Medication Usage ▶ Mental Health and Cognitive Development ▶ Nutrition ▶ Pregnancy and Pregnancy Complications ▶ Social Determinants and Health Outcomes
Pregnancy and Pregnancy Complications	▶ What are the pregnancy related risk factors, placenta function and outcomes associated with PE, PTD, GD, IUGR?	▶ Alcohol Consumption ▶ Asthma Control Questionnaire ▶ Australian Eating Survey Food Frequency	▶ Baby Measures ▶ Blood ▶ Cheek swab ▶ Cord Blood ▶ Guthrie blood spot	▶ Fetal Growth ▶ Genomics and Bioinformatics ▶ Microbiome

	▶ Placental micronutrient environment and its relationship to maternal nutrition ▶ The impact of endocrine disruptors on thyroid function and placental TSH pathways ▶ Link between genetics and pregnancy complications ▶ Placental iron transfer and iron bioavailability in infants of asthmatic mothers ▶ The role of eicosanoids in mid-late gestation	▶ Delivery Details ▶ Demographics ▶ Family History ▶ Hyperemesis questions ▶ Medical History ▶ Pregnancy Complications	▶ Placenta and Placenta Measures ▶ Ultrasound Data ▶ Vaginal swab	▶ Neonatal/Child Body Composition ▶ Nutrition
Respiratory	▶ What is the prevalence of asthma in the reproductive age population? ▶ Does maternal asthma worsen with pregnancy and is it related to environmental pollutants? ▶ What pregnancy related variables influence the development of asthma in childhood? ▶ How does rhinitis in pregnancy influence neonatal outcome?	▶ Alcohol Consumption ▶ Asthma Control Questionnaire ▶ Delivery Details ▶ Demographics ▶ Exacerbation Questionnaire ▶ Family History ▶ Medical History ▶ Medication and Lifestyle ▶ Physical Activity ▶ Pregnancy Complications ▶ Sino-nasal Outcome Test ▶ Smoking Status	▶ Blood ▶ Height ▶ Photographs of Rash ▶ Weight, BMI	▶ Immunology ▶ Medication Usage ▶ Pregnancy and Pregnancy Complications
Sleep and Circadian Rhythms	▶ Impact of parental sleep and stress on parental physical, social and mental health ▶ Impact of pregnancy on sleep patterns and sleep disturbance	▶ Adult Sleep Patterns ▶ Australian Eating Survey Food Frequency ▶ Couple Satisfaction Index ▶ Delivery Details ▶ Demographics	▶ Baby Measures ▶ Height ▶ Weight, BMI ▶ Bioimpedance	▶ Education ▶ Mental Health and Cognitive Development ▶ Medication Usage

	▶ Relationship between early identification of snoring and sleep disturbance with pregnancy complications: gestational diabetes, pre-eclampsia, fetal growth restriction, preterm delivery, autism ▶ Impact of parental and child sleep on child development and physical health outcomes ▶ Relationship between environmental and biological factors with parental and child sleep	▶ Depression Anxiety Stress Scale ▶ Edinburgh Post-natal Depression Scale ▶ European Quality of Life 5-Dimension ▶ Infant sleep diary ▶ Medical History ▶ Medication and Lifestyle ▶ Multidimensional Scale of Perceived Social Support ▶ Physical Activity ▶ DSM-5 Self-Rated Level 1 Cross-Cutting Symptom Measure - Adult ▶ Social Readjustment Rating Scale ▶ Pregnancy Complications	▶ NICU body measures in preterm infants ▶ Peapod	▶ Pregnancy and Pregnancy Complications
Social Determinants of Health Outcomes	▶ Impact of social disadvantage on maternal, paternal health in Qld ▶ Does parental social determinants of health (housing, education, employment) impact on pregnancy and birth outcomes? ▶ Social networks and their impact on child development ▶ Social disadvantage and its impact on child nutrition, cognitive development and	▶ Childcare ▶ Demographics ▶ Depression Anxiety Stress Scale ▶ Edinburgh Post-natal Depression Scale ▶ Education History ▶ Employment History ▶ European Quality of Life 5-Dimension ▶ Family history ▶ Multidimensional Scale of Perceived Social Support ▶ Physical Activity	none	▶ Education ▶ Epidemiology and Health Economics ▶ Genomics ▶ Mental Health and Cognitive Development ▶ Nutrition ▶ Pregnancy and Pregnancy complications

	subsequent child educational outcomes ▶ What are the characteristics of individuals who are resilient in the face of early life adversity? ▶ How does developmental trauma and early adversity among individuals affect long-term trajectories	▶ DSM-5 Self-Rated Level 1 Cross-Cutting Symptom Measure - Adult ▶ PBS/MBS Data Linkage* ▶ Residential housing questionnaire ▶ Social Readjustment Rating Scale

STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1 3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5
Objectives	3	State specific objectives, including any prespecified hypotheses	7
Methods			
Study design	4	Present key elements of study design early in the paper	8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	8-9
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up (*b*) For matched studies, give matching criteria and number of exposed and unexposed	8-9
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	20-25
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	20-25
Bias	9	Describe any efforts to address potential sources of bias	11
Study size	10	Explain how the study size was arrived at	10
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	20-25
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding (*b*) Describe any methods used to examine subgroups and interactions (*c*) Explain how missing data were addressed (*d*) If applicable, explain how loss to follow-up was addressed (*e*) Describe any sensitivity analyses	11
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	n/a
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time (eg, average and total amount)	n/a
Outcome data	15*	Report numbers of outcome events or summary measures over time	n/a

Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (*b*) Report category boundaries when continuous variables were categorized (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	n/a
Discussion			
Key results	18	Summarise key results with reference to study objectives	14
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	15
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	14
Generalisability	21	Discuss the generalisability (external validity) of the study results	14
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	29

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.