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Title page

Original Research Article

A cohort of Indigenous Australian women and their children through pregnancy and beyond: The *Gomeri gaaynggal* study

Short title: The *Gomeri gaaynggal* study

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Abstract

Indigenous Australians have high rates of chronic diseases, the causes of which are complex and include social and environmental determinants. Early experiences *in utero* may also predispose to later-life disease development. The *Gomeri gaaynggal* study was established to explore intrauterine origins of renal disease, diabetes, and growth in order to inform the development of health programs for Indigenous Australian women and children. Pregnant women are recruited from antenatal clinics in Tamworth, Newcastle, and Walgett, New South Wales, Australia, by Indigenous research assistants. Measures are collected at three time points in pregnancy and from women and their children at up to eight time points in the child's first five years. Measures of fetal renal development and function include ultrasound and biochemical biomarkers. Dietary intake, infant feeding, and anthropometric measurements are collected. Standardised procedures and validated tools are used where available. Since 2010 the study has recruited over 230 women, and retained 66 postpartum. Recruitment is ongoing, and *Gomeri gaaynggal* is currently the largest Indigenous pregnancy-through-early-childhood cohort internationally. Baseline median gestational age was 39.1 weeks (31.5-43.2, n=110), median birth weight was 3180g (910-5430g, n=110). Over one third (39.3%) of infants were admitted to special care or neonatal nursery. Nearly half of mothers (47.5%) reported tobacco smoking during pregnancy. Results of the study will contribute to knowledge about origins of chronic disease in Indigenous Australians and nutrition and growth of women and their offspring during pregnancy and postpartum. Study strengths include employment and capacity-building of Indigenous staff and the complementary ArtsHealth program. **Key Words:** Indigenous, Aboriginal, Renal, Diabetes, Nutrition

Introduction

Internationally there are an estimated 370 million people across 70 countries who self-identify as Indigenous, including Aboriginal and Torres Strait Islander people of Australia, Maori people of New Zealand, Indigenous people of the Americas, and the Sami or Laplander people of northern Scandinavia^{1,2}. Disparities in Indigenous and non-Indigenous health continue worldwide. In both economically developed and developing nations where Indigenous people reside, Indigenous people experience poorer health status than the overall population³. There are significant disparities in birth outcomes for Indigenous people in Australia, New Zealand, the United States, and Canada, including higher rates of still birth, infant mortality, and preterm birth for Indigenous infants compared with non-Indigenous⁴. Indigenous infants in Australia and the United States are more likely to be of low birth weight⁴. Prospective pregnancy cohort studies of Indigenous peoples are unfortunately scarce, as they may be of great value in determining the causes and trajectories of poor health in these populations.

Indigenous Australians have a life expectancy ten years lower than non-Indigenous Australians⁵. Renal disease, diabetes, overweight and cardiovascular diseases are particularly prevalent in Indigenous Australians^{6,7}, and are significant risk factors for development of hypertension and stroke. In 2012-13, heart disease affected around 12% of Indigenous Australians.⁷ Overweight and obesity are significant public health concerns in Australia, with Indigenous Australians 1.6 times as likely to be obese as non-Indigenous Australians.⁸ In 2012-13, 66% of Indigenous Australians over 15 years of age were overweight or obese.⁸

The prevalence of preterm and low birth weight babies is higher for Indigenous Australians than for non-Indigenous women.⁹ In 2012, 14.3% of babies of Indigenous mothers were born

preterm, a greater proportion than the 8.3% of babies born preterm to non-Indigenous mothers.⁹ The proportion of babies born of low birth weight (<2500g) to Indigenous mothers (11.8%) was nearly twice that as low birth weight babies born to non-Indigenous mothers (6.0%).⁹

There are many contributing factors to the continuing inequalities in health experiences and life expectancy, including a long history of colonisation and oppression in many of these countries resulting in a legacy of political, economic and social disadvantage for Indigenous peoples. Social and environmental determinants of health include education, employment and income, nutrition, breastfeeding, tobacco use, and chronic infections. Optimal nutrition is a crucial factor influencing growth and development and is protective against ill-health.

Healthy growth in the early years of life can be a good indicator of a child's health and nutritional status. The National Aboriginal and Torres Strait Islander Nutrition and Physical Activity Survey (NATSINPAS) identified areas for improvement in terms of dietary intake for Indigenous Australians, including increasing vegetable and fruit consumption and decreasing foods that are nutrient-poor and energy-dense.¹⁰ Food insecurity can contribute to poor nutrient intake, and the NATSINPAS found that over one fifth of Indigenous Australians were living in a household where someone went without food when food ran out.¹⁰

Breastfeeding provides both short and long term health benefits for mother and child. In 2012-13, the rate of any breastfeeding was 83% for Indigenous children and 93% for non-Indigenous children.⁸ Nearly half (44%) of Indigenous Australians aged 15 and over reported being tobacco smokers in 2012-13.⁸

There is evidence that many chronic diseases have their origins in the intrauterine environment. David Barker proposed and provided epidemiological evidence that under-nutrition during intrauterine life predisposed to earlier onset of chronic disease; poor supply of nutrients programs structural and functional changes in the metabolism of the developing

fetus to anticipate an extrauterine environment with low nutrient availability¹¹⁻¹³. Barker and colleagues showed that low birth weight was associated with an increased risk of coronary heart disease, hypertension, stroke and type 2 diabetes mellitus later in life^{11, 12}. This risk is heightened in children with low weight gain in the first two years of life, especially if followed by rapid increases in body fat mass when a high energy diet is consumed that conflicts with that anticipated from the intrauterine experience¹¹.

The functional units of the human kidney (nephrons) are formed by 34 weeks gestation. Once formed, the number of nephrons in each kidney at birth will not change throughout life. A low nephron number predisposes an individual to chronic renal disease later in life¹⁴. Babies born early, particularly those born before 34 weeks, and those born small for gestational age are more likely to have low nephron numbers. A low nephron number will result in compensatory hyperfiltration by existing nephrons, making these nephrons prone to failure and leading to impaired renal function. Indigenous people are more likely to have a reduction in nephron number¹⁴. In 2012-13 Indigenous Australians were twice as likely as non-Indigenous Australians (rate ratio 2:1) to have signs of chronic kidney disease (CKD) (after adjusting for age), with almost one fifth of Aboriginal and Torres Strait Islander people aged ≥ 18 years having indicators of CKD in 2012-13¹⁵. The rate of CKD for Indigenous women was 16.9% in 2012-13, and Indigenous women are more likely to have kidney disease than non-Indigenous women (rate ratio 3.6).^{7, 15} Rates of CKD are particularly high in remote areas of Australia where 33.6% of people were identified as having indicators of CKD in 2012-13, compared with 13.1% of people living in non-remote areas¹⁵. Diabetes, which poses a high risk for development of early onset renal disease, is also more prevalent in Indigenous Australians¹⁵. Aboriginal and Torres Strait Islander people are more than three times as likely to have diabetes than non-Indigenous Australians with 11% of the Indigenous population identified as having diabetes, diagnosed by fasting plasma glucose test (≥ 7.0

mmol/L indicative of diabetes) and glycated haemoglobin test (HbA1c $\geq 6.5\%$) in the Australian Aboriginal and Torres Strait Islander Health Survey 2012 -13 ¹⁵.

Preterm birth contributes to the prevalence of low birth weight in babies and to the subsequent predisposition to chronic disease development. There is evidence of a relationship between stress during pregnancy and preterm birth ¹⁶. Stressors for Indigenous women include; chronic pre-existing renal disease, chronic infections, cigarette smoking and passive exposure to smoke, and poor nutrition. Social stressors include exposure to major life events (*e.g.* death of a loved one) and racism. In 2012-13, Indigenous Australians were 2.7 times as likely as non-Indigenous Australians to experience high levels of psychological distress (major stressors included death of a family member or close friend, serious illness, unemployment, mental illness, or problems with drugs or alcohol)⁸. Racism is a significant problem. In 2012-13, 16% of Indigenous Australians felt they had been treated badly because they were Indigenous.⁸

Smith and colleagues have previously reported on the 'placental clock': a determinant of the length of human pregnancy gestation ¹⁷. Placental secretion of corticotropin-releasing hormone (CRH) and maternal plasma concentrations of CRH rise exponentially during pregnancy, coinciding with a fall in concentration of CRH binding protein late in pregnancy. The subsequent surge in CRH bioavailability coincides with the onset of parturition, implying that high CRH acts as a prompt for the birth of offspring ¹⁷. In women who deliver preterm babies, the hormone rises more rapidly than normal. The release of CRH is triggered by activation of the hypothalamic pituitary axis and its stimulation of the stress-hormone cortisol, causing a positive feed-forward system (see Figure 1). Therefore any stress in the pregnant woman's life may result in preterm birth, and low birth weight infants. Exploring the reasons for stress-related hypercortisolaemia and methods for its prevention will potentially reduce the incidence of preterm birth of small babies.

The *Gomeri gaaynggal* (Gomeri babies) study aims to explore the relationship between exposure to stressors in the intrauterine environment and offspring health and growth outcomes (Figure 1). A specific aim is to investigate the developmental origins of renal disease and diabetes in Indigenous people, and in doing so to develop methods for the early detection and prevention of these chronic diseases.

Method

Study Design and Setting

The *Gomeri gaaynggal* study is a prospective longitudinal cohort of Indigenous mother-child dyads during pregnancy and up until the children are aged five years.

The study is primarily conducted at the *Gomeri gaaynggal* centre, a facility of the University of Newcastle in Tamworth, New South Wales (NSW), Australia. NSW has the largest population of Indigenous Australians of any Australian state, with one third of the country's Indigenous peoples residing here ¹⁸. The 2011 census estimated 208,476 Indigenous people resided in NSW out of 669,881 Indigenous Australians in the country ¹⁸. There are three recruitment sites in NSW for the study: Tamworth, (rural town), Newcastle (regional city); and Walgett (remote town).

The *Gomeri gaaynggal* centre was established within walking distance of the Tamworth Aboriginal community to facilitate access and reduce socioeconomic barriers to recruitment and retention. Tamworth is in the Hunter New England region of NSW. As of 2012, the population of the Tamworth region was 58,922 persons ¹⁹. In the 2011 census, 8.4% of the Tamworth regional population identified as Aboriginal and/or Torres Strait Islander ¹⁹.

Newcastle is a coastal city in Hunter New England. The population of the Newcastle local government area in 2012 was 157,273 persons, of whom a small percentage (2.6%) identified as Aboriginal or Torres Strait Islander in the 2011 census²⁰.

Walgett is a small remote town in northwest NSW. In the 2011 census, 823 of the 1626 counted residents in Walgett identified as Aboriginal or Torres Strait Islander (99% of whom identified as Aboriginal)²¹. This figure may be a modest estimation, as the Australian Bureau of Statistics estimated that nationally the Aboriginal ‘undercount’ was 17%²¹.

Community Consultation

Before commencing the study, researchers engaged in a two year process of community consultation with Indigenous stakeholders, including Elders, mothers’ groups, schools, employment agencies and local Indigenous health organisations²². Through this consultation it was determined that the research would occur concurrently with a program that would provide immediate benefits to the community. An ArtsHealth program for women in pregnancy and post-delivery was established. As part of the program, a local Indigenous Elder and artist offers art mentorship and visiting health professionals and health students come to discuss a range of health topics. The program offers a safe space, informal health information, contacts in the health services and resources to empower Indigenous women to make active changes to improve their health and that of their children. Further details of this community consultation and its outcomes have been published elsewhere²².

Ethics Approval

The *Gomeroi gaaynggal* study received ethics approval from the following committees: the Hunter New England Human Research Ethics Committee (reference number 08/05/21/4.01); the New South Wales Human Research Ethics Committee (reference number HREC/08/HNE/129); and the Aboriginal Health and Medical Research Council (reference

number 654/08). Protocols are in place to ensure participants are referred to the appropriate health services if adverse results are found. Participants receive no reimbursements or financial incentives to participate.

Recruitment

Recruitment began in 2010 and is continuing at the time of publication. In Tamworth, participants are recruited by Indigenous research assistants at one of two antenatal clinic locations, including an Indigenous antenatal birth service. In Walgett, recruitment is conducted by an Indigenous research assistant at the Walgett Aboriginal Medical Service. In Newcastle, recruitment was through *Birra-li*, the Indigenous antenatal birth services. Engaging with and retaining the Newcastle cohort however proved difficult, and recruitment no longer occurs at this site. Pregnant women who identify as Indigenous Australians, or pregnant non-Indigenous women with Indigenous partners are eligible to participate and can enrol at any stage in their pregnancy. From three months postpartum, mother and infant dyads are eligible for the follow up study. Participants give written, informed consent to participate in the pregnancy study and provide renewed consent to continue into the postpartum follow up study.

Data are collected once per trimester during pregnancy, four times during the infant's first year of life, (three, six, nine and twelve months) and when the child is aged two years. Where there are indicators of potential renal impairment in either mother or child, participant dyads are followed up until the child is aged five years. While attempts are made to see participants as close to these ages as possible, data collection is undertaken at times to suit participants.

Data collected at each time point for women participating in the *Gomeroi gaaynggal* study are shown in Table 1. Table 2 outlines the data collected at each time point for their children. Details of these variables are described below.

Biochemical data

Biological samples (maternal blood, urine and saliva, fetal cord blood, and child urine) are collected at various time points throughout the study (Tables 1 and 2).

Biochemical measures assessed include: (i) plasma and urinary protein, electrolytes, urea, creatinine; (ii) serum cystatin C; (iii) urinary and plasma glucose; (iv) full blood cell count (including white cell count); (v) immunoglobulins; (vi) total immunoglobulin classes (IgA, IgG and IgM) and IgG specific for *Helicobacter pylori*; (vii) red cell folate; (viii) Vitamin B12; (ix) cortisol; (x) cotinine. The efficacy of novel renal biomarkers in this population which is at risk of chronic kidney disease is being investigated.

In addition, we use the samples to examine markers of cardiovascular and kidney function in this cohort of Indigenous women in pregnancy.

Samples in the form of whole blood, serum, plasma, urine and saliva have been stored at -80°C in aliquots of 1ml to reduce the impact of freeze-thaw on samples for future use.

Blood Pressure and Ultrasound

Maternal blood pressure is taken using a Riester re-champion® blood pressure machine and cuff. Infants' blood pressure is taken at each study visit from 3 months of age. A GE CRITIKON™ DURA-CUF™ blood pressure cuff for infants (8-13cm circumference) is used.

Ultrasound scans are conducted using a Phillips Cx50 Portable Diagnostic Ultrasound with a 5MHz convex transducer. Gestational age, single or multiple pregnancy, fetal anomalies and viability, and estimated date of delivery are determined at the first trimester scan. In the second trimester, fetal morphology and signs of abnormality are checked. In the final trimester renal arteries, umbilical arterial dopplers, and liquor volume are assessed. Fetal measurements of head circumference, abdominal circumference and femur length are

calculated to estimate fetal weight at each scan; fetal growth is monitored throughout pregnancy. Fetal kidney measures are anterior-posterior, transverse, and length. These are taken as soon as the kidneys can be visualised and kidney volume is calculated from these measures²³.

Questionnaires

Nutritional Assessment

Measures of dietary intake of women and infants are collected via:

- (i) Food Frequency Questionnaires: the Australian Eating Survey for mothers²⁴ and the Australian Child and Adolescent Eating Survey for children²⁵;
- (ii) Infant Feeding Recall (IFR) collects information on initiation and duration of breastfeeding and if infants have regularly consumed the following (and age of initiation): infant formula; cow's milk (as a drink); milk substitutes; solid foods. Questions for the IFR were selected from the NSW Child Health Survey 2001 and the 1995 National Nutrition Survey^{26 27};
- (iii) Current Feeding Practices (CFP) questionnaire asks mothers about their child's sources of nutritional intake in the 24 hours preceding the interview, including intake of: vitamin or mineral supplements; medicine; plain water; sweetened or flavoured water (e.g. soft drinks or cordial); fruit juice; tea or infusion; oral rehydration salts; any other food or fluids. The CFP is based on the recommendations of Webb and colleagues²⁸. Both the IFR and CFP have been used in other cohort studies of women and their children in pregnancy and beyond²⁹;
- (iv) Twenty-four hour food recalls of mothers and infants (via mothers) are conducted to report all food and fluid intake in the 24 hours preceding the interview day.

Psychosocial Assessment

Validated psychosocial tests are all self-administered to determine aspects of psychosocial health for the women participating in the study:

- (i) Stressful Life Events (an excerpt from the National Aboriginal and Torres Strait Islander Health Survey [NATSIHS]). The Stressful Life Events survey has been validated in Indigenous populations ³⁰;
- (ii) Impact of Event Scale (revised). The Impact of Event scale has not been validated in Indigenous people, however it has been used in a variety of population groups by Wadhwa and colleagues ³¹;
- (iii) Kessler 10+. The Kessler 10+ has been found to be a useful tool for measuring psychological distress in middle-aged and older Indigenous Australians ³²;
- (iv) Discrimination survey (excerpt from the NATSIHS). The Discrimination survey has been validated in Indigenous populations ³⁰.

Additional questionnaires elicit information for:

- (i) medical history;
- (ii) self-reported tobacco use;
- (iii) self-reported alcohol consumption
- (iv) maternal age, employment status, and educational attainment.

Details of previous pregnancy history, family medical history and gynaecological history, and offspring's gender, birth weight and Activity, Pulse, Grimace, Appearance, and Respiration (APGAR) score, are obtained through the Obstetrics database set, antenatal records and the midwives birth register.

Anthropometry

Anthropometric measures are performed by an Accredited Practising Dietitian (APD) with Level One Anthropometrist certification from the International Society for the Advancement of Kinanthropometry (ISAK). All circumferences, girths, skinfold thicknesses, and lengths are measured in accordance with the ISAK protocol ³³. Measurements include:

- (i) maternal pre-pregnancy weight (self-reported);
- (ii) maternal height;
- (iii) maternal body composition obtained using InBody 720™ bioelectrical impedance scales (Biospace Co., Ltd., Seoul, Korea) including Body Mass Index (BMI), visceral fat area, body fat mass, skeletal muscle mass, total body water and body fat percentage;
- (iv) at each postpartum study visit maternal girths and circumferences are obtained including: mid-upper arm; waist; gluteal; upper thigh; and calf;
- (v) infant weight is obtained at each postpartum visit using infant scales;
- (vi) infant length is measured crown-to-heel at each postpartum visit;
- (vii) infant girths and circumferences: head, mid-upper arm; abdomen (at level of umbilicus); mid-thigh; and calf;
- (viii) skinfold thicknesses of infants are obtained using Harpenden skinfold calipers at the following sites: subscapular; biceps; iliac crest; front thigh; and medial calf ³³.

Data Management

Participants are given unique study identification numbers in order to avoid labelling documentation with identifying details. Data is collected either electronically or on paper, and is transferred to electronic storage. Data is stored electronically in excel spreadsheets only available to members of the research team. Paper data is coded and stored in locked filing cabinets accessible by the research team only.

Results

Recruitment for the *Gomeroi gaaynggal* study is ongoing. At the time of manuscript preparation, 236 mother-child dyads have been recruited into the study in their pregnancy. There has been a loss to this cohort of 76 women, including twenty-one women who have either withdrawn or declined to participate in follow up; twenty-three women who have moved from the study sites before consenting to participate; and a further seven women who have either miscarried or withdrawn due to infant death. The Newcastle cohort of 25 women is not eligible for follow up given the difficulties with accessing this population. In addition 34 women are at the time of writing either currently pregnant or have infants <3 months of age. Of the 126 women currently eligible for participation in the post-partum follow up study, over half (52% n=66) have been retained and are attending study visits to date (see Figure 2).

Preliminary results from a baseline sample of n=110 participant dyads are presented below.

The data generally reflected a higher prevalence of values outside normal ranges.

Pregnancy outcomes

Baseline characteristics of mothers are displayed in Table 3. Just over 6% of participants were recorded as having gestational diabetes (diagnosed by a fasting glucose of ≥ 5.5 mmol/l) in their current pregnancy, and 2.6% had type 2 diabetes mellitus. In the general population, 3-8% of pregnant women will develop gestational diabetes³⁴. Median gestational age for this cohort was 39.1 weeks (range: 31.5 – 43.2, n=110), and median birth weight of infants was 3180 grams (910 – 5430g, n=110). Median birth weight was 3093g for females (range: 1620 - 5430g, n = 46) and 3078g for males (910 - 5170g, n = 54). The majority of infants born in this cohort had APGAR scores >7 (82.2%), and 4.4% had scores 0 - 3. Over a third of infants (39.3%) had admission to special care or neonatal care nursery. The twinning rate for this cohort was 4.8%. Further pregnancy outcomes are displayed in Table 4.

Risk factors for chronic disease

Median plasma total cholesterol for women in the cohort was 5.9 mmol/L (range: 2 – 8.6, n=195), averaged over all study visits in pregnancy. Levels above 4 mmol/L indicate increased risk of coronary heart disease, though hypercholesterolaemia naturally occurs in pregnancy. Median plasma triglycerides were 2.4 mmol/L (0.3 - 7.3, n=192, reference range <2 mmol/L). Cholesterol and triglyceride levels of participants will continue to be monitored postpartum. Median plasma glucose was 4.4 mmol/L (2.4 - 12.8, n=208, reference range 3.5 – 7.8 mmol/L random plasma glucose for adults). Nearly half of the cohort to date reported being a tobacco smoker during their pregnancy (47.5%). Eleven women who reported being non-smokers had detectable levels of cotinine but in only two of these women were plasma cotinine levels >1.0 ng/ml.. This corresponds with national data where smoking during pregnancy was reported by 48% of Indigenous mothers in 2012⁹. Further results are displayed in Tables 4 and 5.

Renal function of mothers

Measures of renal function are presented in Table 5. The mean urinary albumin to creatinine and also protein to creatinine ratios showed 16% of samples had evidence of clinical proteinuria. Eighteen women (10% of cohort) had urinary protein to creatinine ratios ≥ 30 mg/mmol, and six had more than one sample with proteinuria. Three women with proteinuria had type 1 diabetes, and one woman had gestational diabetes mellitus, therefore proteinuria is unexplained in most samples. These four women were either normotensive or did not have a recorded blood pressure. Only five women ever recorded a systolic blood pressure ≥ 140 mmHg, and six women a diastolic pressure ≥ 90 mmHg. Both diastolic pressure and plasma Cystatin C (a measure of glomerular filtration rate) showed gestation dependent increases (all

$p < 0.001$). In this population of Indigenous Australian women, the incidence of high blood pressure is low, but there is an increased prevalence of proteinuria.

Discussion

Current participant numbers are modest and initial difficulties with participant recruitment and retention were overcome through the employment of Indigenous staff, development of community trust, provision of transport and improved access to local health services. In the remote community, the involvement of the Walgett Aboriginal Medical Service has greatly assisted with recruitment²². Recruitment is ongoing and is steadily increasing each year, and the *Gomeroi gaaynggal* study is currently the largest Indigenous pregnancy-through-early-childhood cohort of its kind.

Irregularity of attendance at antenatal visits has been a limitation and resulted in an irregular sampling schedule. Additionally, funding was not received to start data collection for the follow up study for a period of time, and therefore there is a potential loss of follow up data from the women and children who were early study recruits. The time commitments are particularly burdensome for women with very young children who are in the ongoing follow up study. In addition, the study design could have been enhanced by collecting psychosocial data in the postnatal period, and collecting pregnancy dietary intake data from the start of the study.

The strengths of this study are many and include the large number of variables measured (see Figure 3), and the use of validated tools for collection of nearly all variables. The use of cotinine as a biomarker of tobacco use/exposure will be validated in Indigenous Australian pregnant women as one of the unique methodologies of this study. Other unique measurements collected include the body composition measures acquired through the InBody 720™ body composition scales. To the authors' knowledge, little work has been done on

body composition of Indigenous women during their pregnancy using bioelectrical impedance scales. The regular and systematic measuring of body composition and growth of mothers and their children, and enquiry into their dietary intake, will contribute to what we know about Indigenous nutrition and growth during pregnancy and the postpartum period. Biological samples collected will be revealing as to cardiovascular and kidney function in this cohort of Indigenous women in pregnancy. To our knowledge, these parameters have not been analysed in a similar population of Indigenous pregnant women, and hence the implications for chronic disease are poorly understood.

The study's three locations reflect the diversity of NSW's Indigenous population in regional, rural and remote areas¹⁸. Ongoing extensive community engagement involved in the design and founding of the *Gomeri gaaynggal* study resulted in the ArtsHealth program, which has become a popular initiative with women in the local community and an excellent complement to the research components. One of the greatest assets to the study has been the employment of Indigenous staff, who contribute their expertise and community connections and knowledge. Through their work they are given opportunities to increase their research skills and gain professional qualifications that will see research capacity developed by Indigenous communities.

Community consultation is not only essential before conducting research in Indigenous communities³⁵, it is a crucial process for the success of the research study and has valuable benefits for both the researchers and the community.²².

It is anticipated that earlier recognition of those who are at risk of developing chronic disease (including renal disease and diabetes) and appropriate referrals to health services will lead to better health for participating women and their children. On a larger-scale, the contributions to the literature on early origins of chronic disease amongst Indigenous Australians will

greatly assist in the formation of policy, intervention, and health promotion activities aimed at improving health outcomes for this vulnerable population.

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Conflicts of Interest

The authors declare that they have no conflicts of interest.

Ethical Standards

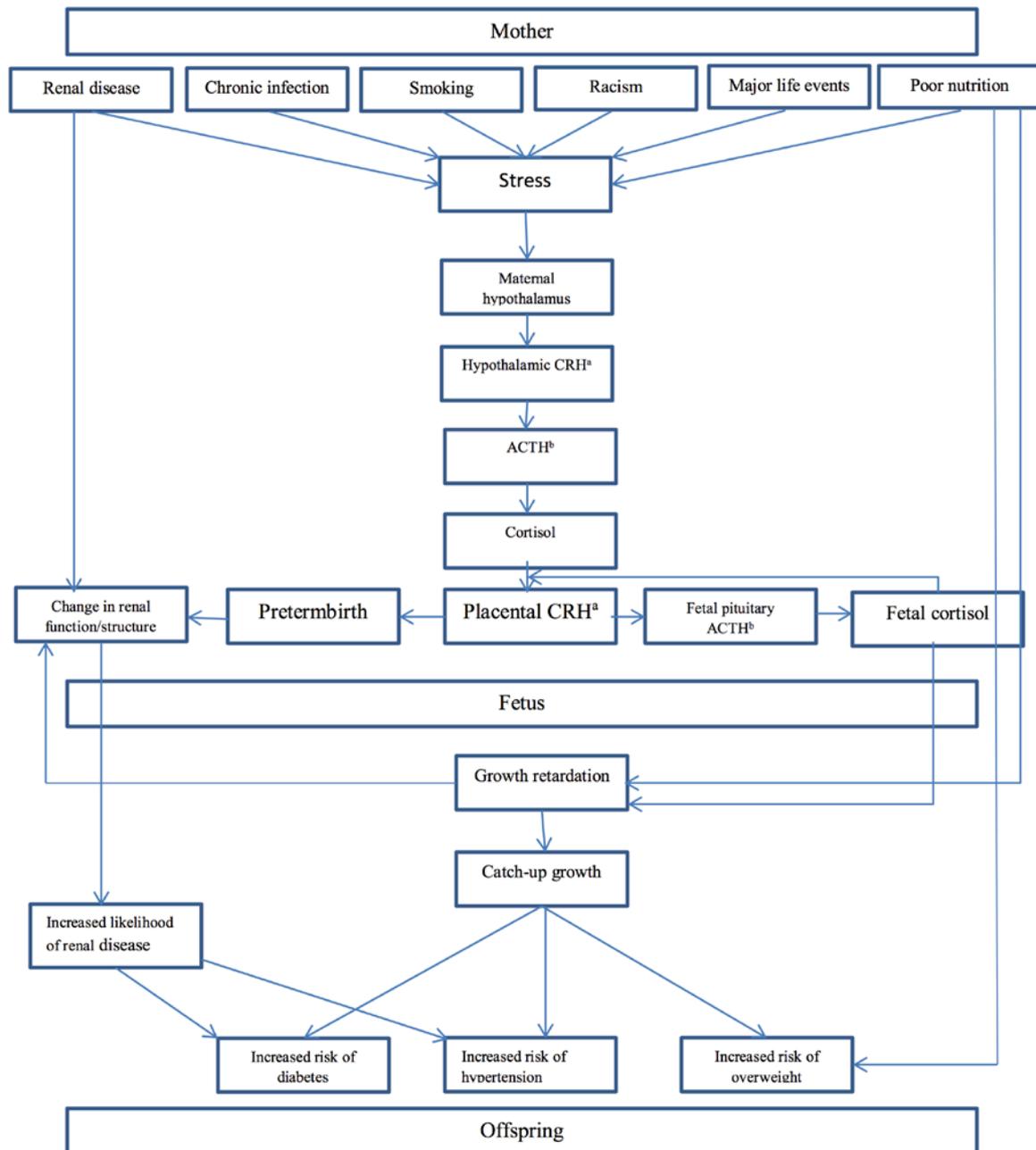
The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national guidelines on human experimentation (the National Statement on Ethical Conduct in Human Research, Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research), and with the Helsinki Declaration of 1975, as revised in 2008, and has been approved by the institutional committees; the Hunter New England Human Research Ethics Committee (reference number 08/05/21/4.01); the New South Wales Human Research Ethics Committee (reference number HREC/08/HNE/129); and the Aboriginal Health and Medical Research Council (reference number 654/08).

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Figure 1. Pathways to Poor Health Outcomes in Young Indigenous Australians People



Key: ^aCRH: corticotrophin-releasing hormone, ^bACTH: Adrenocorticotrophic hormone

Table 1. Data collected of mothers at each study visit for the Gomeroi gaaynggal cohort

| Data Collected | Pregnancy | | | Postnatal | | | | | | | |
|--|-----------------|----|----|-----------------|----|----|-----|------------------|-----|-----|-----|
| | 1T ^a | 2T | 3T | 3m ^b | 6m | 9m | 12m | 2yr ^c | 3yr | 4yr | 5yr |
| Anthropometry | | | | | | | | | | | |
| Maternal anthropometry: InBody weight and body composition | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Maternal anthropometry: height | ✓ | | | | | | | | | | |
| Maternal anthropometry: girths | | | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Maternal pre-pregnancy weight (self-reported) | ✓ | | | | | | | | | | |
| Samples collected | | | | | | | | | | | |
| Maternal blood sample | ✓ | ✓ | ✓ | ✓ | ✓ | | ✓ | ✓ | | | |
| Maternal urine sample | ✓ | ✓ | ✓ | | ✓ | | ✓ | ✓ | | | |
| Maternal saliva collection | ✓ | ✓ | ✓ | | | | | | | | |
| Blood Pressure | | | | | | | | | | | |
| Maternal blood pressure | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Dietary Intake | | | | | | | | | | | |
| Maternal nutrient supplementation history | | | | ✓ | | | | | | | |
| Maternal 24 hour recall | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Australian Eating Survey | | | ✓ | | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ |
| Other | | | | | | | | | | | |
| Maternal and child health questionnaire: full | | | | ✓ | | | | | | | |
| Maternal and child health questionnaire: review | | | | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Maternal psychosocial survey | ✓ | ✓ | ✓ | | | | | | | | |

Key: ^aT=Trimester, ^bm=month, ^cYr= year

Table 2. Data collected of offspring at each study visit for the Gomeroi gaaynggal cohort

| Data Collected | Pregnancy | | | Postnatal | | | | | | | |
|--|-----------------|----|----|-----------------|----|----|-----|------------------|-----|-----|-----|
| | 1T ^a | 2T | 3T | 3m ^b | 6m | 9m | 12m | 2yr ^c | 3yr | 4yr | 5yr |
| Fetal Ultrasound Scan | ✓ | ✓ | ✓ | | | | | | | | |
| Anthropometry | | | | | | | | | | | |
| Child anthropometry: length or height, weight, skinfold thicknesses and girths | | | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Samples collected | | | | | | | | | | | |
| Cord blood: <i>taken immediately post-delivery</i> | | | | | | | | | | | |
| Child blood sample | | | | | | | ✓ | ✓ | | | |
| Infant urine ^d | | | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Blood Pressure | | | | | | | | | | | |
| Child blood pressure | | | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Dietary Intake | | | | | | | | | | | |
| Infant Feeding Questionnaire | | | | ✓ | ✓ | ✓ | ✓ | | | | |
| Current Feeding Practices Questionnaire | | | | ✓ | ✓ | ✓ | ✓ | | | | |
| Child 24 hour recall | | | | | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Australian Child and Adolescent Eating Survey | | | | | | | | ✓ | ✓ | ✓ | ✓ |
| Other | | | | | | | | | | | |
| Maternal and child health questionnaire: full | | | | ✓ | | | | | | | |
| Maternal and child health questionnaire: review | | | | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |

Key: ^aT=Trimester, ^bm=month, ^cYr= year, ^dUrine sample either from nappy or collection from child, as appropriate

Figure 2. *Gomeroi gaaynggal* study numbers

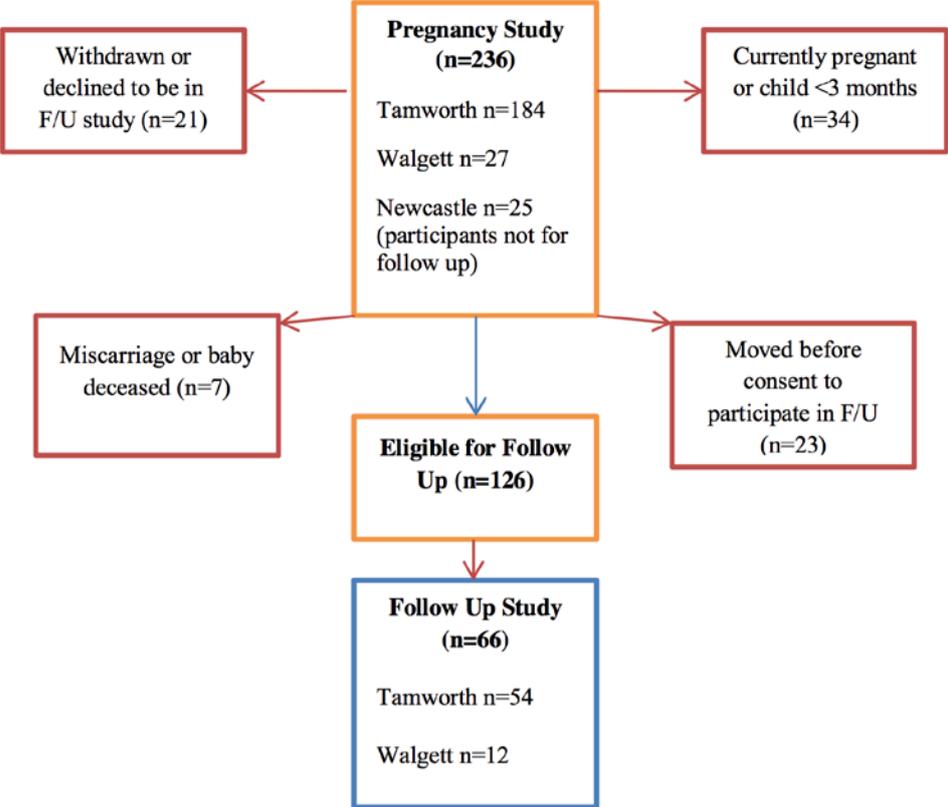


Table 3. Baseline characteristics of participants in the Gomeroi gaaynggal study

| | | Mean (SD) | Range | Median |
|--------------------------------|-----|-----------|--------------|--------|
| Age (years) | | 26 (5.9) | 13.8 – 40.9 | 25 |
| Current Diabetes Status | | % | | |
| Diabetes Type I | | 1.03 | | |
| Diabetes Type II | | 2.56 | | |
| Gestational Diabetes | | 6.15 | | |
| Past Pregnancy history | | % | Range | |
| Total number past pregnancies | ≤1 | 17.07 | 0-23 | |
| | 2-4 | 50.00 | | |
| | 5-9 | 28.06 | | |
| | ≥10 | 4.88 | | |
| Total number live children | ≤1 | 29.27 | 0-9 | |
| | 2-4 | 51.22 | | |
| | 5-9 | 19.52 | | |
| | ≥10 | 0.00 | | |
| Miscarriages | ≤1 | 82.28 | 0-16 | |
| | 2-4 | 12.66 | | |
| | 5-9 | 2.53 | | |
| | ≥10 | 15.2 | | |
| Termination | 0 | 75.95 | 0-3 | |
| | 1 | 17.72 | | |
| | 2 | 5.06 | | |
| | 3 | 1.27 | | |
| SUDI ^a | 0 | 97.47 | | |
| | 1 | 2.53 | | |
| Stillbirths | 0 | 97.47 | | |
| | 1 | 2.53 | | |

a=Sudden Unexpected Deaths in Infants

Table 4. Pregnancy outcomes of participants in the Gomeroi gaaynggal study

| | Total (n=110) | | | |
|--|----------------------|---------------|-----------|--------------|
| | Mean (n) | Median | SD | Range |
| Gestational age at delivery (weeks) | 38.63 (110) | 39.10 | 1.947 | 31.5 - 43.2 |
| Birth weight at delivery (g) | 3179.3 (110) | 3180.00 | 689.79 | 910 -5430 |
| GROW BW ^a centile ³⁶ | 34.1(109) | 25.4 | 29.59 | 0-100 |
| Baby Length at birth (cm) | 49.2 (79) | 49.00 | 2.29 | 45-55 |
| Baby Head Circumference at birth (cm) | 34.37 (83) | 34.50 | 1.98 | 26-38 |
| First APGAR ^b measure | 8.09 (90) | 9.00 | 1.65 | 1-9 |
| Second APGAR ^b | 8.84 (90) | 9.00 | 0.997 | 2-10 |

a= Gestation Related Optimal Weight Birthweight, b=Appearance, Pulse, Grimace, Activity, Respiration

Table 5. Anthropometric, biochemical and haematological measures of participants in the Gomeroi gaaynggal study (combined for all visits during pregnancy)

| | Mean (n) | Median | SD | Range | Normal range ^{a37} |
|--------------------------------------|------------|--------|-------|----------|-----------------------------|
| Body Composition | | | | | |
| Weight (kg) | 85.3 (78) | 84 | 23.5 | 45-148 | |
| Height (cm) | 164.5(109) | 164.00 | 6.6 | 152-185 | |
| Body Mass Index (kg/m ²) | 30.7 (107) | 30 | 8.6 | 15-52 | |
| % Body fat (%) | 41.7 (54) | 43.6 | 11.2 | 17-63 | |
| Visceral fat area (cm ²) | 202 (53) | 158 | 158 | 38-870 | |
| Body fat mass (kg) | 38.8 (54) | 36.9 | 18.9 | 12- 84 | |
| Skeletal muscle mass (kg) | 26.8 (54) | 26.8 | 3.9 | 18-36 | |
| Total Water (L) | 36 (53) | 34.7 | 4.7 | 25-48 | |
| Intracellular Water (L) | 22.2(53) | 21.4 | 2.9 | 15-29 | |
| Extracellular Water (L) | 13.8 (53) | 13.3 | 1.8 | 10-19 | |
| Blood Pressure | | | | | |
| Systolic (mmHg) | 113(167) | 110 | 13 | 80-150 | |
| Diastolic (mmHg) | 68 (167) | 65 | 11 | 45-104 | |
| Renal Function | | | | | |
| Plasma cystatin C (mg/L) | 0.85 (206) | 0.80 | 0.28 | 0.38-2.1 | 0.40-0.99 |
| Plasma sodium (mmol/L) | 136 (209) | 135 | 2.2 | 128-145 | 134-145 |
| Plasma potassium (mmol/L) | 4.1 (207) | 4.0 | 0.5 | 3-6 | 3.5-5.0 |
| Plasma creatinine (µmol/L) | 49 (208) | 48 | 8.9 | 20-83 | 49-90 ^b |
| Urinary creatinine (mmol/L) | 10.4 (168) | 8.7 | 8.2 | 0.1-41.7 | ^c |
| Urinary protein (g/L) | 0.14 (170) | 0.07 | 0.2 | 0.01-1.9 | <0.15 |
| Urinary protein/creatinine (mg/mmol) | 25.7 (168) | 11.8 | 63 | 0-700 | <30 |
| Urinary albumin (mg/L) | 22(171) | 8.00 | 53 | 2-473 | <30 |
| Urinary albumin/creatinine (mg/mmol) | 2.8 (170) | 1.4 | 5.461 | 0.2-50 | <3.5 ^d |
| Nutritional Biomarkers | | | | | |
| Plasma glucose (random) (mmol/L) | 4.6 (208) | 4.4 | 1.2 | 2.4-12.8 | 3.5-7.8 |

| | | | | | |
|---|------------|-------|------|-----------|------------------------|
| Plasma total cholesterol (mmol/L) | 6.4 (195) | 5.9 | 5.9 | 2-8.6 | <4 |
| Plasma triglycerides (mmol/L) | 2.5 (192) | 2.4 | 1.1 | 0.3-7.3 | <2 |
| Plasma vitamin B12 (pmol/L) | 169 (154) | 150 | 74 | 59-403 | 138-652 |
| Red cell folate (nmol/L) | 1505 (168) | 1358 | 750 | 280-4381 | 285-1475 |
| Immune/Inflammatory markers | | | | | |
| C-Reactive Protein (mg/L) | 8.9 (180) | 5.8 | 13 | 0.2-109 | <5.0 |
| IgA (g/L) | 7. (162) | 1.7 | 68 | 0.5-862 | 0.69-3.37 |
| IgM (g/L) | 1.2 (161) | 1.1 | 0.6 | 0.3-3.4 | 0.48-2.38 |
| IgG (g/L) | 10.4 (162) | 8.7 | 18.3 | 3.4-240 | 6.72-14.40 |
| IgG <i>H.pylori</i> (U/ml) | 16.2(101) | 8.9 | 17.3 | 2-82 | ^c |
| Full Blood Count | | | | | |
| White Blood Cells (x10 ⁹ /L) | 10.3 (177) | 10.30 | 2.7 | 3-18 | 4-11 ^e |
| Red Blood Cells (x10 ¹² /L) | 4 (176) | 4.0 | 0.4 | 2.6-5.1 | 3.8-5.2 ^f |
| Haemoglobin (g/L) | 116 (179) | 117 | 13.3 | 11-138 | 115-160 ^d |
| Haematocrit | 0.35 (179) | 0.35 | 0.03 | 0.25-0.43 | 0.34-0.47 ^d |
| Other Measures | | | | | |
| Plasma cortisol (random) (nmol/L) | 418 (154) | 423 | 133 | 13-878 | 80-535 |
| Cotinine (ng/ml) | 67 (148) | 0.8 | 99 | 0-580 | ^c |

a=Reference ranges are non-pregnant male/female ranges unless otherwise stated, b=reference range for females ≥19 years old, c= reference range not defined by laboratory, d= reference range for adult female e= reference range for >21 years male and female, f = reference range for pregnancy 1-42 weeks gestation

Figure 3. Measures in the *Gomeroi gaaynggal* study

| The <i>Gomeroi gaaynggal</i> Study | | | |
|--|--|--|---|
| Biochemical Data | Ultrasound and Blood Pressure | Ultrasound and Blood Pressure | Anthropometrics |
| -Renal Measures <i>Prorenin</i> <i>Albumin</i> <i>Glucose</i> <i>Uric acid</i> <i>Renin</i> <i>Electrolytes</i> <i>Creatinine</i> <i>Protein</i> <i>Angiotensin-converting enzyme</i> <i>Angiotensin</i> <i>Cystatin C</i> -Immunological Measures <i>Total Ig</i> <i>IgG for Staph, Bacterial and Viral</i> <i>PCR</i> <i>Cytomegalovirus-10</i> <i>Helicobacter pylori</i> -Metabolic and Cardiovascular Measures <i>Homocysteine</i> <i>B12</i> <i>Folate</i> <i>Transferrin</i> <i>Liver function tests</i> <i>Triglycerides</i> <i>Cholesterol</i> -Tobacco-by-products <i>Cotinine</i> -Stress Hormones <i>Cortisol</i> <i>Corticosteroid-binding globulin</i> <i>Corticotrophin-releasing hormone</i> -Haematology <i>Full Blood Count</i> <i>ABO blood</i> <i>Lewis blood groups</i> <i>Haematocrit</i> <i>Haemoglobin</i> -Reproductive Health <i>Estrinol</i> <i>Estradiol</i> <i>Progesterone</i> | -Blood Pressure -Ultrasound <i>Foetal renal volume</i> <i>Gestational age</i> <i>Foetal anomaly and viability</i> <i>Date of delivery</i> <i>Renal and umbilical arteries</i> <i>Liquor volume</i> <i>Estimates of foetal weight</i> | -Nutritional Assessment <i>Australian Eating Survey</i> <i>Australian Child and Adolescent Eating Survey</i> <i>Infant Feeding Recall</i> <i>Current Feeding Practices</i> <i>Maternal 24 hour recall</i> <i>Child 24 hour recall</i> -Psychosocial Assessment <i>Stressful Life Events</i> <i>Kessler 10+</i> <i>Discrimination survey</i> -General Health -Self-reported Tobacco Use -Self-reported Alcohol Consumption -Demographic and Socioeconomic information | -Maternal and Child Weight -Maternal Height -Child Length -Maternal Circumferences <i>Waist</i> <i>Gluteal</i> <i>Mid-upper arm</i> <i>Thigh</i> <i>Maximum calf</i> -Child Circumferences <i>Head</i> <i>Abdomen</i> <i>Mid-upper arm</i> <i>Mid-thigh</i> <i>Maximum calf</i> -Child Skinfolds <i>Subscapular</i> <i>Bicep</i> <i>Front thigh</i> <i>Iliac crest</i> <i>Medial calf</i> -Maternal Body Composition <i>InBody 720</i> |