









# The early implementation phase of the Omega-3 Test-and-Treat Program for reducing the risk of preterm birth, South Australia, 2021–22: an implementation evaluation study

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**The known:** Preterm birth is associated with high infant morbidity and mortality. Omega-3 fatty acid supplementation can reduce the risk of preterm birth for women with low omega-3 fatty acid levels, but systematic identification of and treatment of low omega-3 fatty acid status during pregnancy is not undertaken.

**The new:** The Omega-3 Test and Treat Program is a feasible approach for identifying pregnant women who could benefit from omega-3 fatty acid supplementation. The characteristics of the women who were tested were similar to those of women who were not, indicating the broad and equitable reach of the program.

**The implications:** The Omega-3 Test and Treat Program could be conveniently integrated into routine antenatal care to reduce the risk of preterm birth in Australia.

Preterm birth (delivery before 37 weeks' gestation) is the leading cause of death of children under five years of age;<sup>1,3</sup> the associated mortality and morbidity are greatest for early preterm births (delivery before 34 weeks' gestation).<sup>1,2,4</sup> About two-thirds of preterm births have no known biological causes,<sup>5</sup> and effective prevention strategies are needed.<sup>6</sup>

Omega-3 long chain polyunsaturated fatty acid supplementation<sup>7</sup> has emerged as a promising intervention for preventing preterm birth in women with low omega-3 fatty acid levels; it can significantly reduce the risk of preterm birth and improve infant outcomes.<sup>8–14</sup> The 2021 Australian *Pregnancy Care Guidelines* (section 4.3.9) recommend omega-3 fatty acid supplementation (800mg docosahexaenoic acid [DHA] and 100mg eicosapentaenoic acid [EPA] daily) for women with low levels to reduce the risk of preterm birth.<sup>15</sup> Similar evidence-based recommendations have since been adopted by international guidelines.<sup>16–18</sup>

Despite updates to clinical practice guidelines, identifying women with low omega-3 levels remains difficult. Because dietary omega-3 intake does not always reflect blood levels, blood testing is the gold standard for assessing omega-3 status.<sup>19</sup> However, a major problem in clinical practice is the lack of an established omega-3 testing protocol, and expertise among health professionals is limited with regard to the role of omega-3 fatty acids during pregnancy.

We therefore developed the Omega-3 Test-and-Treat Program in South Australia, the first preventive health strategy to integrate omega-3 fatty acid blood testing and targeted supplementation guidance into routine antenatal care. The program identifies women with low omega-3 levels during the first 20 weeks of

## Abstract

**Objective:** To assess the feasibility of embedding omega-3 fatty acid testing and targeted supplementation (the Omega-3 Test-and-Treat Program) into routine antenatal care to reduce the risk of preterm birth.

**Study design:** Prospective implementation evaluation study, using the Quality Enhancement Research Initiative (QUERI) framework.

**Setting, participants:** Women with singleton pregnancies undergoing routine antenatal screening during early pregnancy (before 20 weeks' gestation) and their health care providers, South Australia, 19 April 2021 – 30 June 2022.

**Intervention:** Addition of omega-3 fatty acid testing option to SA Pathology test referral forms for the South Australian Maternal Serum Antenatal Screening (SAMSAS) program, with the aim of identifying women with low omega-3 fatty acid levels during early pregnancy and providing evidence-based supplementation guidance for reducing the risk of preterm birth.

**Main outcome measures:** Program feasibility (uptake and fidelity); representativeness of women tested for omega-3 fatty acid status; and omega-3 fatty acid status, by proportion of total serum fatty acids (low, < 3.7%; moderate, 3.7–4.3%; sufficient, > 4.3%).

**Results:** A total of 4801 requests for omega-3 fatty acid tests (26.1% of 18 362 SAMSAS referrals) were submitted to SA Pathology during the initial implementation phase of the Omega-3 Test-and-Treat Program. The monthly number of test requests increased from 15 (2.4% of 627 SAMSAS referrals) in April 2021 to 340 (29.4% of 1156 SAMSAS referrals) in June 2022. The socio-demographic and clinical characteristics of women referred for omega-3 fatty acid testing were similar to those for women who were not. Serum samples were insufficient for omega-3 fatty acid testing in 19 cases; of the 4782 tests performed, omega-3 fatty acid levels were low in 702 (14.7%), moderate in 1638 (34.2%), and sufficient in 2442 tests (51.1%). Of 5057 samples received by the Omega-3 Laboratory, 4935 (97.6%) were analysed within 72 hours. Thirty-three of 4801 omega-3 fatty acid test referrals (0.7%) were for women beyond 20 weeks of pregnancy; 58 referrals (1.2%) were for women with non-singleton pregnancies.

**Conclusion:** The Omega-3 Test-and-Treat Program is a feasible approach to reducing the risk of preterm birth with a targeted nutritional intervention that could be integrated into routine antenatal care in Australia.

singleton pregnancies and provides tailored supplementation recommendations based on their test results. The effectiveness of the program for reducing the risk of preterm birth will be assessed by comparing de-identified pregnancy outcomes before and after program implementation.

In this article, we report our assessment of the feasibility of embedding the Omega-3 Test-and-Treat Program into routine

antenatal care by examining uptake, fidelity to program criteria, and whether early participants were representative of all women undergoing early pregnancy screening. We outline pre-implementation and early implementation activities, highlighting factors important for integrating the strategy into routine care.

## Methods

Our prospective implementation study applied steps 1 to 4 of the Quality Enhancement Research Initiative (QUERI) framework<sup>20</sup> to describe the pre-implementation phase and assess the early implementation phase of the Omega-3 Test-and-Treat Program during 19 April 2021 – 30 June 2022. We report our study according to the Standards for Reporting Implementation Studies (StaRI) guidelines.<sup>21</sup>

### QUERI 1: Identify and prioritise gaps in care and clinical needs

Omega-3 fatty acid supplementation could prevent a proportion of the 13.4 million preterm births that occur around the world each year.<sup>22</sup> A 2018 Cochrane review (19927 women; mostly singleton pregnancies) found that routine omega-3 fatty acid supplementation from mid-pregnancy until birth reduced the risk of early preterm birth by 42% and that of preterm birth by 11%. Most included trials were conducted in upper middle or high income countries prior to the widespread use of prenatal supplements containing low dose (about 200 mg/day) omega-3 fatty acids (DHA, EPA).<sup>8</sup> Subsequent large scale studies have confirmed the review findings,<sup>9,11,23</sup> and have also indicated that supplementation is most effective in women with low omega-3 fatty acid levels,<sup>9,11,12</sup> which suggests that dietary intake or omega-3 fatty acid status influences the risk of preterm birth.<sup>9-12</sup>

In our Omega-3 to Reduce the Incidence of Preterm Birth randomised trial, 5517 pregnant women (5544 pregnancies) received 800 mg DHA/100 mg EPA or control supplements daily, beginning before 20 weeks of pregnancy and continuing until 34 weeks of pregnancy or delivery. Supplementation with omega-3 long-chain polyunsaturated fatty acids did not reduce the overall incidence of early preterm birth (< 34 weeks).<sup>11</sup> However, secondary analyses of outcomes for women with singleton pregnancies found that the risk of early preterm birth was higher for women with low baseline omega-3 fatty acid levels and that they were more likely to benefit from supplementation; for women with sufficient levels, supplementation may have increased the risk of early preterm birth.<sup>12</sup> These findings highlight the need to correctly identify which pregnant women should receive omega-3 fatty acid supplements.

### QUERI 2: Identify evidence-based practices

Australian<sup>15</sup> and international guidelines<sup>16-18</sup> recommend supplementation for pregnant women with low omega-3 fatty acid levels, but do not recommend how these women should be identified, hindering an effective supplementation strategy. Omega-3 fatty acid testing was not routinely available in clinical practice in South Australia prior to the Omega-3 Test-and-Treat Program. It is essential that women with low omega-3 fatty acid levels be identified early in pregnancy and to provide targeted, evidence-based supplementation advice based on individual omega-3 fatty acid levels. These components are the foundation

of the statewide Omega-3 Test-and-Treat Program, developed to support the implementation of the Australian guidelines by applying a precision approach to identifying women who require supplementation. Omega-3 fatty acid testing was funded by research grants and provided at no cost to the tested women or the referring clinicians.

### QUERI 3: Identify barriers and facilitators

To reliably identify women with low omega-3 fatty acid levels during early pregnancy, we selected a blood test based on the findings of the Omega-3 to Reduce the Incidence of Preterm Birth trial.<sup>11,12</sup> We did not consider dietary intake as a screening tool because of the strength of the trial data and the recognised low correlation of dietary intake with blood omega-3 fatty acid levels.<sup>19</sup>

An implementation steering committee was formed to identify barriers to integrating the omega-3 fatty acid blood testing into antenatal care in South Australia and to develop solutions. The committee comprised researchers, representatives from pathology services and local and regional health services, obstetricians, midwives, general practitioners, and community members. The committee concluded that adding omega-3 fatty acid testing to an existing early pregnancy screening program could overcome difficulties in reaching health professionals and women. The South Australian Maternal Serum Antenatal Screening (SAMSAS) program (South Australia Pathology) provides about 80% of early pregnancy screens in the state. Integrating the Omega-3 Test-and-Treat Program into established workflows enabled identification of women with low omega-3 levels during routine first trimester screening, ensuring timely supplementation advice.

As published low omega-3 fatty acid status definitions were based on whole blood assays,<sup>11,12</sup> but the SAMSAS program assesses serum levels, we developed and validated equations for converting the proportion of total omega-3 fatty acids (DHA, EPA, alpha-linolenic acid, docosapentaenoic acid) from whole blood to serum levels.<sup>24</sup> We then defined cut-off points for serum omega-3 fatty acid status by proportion of total serum fatty acids, consistent with SAMSAS processes and facilitating the integration of testing into screening workflows: low, < 3.7%; moderate, 3.7–4.3%; sufficient, > 4.3%. We advised that testing be undertaken only for women with singleton pregnancies, as evidence for supplementation benefiting women with non-singleton pregnancies is limited.

### QUERI 4: Implement and test the intervention in practice

#### *Embedding the omega-3 fatty acid test into routine workflows*

An “omega-3 status” checkbox was added to SAMSAS referral forms so that health professionals could easily order the test. Maternal blood samples were processed at the SA Pathology laboratory and forwarded to the South Australian Health and Medical Research Institute (SAHMRI) omega-3 laboratory for analysis. Serum fatty acid concentrations were measured using gas chromatography, as previously described,<sup>24</sup> and the results were returned to SA Pathology for reporting to health professionals.

Quality measures included developing standardised protocols for inter-laboratory processes covering sample receipt, omega-3 fatty acid testing, and result validation and reporting. Staff from

both SA Pathology and SAHMRI underwent training to support the secure transfer of samples, accurate reporting, and consistent auditing.

### Developing tailored advice and educational materials

Health professional and community member reference groups were established to co-design and endorse Omega-3 Test-and-Treat Program educational materials. Feedback was gathered at meetings every two months, enabling iterative refinements to enhance information delivery. The health professional group included general practitioners, obstetricians, midwives, SA Pathology staff, communications and marketing personnel, and representatives from the SAHMRI Aboriginal Communities and Families Health Research Alliance. The community members included women with lived experience of preterm birth.

Health professionals noted the need for clear advice on test interpretation and supplementation, and requested alignment with other SAMSAS results to enable simultaneous delivery of advice to women. Pathologists emphasised the importance of categorising critically low and high omega-3 fatty acid levels to distinguish extreme values associated with health risk. As there are no established reference ranges, the cut-offs for critically low (<1%) and critically high (<10%) omega-3 fatty acid levels were determined by expert opinion to reflect extreme physiological values. Critically low levels may indicate essential fatty acid deficiency; critically high levels could reflect very high supplementary intake beyond typical safe ranges, but no formal clinical or regulatory thresholds have been established.

Community members emphasised the need for clear supplementation guidance, including what to take, when to start, and how long to continue. They strongly preferred advice about micro-algae omega-3 fatty acid sources because of their sustainability and suitability for vegan or vegetarian women, who are particularly likely to have low omega-3 fatty acid levels. Supplementation advice was based on individual omega-3 fatty acid status. Women with low levels (less than 3.7% of total serum fatty acids) were advised to commence daily supplementation with 800mg DHA/100mg EPA until 37 weeks of pregnancy, in accordance with the Australian *Pregnancy Care Guidelines*. Specific brands were not endorsed, but examples were provided. Guidance for each omega-3 fatty acid status category for health professionals was available in brochures ([Supporting Information](#)) and online,<sup>25</sup> and was supported by program telephone and email advice.

### Implementation strategies

We employed a multifaceted implementation strategy to engage women and their health care providers, ensuring the consistent integration of the Omega-3 Test-and-Treat Program in diverse antenatal care settings. Educating health care providers was crucial but difficult because of the fragmented delivery of antenatal care by separate providers in different sectors and regions. Extensive early outreach — including engagement with key opinion leaders in obstetrics, midwifery, and pathology, and the dissemination of educational materials through state health departments, primary care networks, and professional bodies such as the Royal Australian and New Zealand College of Obstetricians and Gynaecologists and the Australian College of Midwives — was essential for ensuring widespread awareness and adoption. These implementation strategies used multiple channels to reach a diverse audience of health professionals and community members ([Box 1](#)).

## 1 Omega-3 Test-and-Treat Program: implementation strategy description for health professionals and community members

Implementation strategy	Description
<b>For health professionals</b>	
Direct communication	<ul style="list-style-type: none"> <li>Email from SA Pathology director to SAMSAS referrers about the program</li> <li>Email from the South Australian chapter of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists to their members.</li> </ul>
Publications and newsletters	<ul style="list-style-type: none"> <li>Published articles in state newsletters of professional bodies, including SA Pathology, Royal Australian College of General Practitioners, and the South Australian chapter of the Australian College of Midwives, to inform and engage health care professionals.</li> </ul>
Tailored education sessions	<ul style="list-style-type: none"> <li>Education sessions tailored to specific audiences during hospital in-service meetings, grand rounds, and general practitioner obstetric shared care professional development sessions.</li> <li>Podcast for general practitioners, aligned with their continuous professional development requirements.</li> </ul>
Promotional events	<ul style="list-style-type: none"> <li>Hosted World Prematurity Day events and related activities to highlight the importance of omega-3 fatty acid testing for reducing risk of preterm birth.</li> </ul>
Conferences and webinars	<ul style="list-style-type: none"> <li>Webinars for health professionals presented at midwifery, general practitioner, and pathologist conferences, directly targeting these key professional groups.</li> </ul>
<b>For health professionals and community members</b>	
Educational materials	<ul style="list-style-type: none"> <li>Distributed brochures for health professional and women to obstetric and general practitioner clinics and maternity hospitals, accompanied by updated SAMSAS referral forms featuring the omega-3 status test checkbox.</li> </ul>
Digital resources	<ul style="list-style-type: none"> <li>Developed dedicated web pages on SAHMRI and SA Pathology websites that host health professional and community member information and digital versions of educational materials.</li> </ul>
General promotion and advertising	<ul style="list-style-type: none"> <li>Ad hoc promotional interviews in various media, including television, print media, radio.</li> <li>Promotion of the Omega-3 Test-and-Treat Program at the annual SA Pregnancy Expo.</li> </ul>
Informational videos	<ul style="list-style-type: none"> <li>Developed and hosted informational videos tailored to specific audiences, including community members, midwives, and medical staff.</li> </ul>

SAHMRI = South Australian Health and Medical Research Institute; SAMSAS = South Australian Maternal Serum Antenatal Screening. ♦

## Monitoring and evaluation of early implementation interventions

Regular steering committee meetings facilitated ongoing feedback and incremental improvement of program implementation. Project personnel maintained detailed logs of



information dissemination and implementation activities. The proportion of SAMSAS referrals including omega-3 fatty acid test requests, by referring clinician and location, was calculated from monthly SA Pathology reports. This information informed adjustments for improving coverage as program uptake increased. The clinical and demographic characteristics of women were obtained from the SAMSAS referral form by the referring clinician. For both referrals with and without omega-3 fatty acid testing requests, we extracted data on maternal age, gestational age, weight, ethnic background (using fixed SAMSAS categories: Caucasian, non-Caucasian), postcode-based socio-economic status (Index of Relative Socio-economic Advantage and Disadvantage, IRSAD<sup>26</sup>), smoking status, in vitro fertilisation (IVF) use, and referral location.

Program fidelity was monitored using quality measures of timeliness, accuracy, and adherence to eligibility criteria, guided by the Consolidated Framework for Implementation Research.<sup>27</sup> Outcome measures included the proportion of eligible women tested, test results reported within 72 hours, monthly audits of omega-3 fatty acid status (low, moderate, sufficient), and the proportion of results within the expected population range (1–10% of total fatty acids). These measures supported the monitoring of integration of SAHMRI and SA Pathology laboratory processes, and adherence to program operational processes. Test uptake data were obtained from SA Pathology, which records all omega-3 tests ordered in conjunction with SAMSAS referrals at the time of reporting results to health care professionals. Fidelity data were derived from the omega-3 laboratory database, which records the timing of sample receipt. Minor differences between datasets are expected because they capture data at different points in the testing workflow.

### Ethics approval

The program was approved by the Women's and Children's Health Network Human Research Ethics Committee (HREC/20/WCHN/138).

## Results

A total of 4801 requests for omega-3 fatty acid testing (26.1% of 18362 SAMSAS referrals) were submitted to SA Pathology during the initial implementation phase of the Omega-3 Test-and-Treat Program (19 April 2021 – 30 June 2022). Uptake increased rapidly during the early months of implementation and remained consistent thereafter; the monthly number of test requests increased from 15 (2.4% of 627 SAMSAS referrals) in April 2021 to 340 tests (29.4% of 1156 SAMSAS referrals) in June 2022 (Box 2).

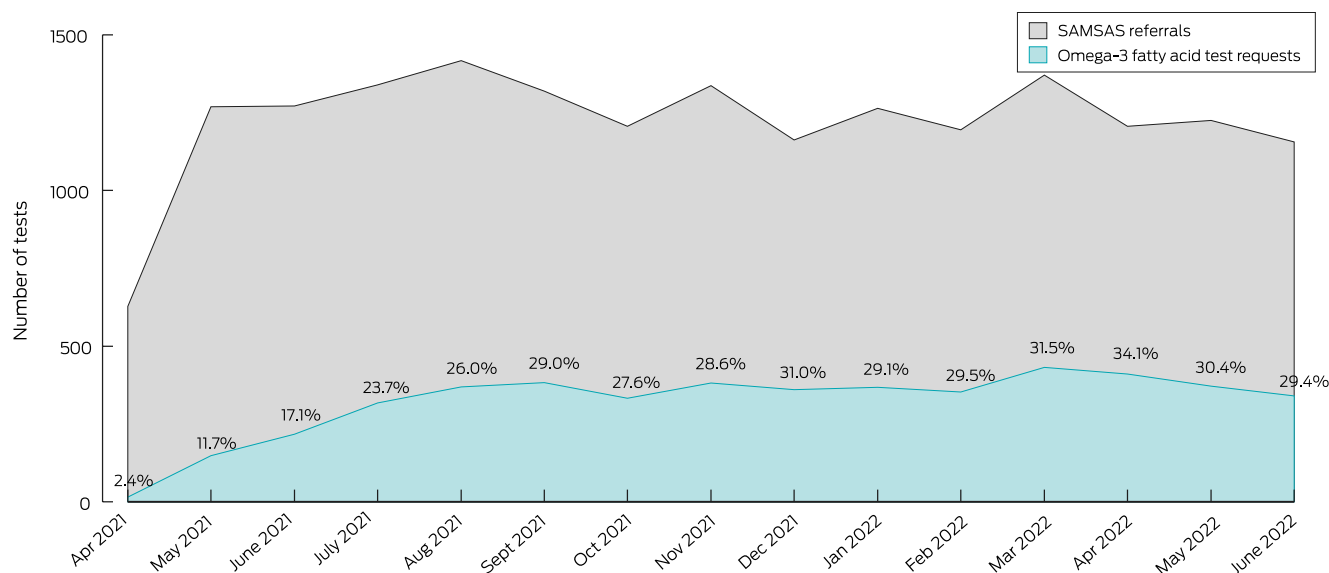
### Characteristics of early Omega-3 Test-and-Treat Program participants

The socio-demographic and clinical characteristics of women referred for omega-3 fatty acid testing were similar to those for women who were not. The mean age of the women for whom omega-3 fatty acid level testing was requested in the 4801 referrals was 30.8 years (standard deviation [SD], 5.1 years) and the median gestational age was 12.1 weeks (interquartile range [IQR], 11.1–13.0 weeks). The proportion of referrals for women who lived in areas of greatest socio-economic disadvantage (IRSAD quintile 1) was slightly smaller than for women who did not (25.6% *v* 33.7%), but the proportions living in areas in IRSAD quintiles 2 and 3 were similar for both groups (Box 3).

### Omega-3 fatty acid status of early Omega-3 Test-and-Treat Program participants

Serum samples were insufficient for omega-3 fatty acid testing for 19 of 4801 referrals. Of the 4782 completed tests, omega-3 fatty acid levels were low in 702 (14.7%), moderate in 1638 (34.2%), and sufficient in 2442 tests (51.1%). The mean maternal age, median gestational age, median maternal weight, proportion who had used IVF, and distribution by referral location were similar for all three groups. The proportion of women classified as non-Caucasian was larger for the low status group (26.4%) than for the moderate (13.8%) and sufficient groups (13.6%), as was

**2 South Australian Maternal Serum Antenatal Screening (SAMSAS) referrals and omega-3 fatty acid test requests during early implementation of the Omega-3 Test-and-Treat Program, South Australia, 19 April 2021 – 30 June 2022\***



\* Omega-3 fatty acid test requests as proportions of all SAMSAS are reported as percentages. ♦

### 3 Characteristics of women with South Australian Maternal Serum Antenatal Screening (SAMSAS) referrals during early implementation of the Omega-3 Test-and-Treat Program, South Australia, 19 April 2021 – 30 June 2022, by whether the referral included an omega-3 fatty acid test request

Characteristic	Omega-3 fatty acid tests ordered	SAMSAS referrals without omega-3 fatty acid testing	All referrals
Tests/referrals	4801 [26.1%]	13 561 [73.9%]	18 362
Maternal age (years), mean (SD)	30.8 (5.1)	30.7 (5.1)	30.7 (5.1)
Gestational age (weeks), median (IQR)	12.1 (11.1–13.0)	12.4 (11.7–13.1)	12.4 (11.6–13.1)
Maternal weight (kg), median (IQR)	69.0 (60.0–82.3)	70.0 (60.0–83.5)	70.0 (60.0–83.0)
Ethnic background*			
Caucasian	2659 (55.4%)	6187 (45.6%)	8846 (48.2%)
Non-Caucasian	745 (15.5%)	2460 (18.1%)	3205 (17.5%)
Unknown	1397 (29.1%)	4914 (36.2%)	6311 (34.4%)
Socio-economic status (IRSAD), quintiles			
1 (most disadvantaged)	1231 (25.6%)	4569 (33.7%)	5800 (31.6%)
2	998 (20.8%)	2667 (19.7%)	3665 (20.0%)
3	1070 (22.3%)	2753 (20.3%)	3823 (20.8%)
4	834 (17.4%)	1899 (14.0%)	2733 (14.9%)
5 (most advantaged)	604 (12.6%)	1555 (11.5%)	2159 (11.8%)
Unknown†	64 (1.3%)	118 (0.9%)	182 (1.0%)
Smoker			
Yes	175 (3.6%)	451 (3.3%)	626 (3.4%)
No	3573 (74.4%)	6664 (49.1%)	10 237 (55.8%)
Unknown	1053 (21.9%)	6446 (47.5%)	7499 (40.8%)
In vitro fertilisation			
Yes	255 (5.3%)	533 (3.9%)	788 (4.3%)
No	2922 (60.9%)	5019 (37.0%)	7941 (43.2%)
Unknown	1624 (33.8%)	8009 (59.1%)	9633 (52.5%)
Referral location			
Metropolitan	3134 (65.3%)	9836 (72.5%)	12 970 (70.6%)
Regional	1604 (33.4%)	3614 (26.6%)	5218 (28.4%)
Unknown†	63 (1.3%)	111 (0.8%)	174 (0.9%)

IQR = interquartile range; IRSAD = Index of Relative Socio-economic Advantage and Disadvantage; SD = standard deviation. \* Categories based on health professional selection from options available in the SAMSAS form. "Non-Caucasian" includes all women not classified by the referring practitioner as Caucasian; we acknowledge the broad and simplified nature of both categories. † Postcode missing or not included in the IRSAD dataset.

the proportion who currently smoked (7.3%; moderate status: 4.6%; sufficient status: 1.9%) (Box 4). No women had critically low omega-3 levels; eleven had high levels; all were less than 11.0% and within the 10% margin of analytical and procedural error.

#### Program fidelity

Of 5057 samples received by the omega-3 laboratory, 4935 (97.6%) were analysed and the results reported within 72 hours. The difference in number from the 4801 test referrals recorded by SA Pathology reflects the timing of data capture: SA Pathology records test numbers at the point a result is reported, whereas the omega-3 laboratory database records samples at receipt. These differences therefore reflect reporting processes rather than repeat testing for individual women. Thirty-three of 4801 omega-3 fatty acid test referrals (0.7%) were for women beyond

20 weeks of pregnancy; 58 referrals (1.2%) were for women with non-singleton pregnancies.

#### Discussion

Our early stage evaluation of the Omega-3 Test-and-Treat Program indicates that it is feasible and can be integrated into routine antenatal care, providing a strategy for reducing the risk of preterm birth with a targeted nutritional intervention. Central to the early success was the engagement of all participants, particularly the collaboration with SA Pathology, the statewide public pathology service. Embedding omega-3 fatty acid testing into SAMSAS antenatal screening pathways streamlined Omega-3 Test-and-Treat Program processes and increased its reach. During the initial implementation period, requests for omega-3 testing increased to more than one-quarter of SAMSAS

#### 4 Characteristics of women with South Australian Maternal Serum Antenatal Screening (SAMSAS) referrals that included omega-3 fatty acid testing requests, South Australia, 19 April 2021 – 30 June 2022, by omega-3 fatty acid status

Characteristic	Omega-3 fatty acid status*			Total†
	Low (< 3.7%)	Moderate (3.7–4.3%)	Sufficient (> 4.3%)	
Number of tests	702 (14.7%)	1638 (34.2%)	2442 (51.1%)	4782
Maternal age (years), mean (SD)	30.3 (5.1)	30.2 (5.1)	31.4 (5.1)	30.8 (5.1)
Gestational age (weeks), median (IQR)	12.4 (11.3–13.1)	12.3 (11.3–13.0)	12.1 (11.0–12.9)	12.1 (11.1–13.0)
Maternal weight (kg), median (IQR)	67.0 (59.0–78.0)	71.0 (61.0–85.0)	69.0 (60.0–81.9)	69.2 (60.0–82.3)
Ethnic background‡				
Caucasian	319 (45.4%)	979 (59.8%)	1349 (55.2%)	2647 (55.4%)
Non-Caucasian	185 (26.4%)	226 (13.8%)	332 (13.6%)	743 (15.5%)
Unknown	198 (28.2%)	433 (26.4%)	761 (31.2%)	1392 (29.1%)
Socio-economic status (IRSAD), quintiles				
1 (most disadvantaged)	206 (29.3%)	451 (27.5%)	564 (23.1%)	1221 (25.5%)
2	162 (23.1%)	344 (21.0%)	490 (20.1%)	996 (20.8%)
3	154 (21.9%)	354 (21.6%)	560 (22.9%)	1068 (22.3%)
4	99 (14.1%)	291 (17.8%)	442 (18.1%)	832 (17.4%)
5 (most advantaged)	70 (10.0%)	176 (10.7%)	355 (14.5%)	601 (12.6%)
Unknown§	11 (1.6%)	22 (1.3%)	31 (1.3%)	64 (1.3%)
Smoker				
Yes	51 (7.3%)	76 (4.6%)	47 (1.9%)	174 (3.6%)
No	498 (70.9%)	1185 (72.3%)	1875 (76.8%)	3558 (74.4%)
Unknown	153 (21.8%)	377 (23.0%)	520 (21.3%)	1050 (22.0%)
In vitro fertilisation				
Yes	26 (3.7%)	75 (4.6%)	152 (6.2%)	253 (5.3%)
No	433 (61.7%)	997 (60.9%)	1483 (60.7%)	2913 (60.9%)
Unknown	243 (34.6%)	566 (34.6%)	807 (33.0%)	1616 (33.8%)
Referral location				
Metropolitan	463 (66.0%)	1009 (61.6%)	1649 (67.5%)	3121 (65.3%)
Regional	228 (32.5%)	608 (37.1%)	762 (31.2%)	1598 (33.4%)
Unknown§	11 (1.6%)	21 (1.3%)	31 (1.3%)	63 (1.3%)

IQR = interquartile range; IRSAD = Index of Relative Socio-economic Advantage and Disadvantage; SD = standard deviation. \* Omega-3 fatty acids as proportion of total serum fatty acids. † The supplied serum sample was insufficient in nineteen cases for assessing omega-3 fatty acid levels. ‡ Categories based on health professional selection from options available in the SAMSAS form. "Non-Caucasian" includes all women not classified by the referring practitioner as Caucasian; we acknowledge the broad and simplified nature of both categories. § Postcode missing or not included in the IRSAD dataset. ◆

referrals, reflecting its successful integration into routine screening protocols and strong engagement by both health professionals and pregnant women.

Further confirming the broad applicability of the program, the demographic and clinical characteristics of women whose omega-3 levels were assessed were similar to those of all women in the SAMSAS screening pathway. This finding suggests that omega-3 fatty acid testing was implemented without demographic bias, indicating broad and equitable access. In the early implementation phase of the program, 702 women (14.7%) had low omega-3 fatty acid levels, consistent with our Omega-3 to Reduce the Incidence of Prematurity trial findings.<sup>11</sup> A substantial proportion of pregnant women could therefore benefit from targeted omega-3 fatty acid supplementation for reducing the risk of early preterm birth.

There were no major differences in mean maternal age, median gestational age, median weight, IVF use, and referral location by omega-3 fatty acid status. However, the proportion of women who smoked was larger in the low omega-3 fatty acid status group, which could be related to the oxidative stress caused by smoking, which influences the metabolism of omega-3 fatty acids.<sup>28</sup> The proportion of women categorised as non-Caucasian was larger in the low status group; other studies have also reported differences in omega-3 fatty acid profile by ethnic background.<sup>29</sup> As the risk of preterm birth is higher for certain groups, including Aboriginal women and women from socio-economically disadvantaged areas,<sup>30,31</sup> diverse input into program design and implementation is important.<sup>32,33</sup> Co-design and collaboration with health professional and community member reference groups, including the Aboriginal Communities and Families Health

Research Alliance, helped the program meet the varied needs of its participants.

Program fidelity was supported by regular audits and feedback guided by the Consolidated Framework for Implementation Research.<sup>27</sup> Most omega-3 fatty acid tests were completed and reported in a timely fashion, and the results were consistent with expectations based on population values. While referrals of women at later than 20 weeks of pregnancy were infrequent, the proportion of referrals for women with non-singleton pregnancies (1.2%) was similar to the overall proportion of non-singleton pregnancies (1.5%) in Australia,<sup>34</sup> which suggests that this eligibility criterion was not consistently applied. As the scope of the program expands, clarifying the eligibility criteria could improve the consistency of program implementation. Although women with non-singleton pregnancies are often excluded from clinical trials, their omega-3 requirements are likely to be greater, and supplementation is considered safe; further research could determine optimal recommendations for this group. Overall, our findings indicate the robustness of the protocols and the effectiveness of the collaboration between SA Pathology and SAHMRI in embedding omega-3 fatty acid testing into routine antenatal care.

The early success of the program was facilitated by its multifaceted approach, guided by implementation science principles, that took critical factors into account, essential for integrating the preventive strategy into routine practice.<sup>35</sup> Tailored education sessions, co-created educational materials, and comprehensive promotion effectively raised awareness of and participation in the program.<sup>36</sup> Educational resources and clinician support tools were designed to be accessible to and relevant for women and their medical practitioners, consistent with approaches described in other antenatal care implementation studies.<sup>37</sup> Educational meetings further optimised health professional engagement and behavioural change. Collaboration with local key opinion leaders in obstetrics, midwifery, and pathology, including state perinatal networks and primary care clinical educators, further extended program reach through information dissemination and professional endorsements.

## Limitations

Several factors influence the implementation of antenatal care guidelines in primary care, including variable practitioner adherence, resource limitations, and the need for continuing training and support.<sup>38</sup> A key factor that would influence practitioner referral of women for omega-3 fatty acid assessment was not explicitly investigated in our study: whether health professionals offered testing to pregnant women, as the women themselves could be considered active adopters of the intervention. Primary care providers often find the implementation of new guidelines difficult because of time constraints, restricted access to up-to-date resources, and the complexity of coordinating care at multiple health services.<sup>38</sup> Overcoming such barriers requires sustained engagement, continuous monitoring, and iterative refinement of implementation strategies. We found that omega-3 fatty acid testing was undertaken for a broad range of women, but the de-identified data analysed precluded assessment of test ordering patterns for individual medical practitioners. Missing

data for some clinician-reported variables (eg, IVF use) may limit the reliability of some comparisons.

## Conclusion

The Omega-3 Test-and-Treat Program is a realistic approach to reducing the risk of preterm birth through omega-3 fatty acid testing and targeted supplementation. Our evaluation of its early implementation found that the approach is feasible, with strong engagement from both women and medical practitioners, supporting the possibility of its system-level adoption. Encouragingly, the omega-3 fatty acid testing rate has continued to increase since the early implementation phase; the mean number of tests is now consistently more than 800 per month, and test requests are included in about 60% of all SAMSAS referrals. This indicates growing integration into routine care. Our findings provide valuable insights that could guide equitable adoption of our approach in other states and territories, inform future expansion strategies and sustainable funding models, and contribute to reducing the incidence of preterm birth in Australia.

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**Data sharing:** The data for this study will not be shared, as we do not have permission from the participants or ethics committee approval to do so.

**Author contributions:** Karen P Best: conceptualisation, data curation, funding acquisition, methodology, project administration, supervision, writing (original draft). Celine Northcott: conceptualisation, data curation, methodology, project administration, writing (review and editing). Lucy A Simmonds: conceptualisation, funding acquisition, methodology, project administration, writing (review and editing). Philippa Middleton: Conceptualisation, Funding acquisition, Methodology, Supervision, writing (review and editing). Lisa N Yelland: conceptualisation, data curation, formal analysis, funding acquisition, methodology, writing (review and editing). Vanessa Moffa: project administration, methodology, writing (review and editing). Khoa Lam: methodology, project administration, resources, validation, writing (review and editing). Penelope Coates: conceptualisation, methodology, resources, supervision, validation, writing (review and editing). Cornelia Späth: project administration, methodology, writing (review and editing). Carol Wai-Kwan Siu: project administration, methodology, resources, supervision, validation, writing (review and editing). Karen Glover: conceptualisation, methodology, writing (review and editing). Rhiannon Smith: conceptualisation, methodology, writing (review and editing). Robert Gibson: conceptualisation, data curation, funding acquisition, methodology, resources, validation, writing (review and editing). Maria Makrides: conceptualisation, funding acquisition, methodology, supervision, writing (review and editing). ■

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## Supporting Information

Additional Supporting Information is included with the online version of this article.