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The impact of mandatory iodine fortification and supplementation on pregnant and lactating women in Australia

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1 **Title:** The impact of mandatory iodine fortification and supplementation on pregnant and
2 lactating women in Australia.

3

4 **Short title:** Iodine fortification and supplementation in Australia

5

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10

11 **Author's contribution**

12 All authors were involved in the conception and design of the study. SH collected and analysed
13 the data. All others were involved in the interpretation and drafting of the manuscript.

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30

31

32 **Abstract**

33 **Background and Objectives:** In Australia, two public health measures were introduced
34 between 2009 and 2010 to reduce iodine deficiency. However there has been a shortage of
35 information regarding their effectiveness and the ongoing prevalence of iodine deficiency in
36 Australia. The primary aim of this study was to assess the extent to which these public health
37 measures have reduced rates of iodine deficiency among pregnant and lactating women.
38 **Methods and Study Design:** A review was conducted to identify all studies published since
39 January 2010 that quantitatively measured the iodine status of pregnant and/or lactating women
40 in Australia. **Results:** We found 25 publications, of which seven were included in this review
41 after our exclusion criteria were applied. Of the seven included publications, three
42 demonstrated the pregnant and lactating women in their studies to be iodine replete (median
43 urinary iodine concentrations (MUIC) greater than 150 µg/L, or a breast milk iodine
44 concentration (BMIC) of greater than 100 µg/L). The remaining four publications found MUIC
45 of pregnant and lactating women to be below the 150 µg/L threshold, in the mild-to-moderate
46 iodine deficiency category. Only two studies, documented iodine sufficiency among pregnant
47 and lactating women in the absence of iodine supplementation. **Conclusions:** Many pregnant
48 and lactating women in Australia remain at least mildly iodine deficient. Antenatal iodine
49 supplementation was the factor most consistently associated with an adequate iodine status.
50 Larger, more representative studies or sentinel studies with a National coordination are needed
51 to understand the differences in iodine status that exist across the country.

52

53 **Keywords:** Iodine; fortification; supplementation; pregnancy; Australia.

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66 **Background**

67 Iodine is a trace element essential for the synthesis of thyroid hormones, which are in turn
68 essential for normal human growth and mental development. An inadequate dietary intake of
69 iodine can impair thyroid function and lead to a spectrum of disorders known as the iodine
70 deficiency disorders (IDD). Depending on the severity of the iodine deficiency, and the time
71 in the human lifecycle at which it occurs, these disorders may include miscarriage, mental and
72 physical retardation, thyroid dysfunction or cretinism.¹ A maternal diet sufficiently rich in
73 iodine is critical throughout pregnancy to ensure an adequate delivery of iodine to the foetus.
74 Even subclinical hypothyroidism in the mother, occurring as a consequence of iodine
75 deficiency, can cause irreversible brain damage in the foetus.^{1,2} The importance of maternal
76 iodine intake continues throughout breastfeeding as the newborn's brain continues to develop,
77 with breast milk providing its sole source of iodine.³

78

79 Determinations of iodine status are typically made with reference to epidemiological criteria
80 developed by WHO for assessing iodine nutrition, which are based on median urinary iodine
81 concentrations (MUIC). The values for pregnant women are provided in the Table 1. In
82 lactating women, breast milk iodine concentration (BMIC) can be used as an alternative
83 measure of iodine status. In such cases, a minimum BMIC value of 100 µg/L is typically used
84 as the threshold to determine maternal iodine adequacy.⁴

85

86

87

88 Research has previously confirmed that the majority of Australian children and pregnant
89 women are mildly-to-moderately iodine deficient.⁶ Table 2 summarises MUIC in pregnant and
90 lactating women in Australia prior to the implementation of fortification and supplementation
91 which ranged from 81⁷ to 109 µg/L.⁸ The consequences of moderate-to-severe iodine
92 deficiency during pregnancy on the cognitive outcomes of offspring are well established. Two
93 meta-analyses indicate that this level of iodine deficiency can result in a population wide loss
94 of intelligence in children of around 10-13.5 intelligence quotient (IQ) points.^{9,10} However
95 evidence supporting a link between mild-to-moderate iodine deficiency during pregnancy, such
96 as that documented in Australia, and detrimental cognitive outcomes in children has only
97 emerged more recently.⁸

98

99

100 In a 2013 longitudinal follow up of a Tasmanian cohort study, the authors found that children
101 whose mothers were iodine deficient during pregnancy had reductions of 10.0% in spelling,
102 7.6% in grammar, and 5.7% in English performance compared with children whose mothers
103 were iodine sufficient. These associations remained significant after adjustment for a range of
104 potential confounders including gestational and maternal age, gender, birth weight, and
105 maternal occupation and education.¹⁴ These results are consistent with the findings of a larger
106 cohort study undertaken recently in the United Kingdom, which documented progressively
107 worsening child IQ scores with worsening degrees of maternal iodine deficiency during
108 pregnancy.¹⁵

109

110 Because of this, Food Standards Australia and New Zealand (FSANZ) instituted a mandatory
111 food fortification program in October 2009 that requires all salt used in bread making in
112 Australia to be fortified with iodine in the range of 25-65 milligrams of iodine per kilogram of
113 salt¹⁶. Similarly, in recognition of the increased iodine requirements associated with pregnancy,
114 the National Health and Medical Research Council (NHMRC) released a public statement in
115 2010 recommending that all women who are pregnant, breastfeeding or considering pregnancy,
116 take an iodine supplement of 150 µg each day.¹⁷

117

118 Following the introduction of these public health measures, there has been a shortage of
119 information regarding their effectiveness and the ongoing prevalence of iodine deficiency in
120 Australia. Considering the importance of an iodine replete diet, and the long-term impact of
121 IDD, this study was undertaken to explore the extent to which the FSANZ fortification program
122 and NHMRC antenatal supplementation recommendation have been effective in addressing
123 rates of iodine deficiency among pregnant and lactating women in Australia. In particular, it
124 asks: are pregnant and lactating women in Australia iodine deficient?

125

126 **Methods**

127 *Identification of studies*

128 The database of peer-reviewed literature, PubMed/MEDLINE, was searched to identify studies
129 and reports published between January 2010 and Jan 2017. Web-based searches, using the
130 internet search engines Google and Google Scholar were also conducted to identify any reports
131 and grey literature (i.e. literature that has not been formally published) that met the inclusion
132 criteria. The references of all retrieved publications were hand searched for any relevant
133 references missing from the database searches.

134

135 *Search strategy*

136 The search terms that were used are provided in Appendix 1. The objective of the search was
137 to identify all publications in the post-fortification period that quantitatively measured the
138 iodine status of pregnant and/or lactating women. The inclusion criteria for the review required
139 that a publication had:

- 140 1. Quantitatively measured the iodine status of pregnant and/or lactating Australian
141 women using urinary or breast-milk iodine concentrations.
- 142 2. Based the above measurement on data collected after October 2009 (the post-
143 fortification period).
- 144 3. Been published between January 2010 and December 2016.

145

146 *Data extraction*

147 Data were extracted from the included studies according to the headings listed in Table 3.

148

149 **Results**

150 A total of 25 publications were retrieved from the literature search including 24 articles and a
151 government report prepared by the Australian Institute of Health and Welfare (AIHW).¹⁸
152 Thirteen articles were excluded on the basis that they did not report a quantitative measure of
153 the iodine status of pregnant or lactating women. A further five articles were also excluded,
154 three because the data collection occurred prior to October 2009, one because its data were
155 collected outside of Australia, and one because it was a duplicate of another included study.¹⁹
156 Details of the excluded articles are in Appendix 2. After applying the exclusion criteria, seven
157 publications were included in this review^{3,18-23} (see Figure 1).

158

159 *Study characteristics*

160 The number of participants in the included studies ranged from 60²¹ to 783.¹⁹ The data used by
161 the AIHW was drawn from the Australian Bureau of Statistics 2011-2012 National Health
162 Measures Survey (NHMS), which comprised blood and urine tests from over 11,000
163 participants aged five and over. However, the number of pregnant and breastfeeding women
164 within this data set was not specified.

165

166 The data used among the publications were collected between 2009 and 2013. Two of the
167 included studies used data that was at least partially collected in the pre-fortification period,

168 prior to October 2009.^{20,23} Four of the included articles were cross-sectional studies^{3,20-22} and
169 the remaining two were prospective cohort studies.^{19,23} Charlton's cross-sectional study
170 reported data for two separate samples of pregnant women, one collected in 2011 and the other
171 in 2012. The AIHW report is based on a cross-sectional analysis.

172

173 *Demographic characteristics*

174 Three of the studies were conducted in Adelaide, South Australia,^{3,19,23} two in the Illawarra
175 region of New South Wales^{21,22} and one in Gippsland in Victoria.²⁰ The AIHW report was the
176 only publication included in the review which was based on a national data set, and women
177 aged 16 – 44.¹⁸

178

179 Women who spoke a language other than English at home were excluded from all three of the
180 studies that found pregnant or breastfeeding women to be iodine replete.^{3,19,22} The other studies
181 did not report on the inclusion or exclusion of participants based on their language status,
182 although 94% of participants in Rahman's study identified as white.²⁰

183

184 Other demographic characteristics assessed for association with iodine status varied across the
185 seven publications. Charlton found no difference in MUIC across age, level of education or
186 number of previous pregnancies,²² while Huynh found positive associations between iodine
187 status and multiparity, alcohol consumption and non-Caucasian ethnicity.³

188

189 *Iodine status*

190 Iodine status was assessed according to MUIC in all of the included publications with the
191 exception of Huynh and colleagues, who measured iodine status according to median BMIC.³
192 In this study, a BMIC of more than 100 µg/L was considered sufficient to provide adequate
193 iodine to meet the needs of breast-fed term infants.

194

195 Of the seven included publications, three demonstrated pregnant and lactating women in their
196 studies to be iodine replete according to either the WHO criteria of a MUIC greater than 150
197 µg/L, or a BMIC of greater than 100 µg/L.^{3,19,22} The remaining four publications found MUIC
198 of pregnant and lactating women to be below the 150 µg/L threshold, in the insufficient
199 range.^{18,20,21,23} Table 3 summarises these results.

200

201 *Supplement use*

202 Perinatal iodine supplementation was the factor most consistently associated with an adequate
203 iodine status. Only two studies, both from Adelaide, documented iodine sufficiency among
204 pregnant and lactating women in the absence of iodine supplementation.^{3,19} No comparisons
205 were made between the iodine status of pregnant and breastfeeding women on the basis of
206 iodine supplementation within the AIHW report as the consumption of iodine supplements was
207 not measured directly as part of the NHMS.¹⁸

208
209 Only one of the included studies assessed changes in iodine status between the pre and post-
210 fortification periods after controlling for supplement use, and both noted improvements in
211 iodine status. Huynh et al estimated the mean BMIC of women not taking iodine supplements
212 to be 1.2 times greater in the post-fortification period than it was prior to fortification.³ Clifton
213 found that the MUIC of pregnant women not taking an iodine supplement before fortification
214 was 84 µg/L (range 83.4 – 393 µg/L, n = 94).²³ However data post-fortification is not available.

215
216 Importantly, all three of the studies that found their sample populations to be iodine replete
217 noted that iodine adequacy was unlikely to be achieved without antenatal
218 supplementation.^{3,19,22} Iodine status according to supplement use is described in Table 3.

219
220 *Data collection during pregnancy and breastfeeding*

221 The MUIC's and BMIC's reported in the included studies were captured at different stages of
222 pregnancy and breastfeeding. These results are described in Table 3.

223
224 **Discussion**

225 The findings of this review describe a mixed picture of the iodine status of pregnant and
226 lactating women in Australia since the introduction of public health measures to reduce rates
227 of iodine deficiency. On face value, there appears to be a generally upward trend in the iodine
228 status of these women, as seen by the increase in MUIC from 79 µg/L in 2009-10,²³ to 189
229 µg/L in 2011-12.¹⁹ However these figures belie the differences that exist between the included
230 studies.

231
232 *Geographical variation*

233 Of the three studies that found the iodine status of their sample population to be adequate, the
234 largest two were both conducted in Adelaide, the capital city of South Australia.^{3,19} These
235 results therefore need to be considered in light of the AIHW finding that iodine status varies

236 across Australia, and is highest in certain states, including South Australia, as well as in major
237 cities, such as Adelaide.¹⁸ Furthermore, both of the Adelaide studies drew their sample
238 populations from pregnant or lactating women participating in the same prospective cohort
239 study – Pregnancy Iodine and Neurodevelopment in Kids (PINK).²⁴ Therefore while these
240 studies report different outputs (MUIC v BMIC) measured at different stages (pregnancy v
241 lactation), they are actually reporting on the same data set and hence largely duplicate their
242 respective results.

243

244 The only other study to find an adequate iodine status among its population was conducted in
245 a small geographical area south of Sydney and was considerably underpowered, having a
246 sample size of just 114.²² Andersen et al,²⁵ have described that a sample size of 125 will give
247 a precision of $\pm 10\%$ using spot urines for a population estimate. It is important to realise that
248 precision alone should not determine the sample size needed to estimate a population MUIC.
249 External validity is also important. For the results to be generalised to a wider population the
250 sample has to be representative of this population.

251

252 *Gestational age and urinary iodine excretion*

253 Research has demonstrated that urinary iodine excretion is elevated in early pregnancy, and
254 decreases with advancing gestational age.²⁶ Studies have shown that early pregnancy MUIC
255 (<16 weeks) can be elevated to such an extent that it significantly exceeds population level
256 controls, thereby giving a false indication of iodine adequacy in the developing foetus.²⁶⁻²⁸ In
257 light of these findings, it is noteworthy that the highest MUIC recorded in this review (189
258 $\mu\text{g/L}$) was obtained by Condo et al,¹⁹ from a population of pregnant women sampled at a mean
259 gestation age of 16.3 weeks (± 2 weeks). The other studies that reported MUIC values and
260 gestational age at collection primarily obtained their samples in the third trimester of
261 pregnancy, which is likely to account for some of the variation in results.^{20,22,23} While Condo's
262 study also reported MUIC at 28 weeks gestation and again found its population to be iodine
263 sufficient (172 $\mu\text{g/L}$), this discussion illustrates the importance of accounting for gestational
264 age at the time of urinary iodine collection. Unfortunately, the AIHW report did not report the
265 gestational ages of the women in its sample.¹⁸

266

267 *Public awareness*

268 As noted above, three of the seven publications included in this review found that pregnant and
269 lactating women in Australia remain iodine deficient despite public health measures to address
270 this issue. This raises questions about the reasons for this ongoing deficiency.

271

272 One likely contributing factor is a low level of awareness within the Australian population
273 regarding dietary sources of iodine, its importance, and the potential implications of iodine
274 deficiency during pregnancy and lactation. Of the three articles in this review that assessed
275 these factors, all three concluded that their study participants were poorly informed in relation
276 to dietary sources of iodine and its importance during pregnancy.^{3,20,22}

277

278 *Role of the health provider*

279 While women have consistently identified health providers as their major source of nutritional
280 advice during pregnancy,²⁹⁻³¹ recent studies have shown that providers' knowledge of iodine
281 requirements in the perinatal period is not adequate. In a survey of 396 healthcare providers,
282 Guess and colleagues found that only 73% of respondents reported recommending iodine
283 supplements in pregnancy, which dropped to 56% when planning pregnancy and 52% during
284 lactation.³⁰ In a similar study, albeit from a different perspective, Martin reported that in a
285 sample of 200 pregnant women in Gippsland Victoria, only 34.5% indicated being made aware
286 of the importance of increasing iodine intake during pregnancy by their medical practitioner.³¹

287

288 The studies included in this review had a number of limitations. First, they all relied on a single-
289 spot urine or breast milk sample to determine iodine status. This is problematic because the
290 rate of iodine excretion reflects iodine intake over a short period of time, leading to significant
291 variability in day-to-day samples, reducing the reliability of iodine status estimates.³² Twenty
292 four hour urinary collections may provide a more accurate estimate of iodine status but are
293 not practical.¹⁹

294

295 Secondly, the majority of the studies were underpowered, with only Condo et al,¹⁹ and Huynh
296 et al,³ utilising a sample size greater than 300, the minimum required by the WHO to reliably
297 determine the iodine status of a population. While it is likely the AIHW also exceeded this
298 minimum, it did not report the number of pregnant women in its sample.¹⁸ Furthermore, women
299 who spoke a language other than English at home were excluded from all three of the studies
300 that reported a finding of iodine sufficiency, and their involvement in the other studies was not

301 specified. According to the 2016 Australian census 22% of households speak a language other
302 than English at home.³³

303

304 In relation to the AIHW report, despite being a national survey, it did not report gestational age
305 at the time of urinary collection, or report data for supplement and non-supplement users
306 separately. Given the influence of antenatal iodine supplementation on iodine status, it was
307 important to report the results of these two groups separately.

308

309 Finally, all of the studies included in this review used a median figure to report the urinary
310 iodine status of their respective study populations. Given the differences in iodine status
311 between the supplement-taking and non-supplement taking cohorts, the median value may
312 overstate the population's urinary iodine concentration.

313

314 **Conclusion and future directions**

315 The findings of this review demonstrate that despite public health measures to address rates of
316 iodine deficiency in Australia, many pregnant women remain mildly iodine deficient. While
317 recent studies out of Adelaide provide grounds for optimism, these results are yet to be
318 replicated across the country. Antenatal iodine supplementation in accordance with NHMRC
319 guidelines continues to be necessary, as fortification alone does not deliver sufficient iodine to
320 meet the increased requirements associated with pregnancy and breastfeeding.

321

322 Given the shortcomings of the studies considered in this review, larger, more representative
323 studies are needed to better understand the iodine status of women across the country. Future
324 studies would benefit from multi-centre, interstate involvement, to better illustrate the influence
325 of geographical, socioeconomic, ethnic and cultural factors that have previously been
326 demonstrated to influence nutritional iodine status.³⁴ Cross-sectional study designs such as that
327 employed by Charlton could readily be adapted to this purpose. Consideration should also be
328 given to using multiple spot-urine samples to provide a better estimate of iodine status.

329

330 Finally, there is a clear need for public health information campaigns and professional
331 education initiatives to better inform the public and healthcare providers about the importance
332 of an adequate iodine intake. As the nutritional choices of pregnant women are shaped by their
333 knowledge of what's important for a healthy pregnancy, improving knowledge about the

334 importance of iodine is a key step in promoting lasting behavioural change that will lead to
335 reductions in the rate of iodine deficiency in Australia.

336

337 **Disclosure statement**

338 The authors have no conflicts of interest to declare

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444

445 **Table 1.** WHO epidemiological criteria for assessing iodine nutrition based on the median
 446 urinary iodine concentrations of pregnant women.⁵

POPULATION GROUP	MEDIAN URINARY IODINE CONCENTRATION ($\mu\text{g/L}$)	IODINE INTAKE
Pregnant women	< 150	Insufficient
	150 - 249	Adequate
	250 - 499	Above requirements
	≥ 500	Excessive [†]
Lactating women[†]	<100	Insufficient
	≥ 100	Adequate

447 [†]Iodine intake is excessive if it is more than the amount required to prevent and control iodine
 448 deficiency. UICs for lactating women are lower than those for pregnant women because of
 449 the iodine excreted in breast milk.
 450

451 **Table 2.** Summary of results for urinary iodine excretion in Australian pregnant and
 452 breastfeeding women before fortification and supplementation

Population	Year	Number	Median	Reference
Pregnant women in Sydney North	1998-99	81	104	Gunton et al, 1999 ¹¹
Pregnant women in Western Sydney	1998-99	101	88	Li et al, 2001 ¹²
Pregnant women in Sydney North	2000	84	109	McElduff et al, 2002 ⁸
Pregnant women in Tasmania	2000-01	285	76	Burgess et al, 2007 ⁷
Pregnant women NSW Central Coast	2004	796	85	Travers et al, 2006 ¹³
Pregnant women in Tasmania†	2003-06	288	81	Burgess et al, 2007 ⁷
Pregnant women in Tasmania	2006	229	86	Burgess et al, 2007 ⁷

453 †24 h urine collection

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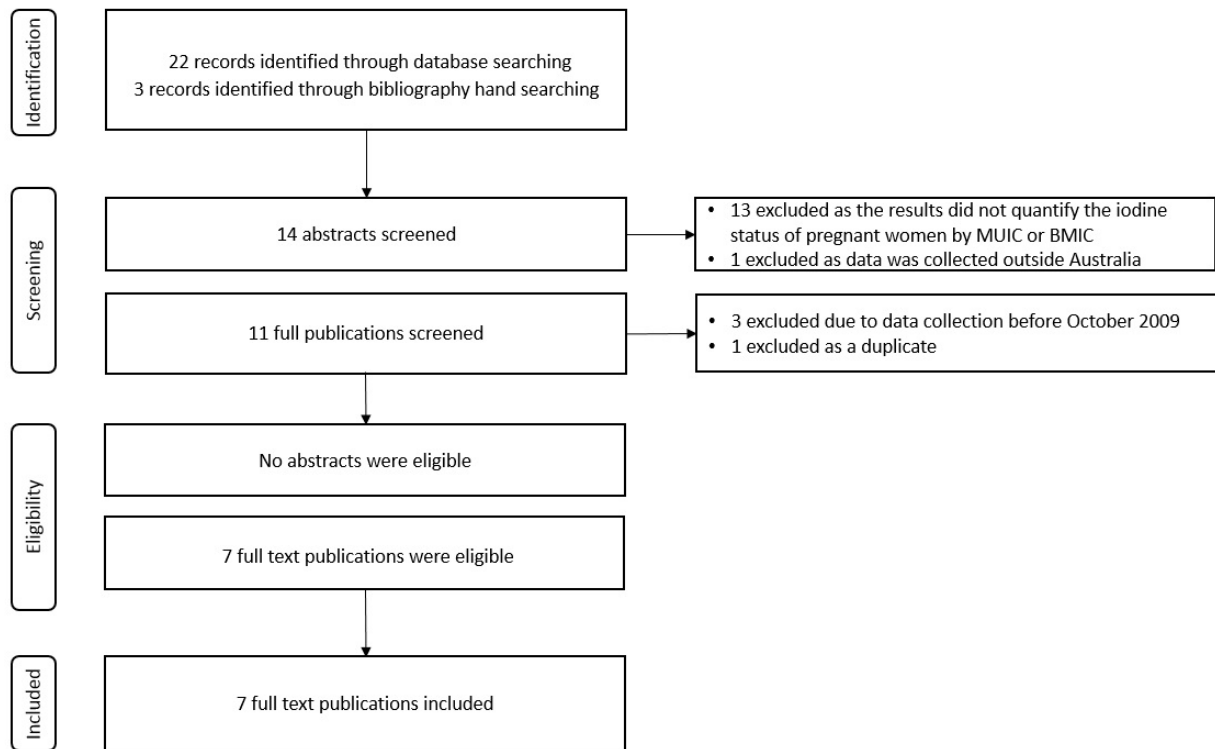
457 **Table 3:** Overview of studies included in the review

Reference	Data collection period	Location	Sample size	Status/period of data collection	Outcome measure
Clifton et al, 2013 ²³	2009 – 2010	Adelaide, SA	196	Pregnant 12, 18, 30 & 36 weeks gestation	MUIC Non-supplement: 84 µg/L
Rahman et al, 2011 ²⁰	2009 – 2010	Gippsland, VIC	62	Pregnant ≥28 weeks gestation	MUIC 95.5 µg/L
Axford et al, 2011 ²¹	2010	Illawarra, NSW	60	Breastfeeding Mean age 2.6 months (SD: 1.0)	MUIC 123 µg/L Non-supplement: 97 µg/L Supplement: 206 µg/L
Charlton et al, 2013 ²²	2011 2012	Illawarra, NSW	147 114	Pregnant 2011: 13-24 weeks (37%) & ≥ 25 weeks (61%) 2012: 13-24 weeks (29%) & ≥ 25 weeks (71%)	MUIC 2011: 145.5 µg/L Non supplement: 109 µg/L Supplement: 178 µg/L 2012: 166 µg/L Non supplement: 124 µg/L Supplement: 202 µg/L
AIHW, 2016 ¹⁸	2011 – 2012	Australia wide	Not	Pregnant & Breast-feeding	MUIC [†]

			Specified	Not specified	
Condo et al, 2016 ¹⁹	2011 – 2012	Adelaide, SA	783	Pregnant <20 weeks gestation (median 16.3 weeks) 28 weeks gestation	Pregnant: 116 µg/L Breast-feeding: 103 µg/L MUIC < 20 weeks: 189 µg/L 28 weeks: 172 µg/L Non supplement: 159 µg/L (MUIC) at < 20 weeks 141 µg/L (MUIC) at 28 weeks Supplement: 221 µg/L (MUIC) at < 20 weeks 187 µg/L (MUIC) at 28 weeks
Huynh et al, 2017 ³	2012 – 2013	Adelaide, SA	653	Breastfeeding Within 7 days of delivery	BMIC 187 µg/L Non-supplement: 137 µg/L Supplement: 195 µg/L

458 †Intakes for pregnant women aged 16–44 this sample of women, delineated by State, includes women who were pregnant and
459 breastfeeding, as well as women who were not.

460



461

462

Figure 1. Flow chart showing identification of individual studies for inclusion.