# Royal Hospital for Women (RHW) BUSINESS RULE COVER SHEET



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SUMMARY	This clinical business rule has been developed to guide clinical practice in fertility treatment at the Fertility & Research Centre, Royal Hospital for Women in the context of Body Mass Index (BMI). It assists in identifying women at risk of adverse outcomes due to BMI outside of the normal ranges and supporting staff in determining the appropriate management prior to commencing treatment.
Key Words	Invitro-fertilisation (IVF), Body Mass Index (BMI), Frozen embryo transfer (FET), Ovulation induction (OI), Intrauterine Insemination (IUI), Oncofertility

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# In vitro Fertilisation (IVF) - Body Mass Index (BMI) for fertility treatment

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This Clinical Business Rule (CBR) is developed to guide safe clinical practice at the Royal Hospital for Women (RHW). Individual patient circumstances may mean that practice diverges from this Clinical Business Rule. Using this document outside RHW or its reproduction in whole or part, is subject to acknowledgement that it is the property of RHW and is valid and applicable for use at the time of publication. RHW is not responsible for consequences that may develop from the use of this document outside RHW.

Within this document we will use the term woman, this is not to exclude those who give birth and do not identify as female. It is crucial to use the preferred language and terminology as described and guided by each individual person when providing care.

#### 1 BACKGROUND

The aim of this clinical business rule is to provide guidance on the recognition and the management of women with a Body Mass Index (BMI) outside of normal ranges when undertaking fertility treatment at the Fertility & Research Centre. This clinical business rule also addresses clinical management for women with a history of bariatric surgery and/or have utilised weight loss medications for weight management when seeking fertility treatment.

#### 2 RESPONSIBILITIES

- **2.1 Medical Director –** Oversee all policy development and supports clinical practice of fellows/registrars
- **2.2 Medical staff** –Provision of inclusive and individualised care, identifying risk, monitoring of results, consenting to treatment, escalation and referral
- 2.3 **Registered nurses –** coordination, education and support to patients undertaking fertility treatment inclusive of direct patient contact, counselling and monitoring.

#### 3 PROCEDURE

#### 3.1 Clinical Practice

#### General guidelines

 Obtain medical history from woman at initial medical consultation, ensure any history of bariatric surgery or use of weight management medication is disclosed

Measure height and weight of woman and calculate the Body Mass Index (BMI) based on the below formula

Weight (kg)	
Height (m <sub>2</sub> )	

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e.g. For a woman 70kg and 1.70m tall the BMI is calculated as 70/(1.7)2 = 24.2kg/m2

- Document BMI in medical record
- BMI to be calculated at the commencement of every In-vitro Fertilisation cycle
- Determine referral pathway and initial plan of care based on BMI result:

	BMI < 18 kg/m2	BMI 18-35 kg/m2	BMI > 35 kg/m2
Management	<ul> <li>Refer woman to dietician, general practitioner +/- endocrine for weight optimisation prior to pregnancy</li> <li>Consider referral to PLaN (Pregnancy planning, lifestyle and Nutrition)</li> <li>If BMI 16 arrange obstetric medicine review</li> </ul>	<ul> <li>Proceed with fertility treatment as planned         Ensure medical history obtained and history of bariatric surgery or medical weight management not identified     </li> <li>If BMI &gt;30 increase pre-conception folate supplementation is 5mg/day</li> </ul>	<ul> <li>Ensure preconception folate supplementation is 5mg/day</li> <li>Consider attending Vitamin D, HbA1c, fasting glucose</li> <li>Medical team to consider referring woman to dietician, general practitioner +/- endocrine for weight optimisation prior to pregnancy</li> <li>Consider referral to PLaN (Pregnancy planning, lifestyle and Nutrition)</li> <li>Arrange anaesthetic review via preadmission clinic (if applicable to cycle)</li> <li>If BMI &gt;38 arrange obstetric medicine review</li> <li>Should be assessed for complications of their high BMI including for diabetes, hypertension, consideration of obstructive sleep apnoea, PCOS, NASH, eating disorders, depression</li> </ul>

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Refer to Appendix A and B for specific cycle management

Women utilising pharmacological methods for weight loss

 GLP1 or GLP1-GIP agonist medications e.g. Semaglutide, Liraglutide, Tirzepatide, Dulaglutide should be ceased 2 months prior to commencing fertility treatment

Women with history of bariatric surgery

#### Types of bariatric surgery

Restrictive	- Vertical banded gastroplasty
	<ul> <li>Laparoscopic adjustable gastric band</li> </ul>
	- Sleeve gastrectomy
Malabsorptive	- Jejunoileal bypass
	<ul> <li>Biliopancreatic diversion (including duodenal switch)</li> </ul>
Combination of restrictive and malabsorptive	- Roux -en-Y gastric bypass

- Ensure minimum of six months between bariatric surgery and the commencement of fertility treatment; women who have undergone weight loss surgery should not commence IVF or fertility treatment during times of rapid weight loss
- Present case to multidisciplinary team (MDT) for discussion with obstetric medicine
  physicians and fertility specialists; treatment is only to commence after review and
  approval by the obstetric medicine physicians and discussion at MDT.
- Consider prescribing long active contraceptive e.g. Mirena IUD during rapid weight loss timeframe
- Women 40 years of age in rapid weight loss timeframe, who's treatment commencement is delayed due to same, able to continue In vitro fertilisation (IVF) treatment until their 42<sup>nd</sup> birthday.
- Ensure woman daily supplemental intake includes:
  - Folic acid (5mg/daily)
  - Copper (2mg/daily)
  - Zinc (15mg/daily)
  - Selenium (50 µg)
  - Iron (45-60 mg or >18 mg after AGB)

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- Thiamine (>12 mg)
- Vitamin E (15 mg)
- Beta carotene (Vitamin A, 5000IU)
- Ensure following investigations are attended every 3 months during the pre-conception period:
  - Full blood count (FBC)
  - Electrolyte, urea, creatinine (EUC)
  - Liver function tests (LFTs)
  - Calcium, magnesium, phosphate (CMP)
  - Coagulation studies
  - Iron studies
  - Folate
  - Vitamin B12
  - Vitamin D
  - Zinc
  - Copper
  - Selenium

#### 3.2 Documentation

- Artemis
- Patients file
- eMR

#### 3.3 Education Notes

Body mass index (BMI) is defined as a person's weight in kilograms (kgs) divided by the square of the person's height in metres (m), ie, BMI = weight (kg) / height (m) squared

For example, an adult who is 1.75m tall and weighs 70kg would have a BMI of:

$$BMI = 70 / (1.75 * 1.75) = 22.9$$

The World Health Organization has made the following classification for adults over the age of 20 years<sup>1</sup>

- BMI below 18.5 underweight
- BMI 18.5 24.9 normal weight range
- BMI 25.0 29.9 overweight
- BMI 30.0 34.9 obesity class I
- BMI 35.0 39.9 obesity class II
- BMI 40 and above obesity class II1

**Low** BMI is associated with fertility and pregnancy risks, including:

Reduced likelihood of achieving a pregnancy / reduced embryo implantation rate<sup>23</sup>

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- Miscarriage<sup>4</sup>
- Reduced live birth rate after IVF treatment<sup>4</sup>

#### **<u>Elevated</u>** BMI is associated with fertility and pregnancy risks including:

#### Fertility and conception:

- Longer time to conceive<sup>5 6</sup>
- Infertility <sup>67</sup>
- Poorer egg and embryo quality 8 9 10
- Decreased likelihood of embryo implantation<sup>11 6 12 13</sup>
- o Miscarriage 14 16 6 13 12 15
- Lower live birth rate after fertility treatment<sup>13</sup>

#### During pregnancy:

- Diabetes (type 2 diabetes and gestational diabetes) <sup>17 18 19 16 20</sup>
- o Hypertension / pre-eclampsia 18 21 22 16 20
- o Thromboembolism (DVTs, pulmonary embolisms) <sup>21 22</sup>
- Depression and anxiety <sup>23 24 25 26</sup>
- o Fetal congenital abnormalities including neural tube defects <sup>21</sup> <sup>27</sup> <sup>16</sup> <sup>10</sup>
- o Preterm birth 27 28 16 20 29
- Fetal growth restriction 30 31
- Macrosomia / large for gestational age 18 30 20
- Stillbirth <sup>16</sup> <sup>10</sup> <sup>20</sup> <sup>31</sup> <sup>32</sup>
- Maternal death <sup>22 34</sup>

#### During delivery:

- Increased risk of for induction of labour 35 36
- Prolonged labour, failure to progress in labour<sup>37 38 39</sup>
- o Difficulties with fetal heart rate monitoring 40
- Shoulder dystocia<sup>15</sup>
- Increased risk of caesarean section <sup>18 21 31 16 41 20 39</sup>
- Post-partum haemorrhage<sup>42 43</sup>
- Perinatal maternal death <sup>22 44</sup>

#### Anaesthetic risks:

- o Difficulties with analgesia provision in labour<sup>45</sup> 46
- Need for general anaesthetic for caesarean section
- o Difficulty maintaining an adequate airway / failed intubation<sup>45 46 47 48</sup>

#### After delivery:

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- Increased risk of need for ICU care post-delivery 41 49
- Delayed wound healing and infection<sup>18</sup>
- o Thromboembolism (DVTs, pulmonary embolisms) <sup>21</sup>
- Greater likelihood of difficulties with breast feeding 50 51 52
- Postnatal depression <sup>26 25 52</sup>

#### Impact on the baby / child:

- Birth trauma<sup>18</sup>
- Neonatal complications including jaundice, hypoglycaemia, respiratory distress, admission to neonatal intensive care and neonatal/infant death<sup>18 32 27 31 41</sup>
- Long term consequences for the baby including less favourable neonatal body composition, infant weight gain and increased likelihood of developing obesity, metabolic disease, diabetes, asthma or cardiovascular disease in later life<sup>54</sup> 55 56 10 57

#### Weight loss pre-pregnancy improves pregnancy outcomes but significant weight loss periconception may be inadvisable.

Bariatric surgery and pharmacological agents can be used to assist weight loss including GLP-1 and GLP-1/GIP agonists, phenteramine/topiramate, Naltrexone/bupropion and others have been proposed to improve pregnancy outcomes in women with high BMI. In most studies, bariatric surgery reduces rates of gestational diabetes and hypertensive disorders of pregnancy. It is also associated with increased rates of small for gestational age babies. There is less evidence available for the impact of pharmacological weight loss methods and the impact on pregnancy and its outcomes.

Where nutrition is compromised in the setting of rapid weight loss, conception is inadvisable. For example, most bariatric surgical guidelines suggest deferring pregnancy for 12-18 months following surgery. This relates primarily to the GLP-1 and GLP-1/GIP agonists and bariatric surgery, but rapid weight loss at the time of conception and in early pregnancy is not recommended regardless of method of weight loss.

#### Background - GLP-1 agonist and other weight loss Medications

GLP-1 agonist and GLP-1/GIP agonist medications are gastrointestinal incretin hormones administered either as an injection or a tablet to improve blood sugar control in adults who have type 2 diabetes. They are also frequently used to aid weight loss. Weight loss during pregnancy is not recommended, nor is rapid weight loss immediately prior to pregnancy<sup>58</sup>

#### These medications may include:

- Semaglutide brand names include Ozempic, Rybelsus, Wegovy
- Dulaglutide brand names include Trulicity
- Tirzepatide brand names include Monjarou
- Liraglutide brand names include Saxenda

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There are two main concerns relating to the use of the GLP1 or GLP1-GIP agonist medications whilst a patient is undergoing fertility treatment:

- Anaesthetic concerns relating to the delayed emptying of the stomach. The administration of sedation or general anaesthetic inhibits physiological mechanisms that usually prevent stomach contents refluxing back into the mouth and being aspirated into the lungs. Patients' who fast for six hours prior to surgery usually have minimal stomach contents, however whilst a patient is using a GLP1 or GLP1-GIP agonist weight loss medication, they may have a full stomach at the time of anaesthetic administration, despite fasting prior to their surgery. The delay in stomach emptying can persist for up to eight weeks after the cessation of these medications<sup>59</sup>
- The effect of GLP1 or GLP1-GIP agonist medications on fertility has not been established. although a higher rate of miscarriage in animals has been reported<sup>60</sup>. GLP1 or GLP1-GIP agonist medications are pregnancy category D indicating that there is evidence of risk to the fetus as a result of the use of GLP1 or GLP1-GIP agonist medications. In pregnant rats, there is evidence of embryo-fetal toxicity including lethality, impaired fetal growth and an increased rate of fetal malformations including kidney, liver and skeletal abnormalities. Abnormalities were also observed in the fetuses of pregnant monkeys and there was an increased rate of early pregnancy loss <sup>61</sup> GLP1 or GLP1-GIP agonist medications have a long half-life of approximately one week. This means that if a GLP1 or GLP1-GIP agonist medication is administered on one day with no subsequent administration, the circulating blood concentration one week later would be half of what it was at the time of initial administration. Thus, GLP1 or GLP1-GIP agonist medications remain in the blood and tissue for a prolonged amount of time after administration<sup>61</sup>. Consequently, the manufacturers of GLP1 or GLP1-GIP agonist medications recommend that patients use contraception whilst being treated with a GLP1 or GLP1-GIP agonist medication and that pregnancy should be avoided for at least two months after the cessation of use of a GLP1 or GLP1-GIP agonist medication<sup>60 61</sup>

To date, there have been no studies to determine whether the administration of GLP1 or GLP1-GIP agonist medications to male partners affects their fertility or if this administration increases the risk of fetal abnormalities. As a general rule, paternal exposures are unlikely to increase risks to a pregnancy, therefore current advice does not recommend the cessation of use of GLP1 or GLP1-GIP agonist medications by the male partner prior to commencing attempts to conceive or undergoing fertility treatment.<sup>60</sup>

#### **Background – Bariatric Surgery**

Bariatric surgical procedures may include:

- Sleeve gastrectomy in which the volume of the stomach is reduced by 75%; weight loss occurs due to the limitation on food intake capacity and the excision of ghrelin-secreting cells in the stomach<sup>62</sup>
- Roux-en-Y gastric bypass in which the volume of the stomach is reduced to 15-30mL and the proximal small intestine is surgically bypassed with food being diverted to the distal

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small intestine; weight loss occurs due to the limitation on food intake capacity, the reduced absorption of nutrients and the increase in gut hormone secretion decreases appetite <sup>62</sup>

- Adjustable gastric band procedures which involve the placement of an inflatable restrictive band around the upper stomach, narrowing the opening to the lower stomach; weight loss occurs secondary to the limitation of food intake and a reduction in appetite <sup>63</sup>
- Biliopancreatic diversion with duodenal switch
- Intragastric balloon
- Vertical banded gastric gastroplasty

Whilst bariatric surgery has been demonstrated to result in weight loss and improvement in obesity-related comorbidities<sup>62 63 58</sup> it is associated with a number of adverse events including:

- Surgical complications
- Postprandial dumping syndromes<sup>58</sup>
- Micronutrient deficiencies<sup>58</sup>
- Derangements in endocrine and metabolic homeostasis 64 65 66
- Pregnancy related complications including small for gestational age, preterm birth, congenital abnormalities, perinatal mortality and maternal morbidity/mortality<sup>67</sup>

Gastric bypass may lead to deficiencies in macronutrients including vitamin A, vitamin B12, vitamin D, calcium, iron, selenium, zinc and copper; and the patient may need to supplement their diet with a multivitamin. Protein intake should also be greater than 60g/day<sup>78 79</sup>

Risks in pregnancy associated with prior bariatric surgery include:

- Surgical complications small bowel obstruction, internal herniation<sup>58</sup> gastric band erosion, cholelithiasis, gastric band slippage<sup>58</sup>
- Upper abdominal pain occurs in 46% of pregnancies after bariatric surgery, with associated risk of preterm birth and lower birth weight in women in which abdominal pain occurs<sup>69</sup>
- Internal herniation occurs in 32.8% of pregnancies<sup>69</sup>

Several consensus guidelines recommend the avoidance of pregnancy after bariatric surgery due to rapid post-operative weight loss, these include:

- Medical Journal of Australia Pregnancy should be delayed by at least 12-18 months after bariatric surgery<sup>69</sup>
- New Zealand Ministry of Health Women who have undergone bariatric surgery should not conceive for twelve months after surgery during the period of rapid weight loss<sup>70</sup>
- American Association of Clinical Endocrinologists, the Obesity Society, and American Society for Metabolic and Bariatric Surgery – Pregnancy should be delayed by at least 12-18 months after bariatric surgery<sup>72</sup>
- UK Consensus guidelines Postpone pregnancy until a stable weight has been achieved<sup>58</sup>

As obesity is associated with impaired fertility secondary to PCOS and metabolic syndrome, many obese women may believe they are infertile and, consequently believe the use of contraception is not warranted. Spontaneous fertility improves after bariatric surgery <sup>58 73 74</sup> therefore contraception

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should be discussed in women who plan to undertake or have recently undertaken bariatric surgery. Long active contraceptive methods such as the Mirena IUD are preferred due to the decreased efficacy of the oral contraceptive pill due to post-operative malabsorption<sup>75 76 77 78</sup> and the relative contraindication for combined oral contraceptive use in obese women due to the risk of venous thromboembolism<sup>58</sup>

#### 3.4 CBR implementation plan

The revised CBR will be distributed to all medical, nursing and midwifery staff via @health email. The CBR will be discussed at ward meetings, education and patient quality and safety meetings. Education will occur through in-services, open forum and local ward implementation strategies to address changes to practice. The staff are asked to respond to an email or sign an audit sheet in their clinical area to acknowledge they have read and understood the revised CBR. The CBR will be uploaded to the CBR tab on the intranet and staff are informed how to access

#### 3.5 Related Policies/procedures

- IVF Management & Treatment of a superovulation cycle
   In Vitro Fertilisation (IVF) Management and Treatment of a Superovulation Cycle
- IVF Embryo transfer
   In Vitro Fertilisation (IVF) Embryo Transfer

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#### ABORIGINAL HEALTH IMPACT STATEMENT DOCUMENTATION

- Considerations for culturally safe and appropriate care provision have been made in the development of this Business Rule and will be accounted for in its implementation.
- When clinical risks are identified for an Aboriginal and/or Torres Strait Islander woman
  or family, they may require additional supports. This may include Aboriginal health

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professionals such as Aboriginal Liaison Officers, health workers or other culturally specific services

#### **4 CULTURAL SUPPORT**

- 1. For a Culturally and Linguistically Diverse CALD woman, notify the nominated cross-cultural health worker during Monday to Friday business hours
- 2. If the woman is from a non-English speaking background, call the interpreter service: <u>NSW Ministry of Health Policy Directive PD2017 044-Interpreters Standard Procedures for Working with Health Care Interpreters.</u>

#### 5 NATIONAL STANDARDS

• Standard 5 - Comprehensive Care

#### 6 REVISION AND APPROVAL HISTORY

Date	Revision No.	Author and Approval
6.2.25	1	Dr Rachael Rodgers
17.3.25	1	BRGC

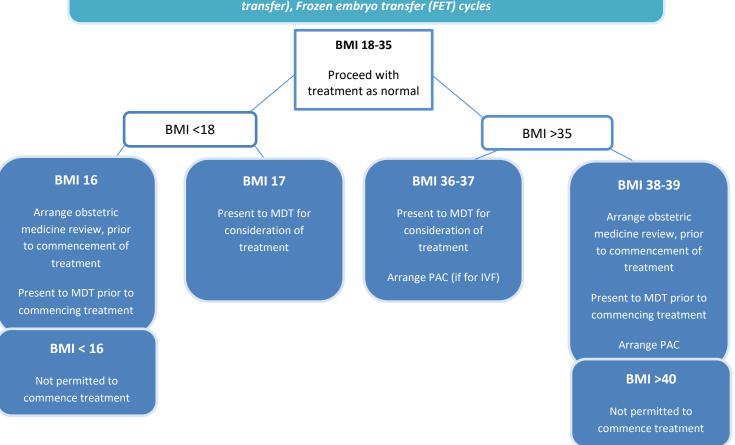
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#### Appendix A

Body Mass Index (BMI) management pathway: Ovulation Induction (OI), Intrauterine Insemination (IUI), Invitro-fertilisation (IVF) Medical indication (egg/embryo freeze or planned fresh embryo transfer), Frozen embryo transfer (FET) cycles



Women who are not approved to undertake an <u>embryo transfer</u> at the Fertility and Research Centre should be made aware that they have the ability to transport their embryo(s) to another IVF clinic for use

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# In vitro Fertilisation (IVF) - Body Mass Index (BMI) for fertility treatment

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### **Appendix B**

Body Mass Index (BMI) management pathway: Oncofertility indication (egg/embryo freeze)

