

# Case study: Exclusion of married adolescents in a study of gestational diabetes mellitus

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# The study on gestational diabetes mellitus in Malappuram, Kerala

- The primary objectives of the study were to examine the patterns of and factors associated with post-partum diabetes screening of women who had GDM during their most recent pregnancy,
- To document patterns of post partum morbidity among these women and
- To determine health providers' perspectives on what would be appropriate follow up for women with GDM

Study site: Malappuram

District – the largest district in Kerala

Population: 4, 112,920 (2011 Census)

Density: 1157 persons per sq km (2011 Census)

Literacy rate: 93.6%

Female work participation: 7.6% (2011 Census)

TFR: Kerala-1.6 (2011);

Malappuram-2.2 (Gullimoto and Rajan 2013)

Blood sugar levels: 14% of women aged 18 and above report blood sugar levels of 140mg/dl and more



# Study Methodology

- Study type: Mixed method approach, using quantitative and qualitative approaches
- Sample size: 200 married women diagnosed with GDM during their most recent pregnancy
- Method of recruitment: Institutional deliveries are the norm and therefore using hospital based records to identify women with GDM and examining the potential follow up six weeks following the birth was planned
- Study site: Four hospitals (3 private and 1 public) which account for a significant proportion of births in Malappuram district were sites for recruitment of women who had delivered recently – ie before three to six months
- Study instrument: structured interview schedule for the women and in depth interview guide for health care providers

# Marriage, the law and demographics of Malappuram district

- Marriages are near universal in Malappuram with 84.1 percent of the women and 70.3 percent of the men 15 years or more ever married (Census of India, 2011)
- The legal age at marriage in India is 18 for women and 21 for men
- In Malappuram district, 2.3% and 9.4% of the girls were married by the ages 18 and 21 respectively (Census of India, 2011)
- This means a small proportion of girls are married before they are legally allowed to marry

# The legal – ethical quagmire

- Persons below age 18 are not recognised as adults under Indian Law (Indian Majority Act 1875)
- Marriage before age 18 is not legal (Prohibition of Child Marriage Act 2006)
- After marriage, women in India and in Malappuram tend to move to the affinal home and parents are generally in the same home
- Indian Law does not have a notion of an emancipated minor
- Persons below the age of 18 need to provide assent prior to participation in research
- The assent is accompanied with consent from the legal guardian of the person below age 18
- When alive, parents are the recognised legal guardians of persons below age 18

## Ethical regulatory requirements

- Who then would be the legal guardian of the married woman who is below years of age and living in her affinal home?
- From whom would a researcher be expected to obtain consent for such a woman to participate in research?

# Possible options for researchers -1

- Asking the woman to participate and attempting to obtain consent from parents
- Risk:
  - The in-laws have socio-cultural power in society vis-a-vis the girls parents' and seeking parental consent could be seen as insulting to the in-laws; and
  - the parents may not be available in the neighbourhood



## Possible options for researchers - 2

- Treating the parents-in-law as standing in loco parentis and seeking consent from them
- Risk:
  - The marriage is not legal, in these circumstances it would be seen as legitimising what is illegal
  - The parents in law may not have the best interests of the married adolescent as culturally they are seen as having control over the woman

## Possible option for researcher - 3

- Asking the husband to consent
- Risk:
  - He might himself not be an adult
  - He might be a migrant to the gulf regions and not available
  - It undermines the woman's autonomy to decide for herself
  - In sexual and reproductive health issues, the partner's position may conflict with that of the woman herself

# Action taken

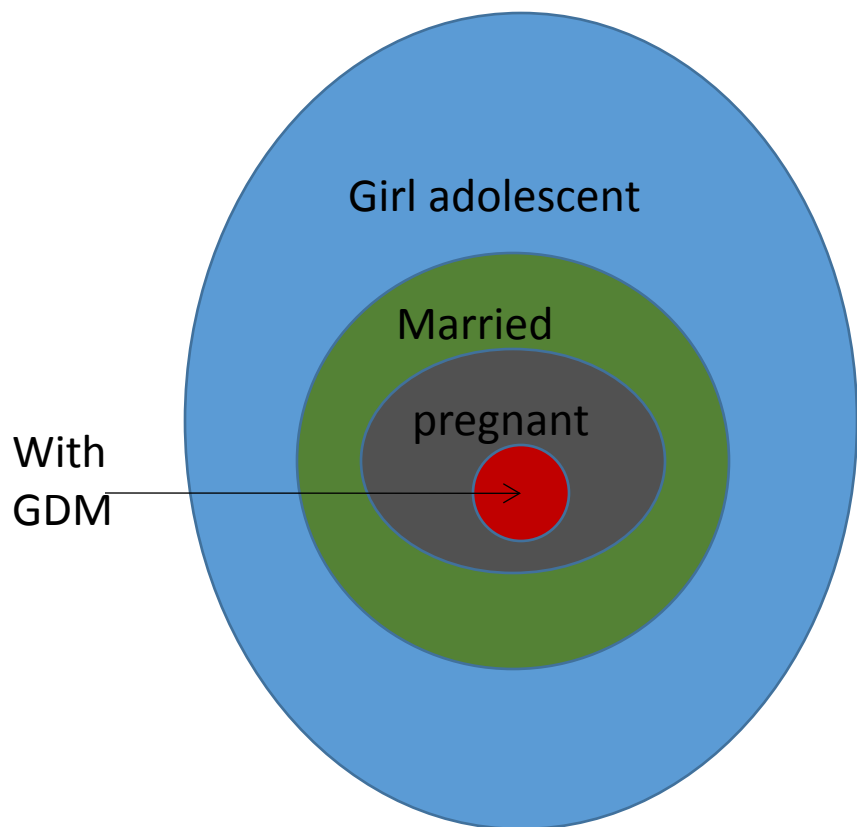
- The study was being undertaken for completion of a Masters' in Public Health
- Time available to complete data collection for the study was less than three months
- Attempting to obtain assent and consent would have extended the time to completion
- The district is the largest district and most densely populated district of Kerala
- Accessing married adolescents and their parents would mean traversing across the district for consent purposes
- Ethics committees may be reluctant to permit alternatives

**Solution: Exclude married women below age 18**

# The potential for bias in estimation

- Gestational Diabetes Mellitus is associated with higher maternal age
- However, most of the studies that examine GDM have not had a large number of women below age 18
- The reported age pattern of GDM could be affected by this artifact
- All women who get pregnant are at risk for GDM
- If women are likely to get pregnant at any age, then risk of GDM also exists for them
- Then they should be equally included in studies on GDM
- Not including them could affect the determination of age pattern of GDM
- Excluding these women would yield biased estimates of GDM and screening risks

# The potential ethical risk



## The risks

- Adolescent women below age 18 are already vulnerable (age, power relations in the family)
- The married adolescent's vulnerability is further enhanced by the marital status and pregnancy
- Research on potential of the screening programmes for GDM would benefit such women to access appropriate follow up care
- To exclude them from research due to administrative and logistic inconveniences is also unethical

# Our suggestions...

- 1. Recognise the married adolescent as an emancipated minor and seek her consent alone
- Benefit: She could as well be the person most educated in the household and capable of making decisions for herself and her child
- 2. Ask her who within the household where she resides would be an adult who has her well being at heart – according to her, whose consent she would not mind seeking
- Benefit: Social support and not undermining the married adolescent in her affinal home

# Problems in implementation

- Suggestion 1. Recognise the married adolescent as an emancipated minor and seek her consent alone
- Need for change in laws as it is a legal position
- Laws are difficult to change
- Suggestion 2. Ask her who within the household where she resides would be an adult who has her well being at heart – according to her, whose consent she would not mind seeking
- Regulatory creep due to clinical trials and their regulation has made Ethics Committees wary of giving leeway to researchers
- This affects all researchers as Ethics Committees are becoming the regulators' arm instead of a watchdog for the human subject/participant in research
- Need for guidance to evolve locally to address this issue

Thank you