CHAPTER 1: INTRODUCTION

The FAO/WHO Expert Consultation (WHO/FAO Expert consultation, 2004) stated that in most locations in the world in broadband around the equator (between latitude 42°N and 42°S), the most physiologically relevant and efficient way of acquiring vitamin D is to synthesize it endogenously in the skin from 7-dehydrocholestrol by 30 minutes of skin exposure of the arms and face to the sun. By this criterion, vitamin D deficiency is unexpected in India which lies within the defined broad band. However, several factors may interfere with the skin exposure to sun's rays and can contribute to vitamin D deficiency in India such as traditional lifestyle, clothing, pollution, geographical location, seasons of the year, skin types (Indian skin type is V) etc. All these factors reduce exposure to sunlight and, hence, can result in vitamin D deficiency.

Osteomalacia in *purda* wearing north Indian Women in the early part of the last century was a well-recognized clinical entity (Teotia, & Teotia, 1972, Teotia, Teotia & Singh, 1979, Teotia, Teotia & Nath, 1995, Teotia & Teotia, 1997 and Teotia & Teotia, 2008). However, by the mid-20th century, as physicians did not report osteomalacia in women and congenital rickets in infants, it seemed as if these were no longer a clinical problem, and the vitamin D status of pregnant women became less of a concern (Gopalan, & Ramachandran, 2008). In the seventies, neonatal hypocalcaemia among Asian immigrants in UK was attributed to poor maternal exposure to sunlight among the immigrants and vitamin D supplementation during pregnancy to the 'at risk' Asian mothers in UK was suggested as the remedy (Hodgkin et al., 1973 and Brooke et al., 1980). As obstetricians in India did not see osteomalacia and paediatricians did not report hypocalcaemia in neonates, it was assumed that Indians in India did not face these problems.

The availability of technology for vitamin D estimation in terms of 25(OH)D assay, enabled several investigators to estimate the prevalence of asymptomatic Vitamin D deficiency in population groups (Hollis, 2005 and Harinarayan et al., 2008). Data from some epidemiological studies indicate that biochemical deficiency is common in both south and north India (Harinarayan et al., 2008 and Goswami, Mishra & Kochupillai,

2008). Studies carried out in Lucknow have shown very high levels of vitamin D deficiency in pregnant women (Sachan et al.,2005) vitamin D deficiency as defined by low circulating 25(OH)D concentrations is common during infancy and childhood (Goswami, Mishra & Kochupillai, 2008). During the last two decades, there have been increased reports of neonatal hypocalcaemia and rickets from different parts of the world (Pettifor, 2008). There are also an increasing number of reports from India on neonatal hypocalcaemia, hypocalcemic symptoms in young infants, vitamin D deficiency in breastfed infants, and clinical and radiological rickets in children of all ages (Balasubramanian & Ganesh, 2008). Studies from India has reported vitamin D deficiency across the age groups (Kamboj, Dwivedi and Toteja, 2018) and in both the sex from all over India (Trilok Kumar, Chugh & Eggersdorfer, 2015 and Goswami, Mishra & Kochupillai, 2008).

In view of the high prevalence of biochemical vitamin D deficiency, low calcium intake, and known adverse consequences of poor vitamin D status on the mother-child dyad, calcium and vitamin D supplementation during pregnancy had been advocated. Studies from UK had reported a reduction in neonatal tetany following calcium and vitamin D supplementation during pregnancy (Brooke et al., 1980).

National Guidelines for "Calcium Supplementation During Pregnancy and Lactation" have been drawn up by the Maternal Health Division, Ministry of Health & Family Welfare (Government of India) in December 2014 (MOHFW, 2014). The guidelines envisage calcium 500mg (as calcium carbonate salt) and 250 IU vitamin D are to be taken twice daily just after meal; calcium and vitamin D supplementation should begin from the second trimester of pregnancy and continue till six months postpartum. Iron and Folic Acid (IFA) tablets are not to be taken simultaneously with calcium tablets.

The supplementation is to be carried out in all settings – hospital antenatal clinics, antenatal clinics in MCH centres and primary health care institution (PHCI). In community settings, ANMs are to distribute these supplements to pregnant women attending Village Health and Nutrition Day (VHND). In case of pregnant women not coming to VHND, ASHA has the responsibility to deliver the supplements to the pregnant women. In Government hospitals, a wide variety of calcium and vitamin D

preparations have been used. The tablets are provided to all pregnant women attending the antenatal clinic when available. Regularity of intake of supplementation is not monitored in these women. All women do not come for regular follow up; it is not possible for the hospital to ensure that they do come back to the same hospital for follow up visits. There is therefore a paucity of data on the regularity of calcium and vitamin D intake in pregnant women and the effect of calcium and vitamin D supplementation on the course and outcome of pregnancy.

Majority of pregnant women attending the antenatal clinics are anaemic. The National Iron Plus Initiative (NIPI, MOHFW 2013) envisages that anaemic pregnant women should receive 2 tablets of IFA (100mg of elemental iron and 500 µg of folic acid) daily. Majority of families have three meal pattern and it will not be possible for them to take 2 tablets each of IFA and calcium & vitamin D separately after different meals. In view of the well-documented adverse consequences of anaemia on the mother-child dyad, many physicians prioritized supplementation with 2 IFA tables and gave one tablet of calcium and vitamin D to pregnant women attending the antenatal clinic in government hospitals.

Nutrition Foundation of India carried out a short-term research study on the side effects of IFA (containing 60 mg elemental iron and 500 mcg) and calcium and vitamin D (containing 500mg elemental calcium and 250 IU vitamin D) supplementation to fit two tablets of IFA and two tablets of calcium and vitamin D within the usual three meal pattern and found out that there were no significant increase in the side effects between single tablet of IFA and two tablets of IFA consumed together; whereas there was a statistically significant increase in the side effects between single tablet of calcium and vitamin D and two tablets of calcium and vitamin D consumed together (Ramachandran, Pramanik & Kalaivani, 2019).

Therefore, for the research component of the present study, it was decided to provide one tablet of IFA each with breakfast and dinner (provided by the PHCI) and provide 1 tablet of calcium and vitamin D provided by our institution with lunch.

So far there have been no publications on the impact of providing one tablet of calcium and vitamin D to pregnant women on the vitamin D status of pregnant women. So, a study was taken up in research mode where the calcium and vitamin D tablets were provided by our institution and the regularity of intake was carefully monitored and the

impact of the supplementation was assessed by comparing the pre and post supplementation Vitamin D levels of providing one tablet of calcium and vitamin D to pregnant women.

Under service conditions Government hospitals are supplied with different brands of calcium and vitamin D tablets; there are gaps in supply of the calcium and vitamin D supplements to the hospitals. Pregnant women attending antenatal clinics are given calcium and vitamin D tablets of available brands as and when they are available. The antenatal clinics do not document the regularity of supply or pregnant women's compliance in intake of supplements. There is therefore a paucity of data on coverage and compliance with calcium and vitamin D supplementation in pregnant women.

In community settings many women do not attend antenatal clinics; women attending the health and nutrition days in Anganwadi or when home visits are done by ANM /ASHA pregnant women who do not attend the antenatal clinic are to be provided with calcium and vitamin D supplementation. There is no data on the coverage, compliance and continuation of use of calcium and vitamin D supplementation in community settings.

The National guidelines on calcium and vitamin D supplementation were laid by GOI in the year of 2014. There is paucity of data on coverage, compliance (the number of supplements the pregnant women received and, consumed) or the impact of calcium and vitamin D supplements in hospital or in community settings.

It is essential to obtain data on coverage and compliance with the calcium and vitamin D supplementation in the hospital under research and service conditions and in the community settings, so that problems in the implementation of the supplementation programme can be identified and appropriate mid-course corrections can be done.