

**Summer Training at
Sun Pharmaceuticals Industries Ltd.,
Mumbai**

**Iron Deficiency Anaemia- Exploring the Decision Making Process in the
Treatment of Iron Deficiency Anaemia by Gynaecologist**

**By
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**Under the guidance of
Brig. (Dr.) S.K.Puri**

**MBA Pharmaceutical Management
2015-2017**



**The IIHMR University, Jaipur
2016**

CERTIFICATE

TO WHOMSOEVER MAY CONCERN

This is to certify that **Mr.Dhruv Malha**, student of MBA Pharmaceutical Management (MBA PM) from The IIHMR University, Jaipur has undergone internship training at **Sun Pharmaceuticals Ltd, Mumbai** from **4th April 2016** to **1st June 2016**.

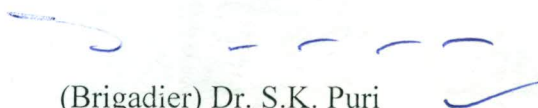
The Candidate has successfully carried out the study designated to him during internship training and his approach to the study has been sincere, scientific and analytical.

The Internship is in fulfillment of the course requirements.

I wish him all success in all his future endeavors.



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TO WHOMSOEVER IT MAY CONCERN

This is to certify that **Mr. Dhruv Malha** of Indian Institute of Health Management & Research has undergone her summer project in Sun Pharmaceutical Industries Ltd in **Spectra Division PMT Department** from **April 04, 2016** to **June 1, 2016**. His project title was **"Iron Deficiency Anemia" - Exploring the decision making process in the treatment of IDA by gynaecologists.**

He has completed the project to the satisfaction of his project guide and the organisation.

We wish him success in all future endeavors.

For **SUN PHARMACEUTICAL INDUSTRIES LTD.**

RAVI JAGGI
DEPUTY GENERAL MANAGER – HUMAN RESOURCES

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I would like extend my sincere and heartfelt thanks to Mr Dilip Shanghvi, Managing Director Sun Phrama Laboratories Ltd. For providing me an opportunity to learn and develop professionally.

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I hope that I can use this experience and knowledge that I have gained in this internship and make a greater contribution to the industry in the coming future.

Abbreviations

Abbreviations	Full Form
IDA	Iron Deficiency Anemia
PPH	Post Partum Haemorrhage
IUGR	Intrauterine growth restriction
LBW	Low Birth Weight
NHM	National Health Mission
NFHS	National Family Health Survey
CDC	Centre For Disease Control
WHO	World Health Organisation
RBC	Red Blood Corpuscles
HB	Haemoglobin
FA	Fanconi Anemia
GI	Gastrointestinal
MoHFW	Ministry of Health and Family Welfare
MWCD	Ministry of Women & Child Development
IFA	Iron Folic Acid
SCOGS	Select Committee on GRAS Substances
FDA	Food and Drug Administration
Govt.	Government
GRAS	Generally Recognized As Safe
CBC	Complete Blood Count
FOGSI	Federation of Obstetric and Gynaecological Societies of India

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Executive Summary

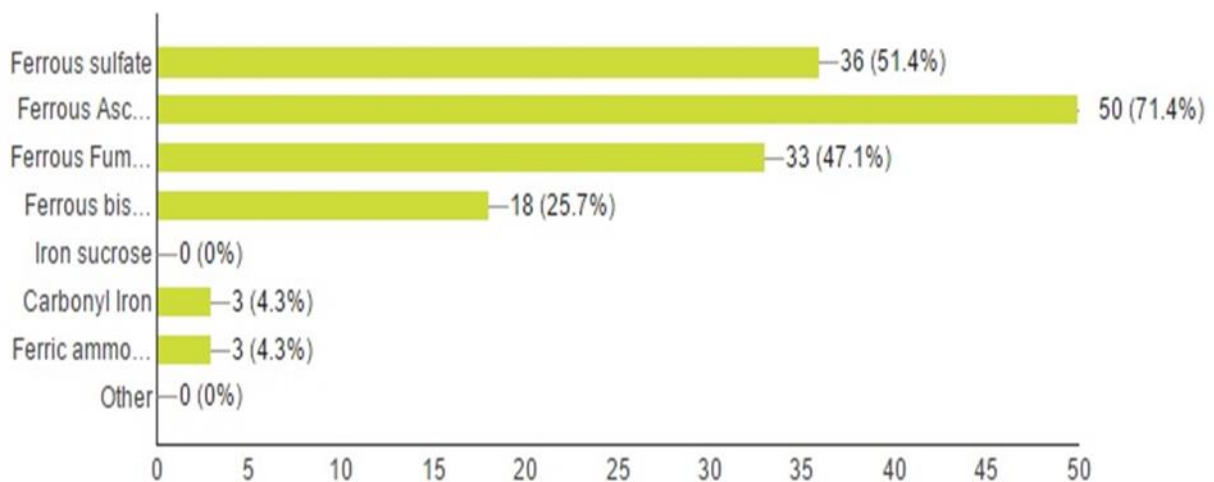
The project assigned was “Exploring the decision making process in the treatment of Iron Deficiency Anemia by Gynaecologist” with primary objectives being:

- ✓ To identify the need gaps in the treatment of IDA
- ✓ To identify the most suitable iron molecule/salt in clinical practice
- ✓ To identify the choice of brand of gynaecologists

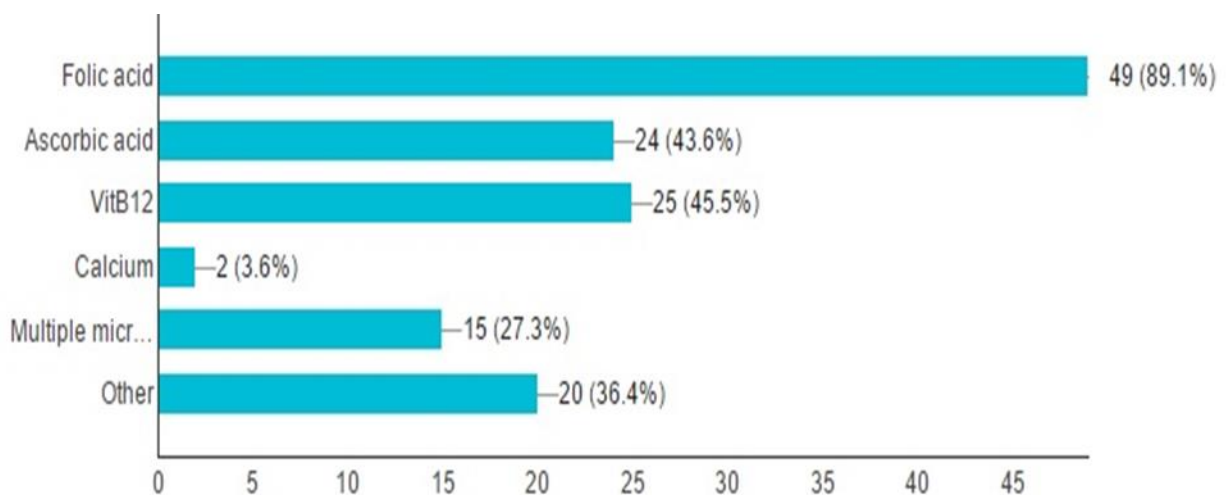
After meeting the gynaecologists, following findings were observed:

To market a hematinic brand, it is crucial to understand the decision making process of the gynecologists for the treatment of IDA.

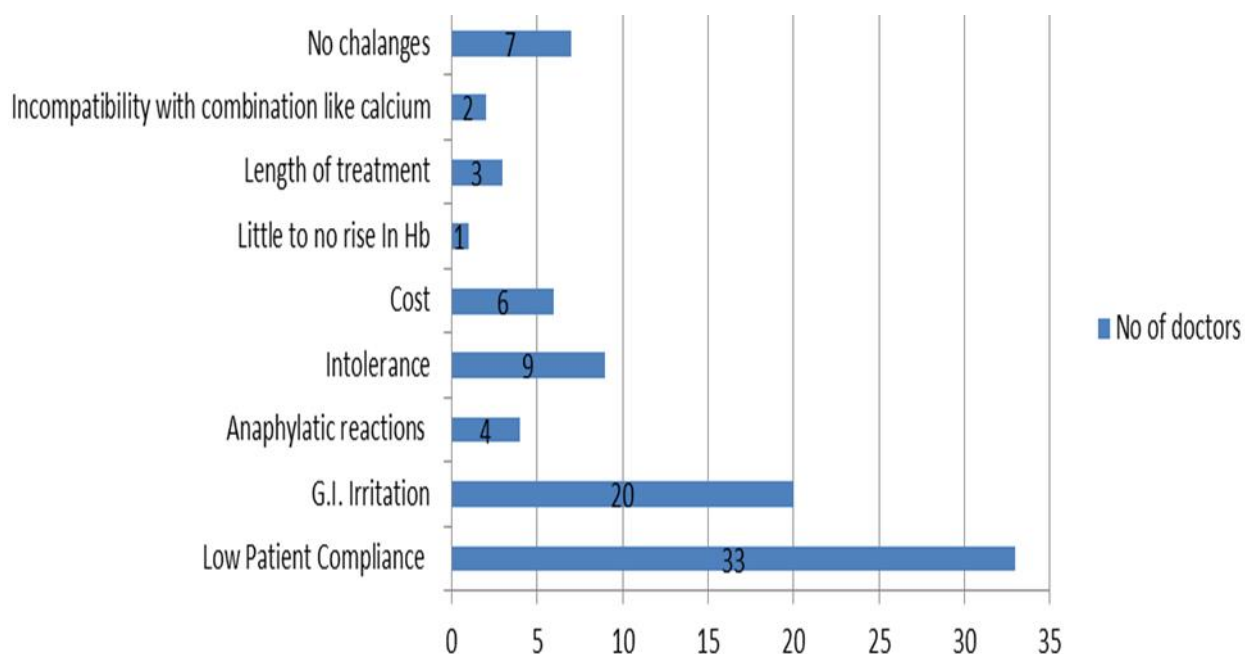
- A hematinic formulation with a Ferrous Ascorbate molecule is more preferred by the doctors.



- Folic acid, ascorbic acid and B12 formulation is preferred due to enhancement in absorption.



- The main challenge faced by gynaecologist in treatment of IDA is Non- compliance of patient.
- The other main challenge in the Iron therapy is Intolerance of Iron causing GI irritation.



- Shape and size of the solid dosage formulation should also be small.
- The length of the treatment is long.

The report also provides a way ahead for the organization with Ferrous Ascorbate being the molecule to venture ,folic acid, ascorbic acid B12 and zinc formulation should be used in addition to iron.

A control release formulation could enhance the compliance. Using target drug delivery systems like liposomal iron will decrease the GI irritation.

Shape and size of the solid dosage formulation should also be small.

Strong promotional activities along with the clinical data support is required to influence gynecologists in the decision making process for the treatment of IDA.

Focus could be given on a better packing of drug making it patient compliant. For example a calendar /days based packing of tablets.

Company Profile

Sun Pharma is a leading global specialty generic and India's top pharmaceutical company. Sun Pharmaceuticals was established by Mr Dilip Shanghvi in 1983 in Vapi with five products to treat psychiatry ailments. Cardiology products were introduced in 1987 followed by gastroenterology products in 1989.

Today it is the largest chronic prescription company in India and a market leader in psychiatry, neurology, cardiology, orthopaedics, ophthalmology, gastroenterology and nephrology.

The 2014 acquisition of Ranbaxy made the company the largest pharma company in India, the largest Indian pharma company in the US, and the 5th largest speciality generic company globally. Over 72% of Sun Pharma sales are from markets outside India, primarily in the US.

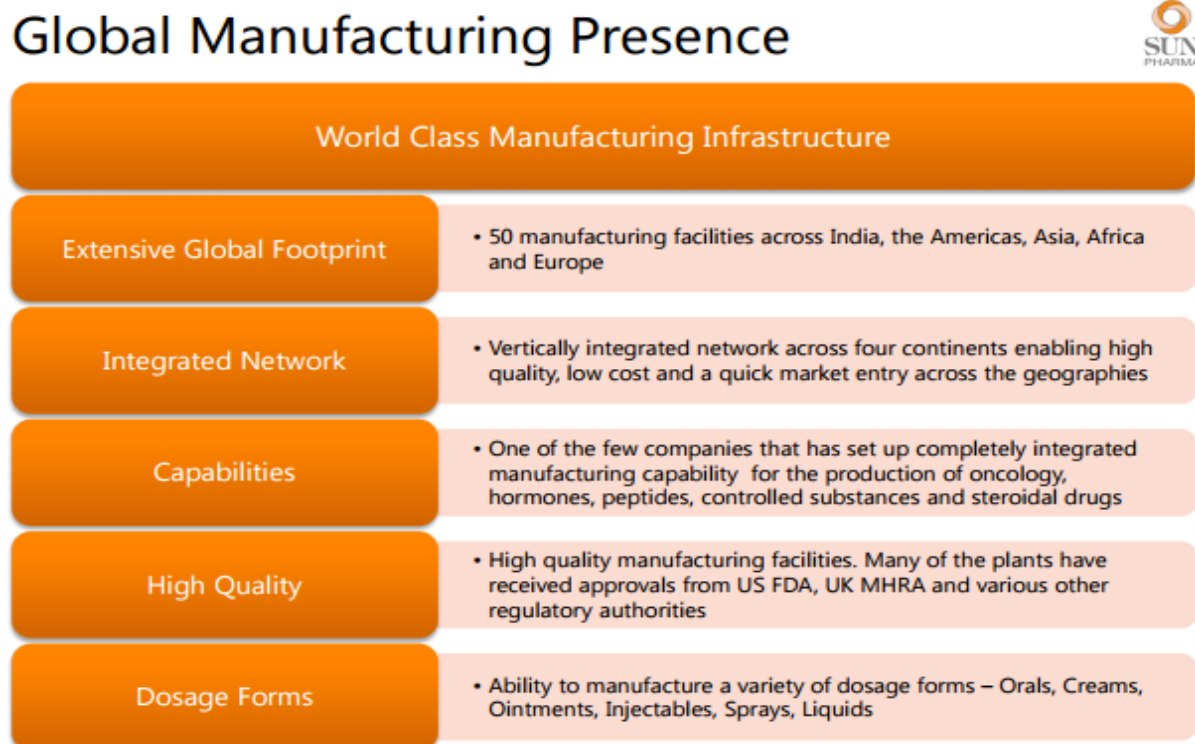
Table 1: Sun pharma profile

5 th Largest Global Specialty Generic Company	
US	• Ranked 5 th in US* / Largest Indian Pharma Company in US
India	• No. 1 Pharma Company in India
Emerging Markets	• Largest Indian Pharma Company in Emerging Markets
Europe	• Expanding presence in Europe
Manufacturing Footprint	• 50 manufacturing sites across the world
Market Presence	• Presence in more than 150 countries across branded and generic markets
Product Portfolio	• Portfolio of more than 2,000 products across the world
Employees	• 30,000+ global employee base
Quality Compliance	• Multiple facilities approved by various regulatory authorities across the world including USFDA
R&D and Manufacturing	• Capabilities across dosage forms like injectables, sprays, ointments, creams, liquids, tablets and capsules
Addressable Segments	• Specialty products, branded generics, complex generics, pure generics & APIs

* Source: Evaluate Pharma for 12 months ended Dec 2014

It has a wide basket of 159 products pending approval for the US market consisting of a pragmatic mix of complex, patent challenge and normal generic products. In India, the Company enjoys prescription leadership across 13 different classes of doctors with 30 brands featuring among top 300 pharmaceutical brands in India. Its footprint across emerging markets covers over 100 countries and all the important markets in Western Europe.

Table 2: Sun pharma global presence



Strategy and Approach

Create sustainable revenue streams

- Focus: Chronic therapies
- Differentiation: Technically complex products
- Speed to market



Seek cost leadership

- Vertical integration : Development through Manufacturing (API and Finished Dosage) to Marketing
- Optimize operational costs

Balance profitability and investments for future

- Acquisitions yielding high ROI
- Development of complex generics

SUN PHARMA JOURNEY FROM 1983-2015

YEAR	DEALS	COUNTRY	RATIONALE
2015	Sun Pharma – Ranbaxy merger	Global markets	5th largest global specialty generic pharma company, No.1 pharma company in India and strong positioning in emerging markets
2015	Acquisition of GSK's Opiates business	Global markets	Vertical integration for controlled substances business
2014	In-licensing agreement with Merck for MK-3222, a biologic for psoriasis	Global markets	Strengthening the specialty product pipeline
2014	Acquired Pharmedica	US	Sterile injectable capacity in the US, supported by strong R&D capabilities
2013	Formation of Sun-Intrexon JV	Global markets	JV for ocular therapies
2013	Acquired URL's generic business	US	Adds 107 products to the US portfolio
2012	Acquired DUSA Pharma, Inc.	US	Access to branded dermatology product
2011	Formation of Sun-MSD JV	Emerging markets	Develop and commercialize technology based combination products
2010	Acquired Taro Pharmaceutical Industries Ltd.	Israel	Access to dermatology and topical product development and manufacturing capabilities
2008	Acquired Chattem Chemicals, Inc.	Tennessee, US	Import registration with DEA, API plant approved by DEA in Tennessee, US
2005	Assets of Able Labs Formulation plant in Bryan	US	Dosage form plant (NJ, US) and IP Dosage form plant (Ohio, US)
1997	Acquired Caraco	Detroit, US	Entry into the US market

INTRODUCTION

According to the World Health Organization, there are two billion people with anemia in the world and half of the anemia is due to iron deficiency. W.H.O. has estimated that prevalence of anemia in developed and developing countries in pregnant women is 14% in developed and 51% in developing countries. In India, anemia affects an estimated 50% of the population. It is estimated that about 20%-40% of maternal deaths in India are due to anemia. Increased requirement of iron during growth and pregnancy and chronic blood loss contribute to higher prevalence in specific groups. Maternal anemia is associated with poor intra-uterine growth and conceiving of low-birth-weight babies.

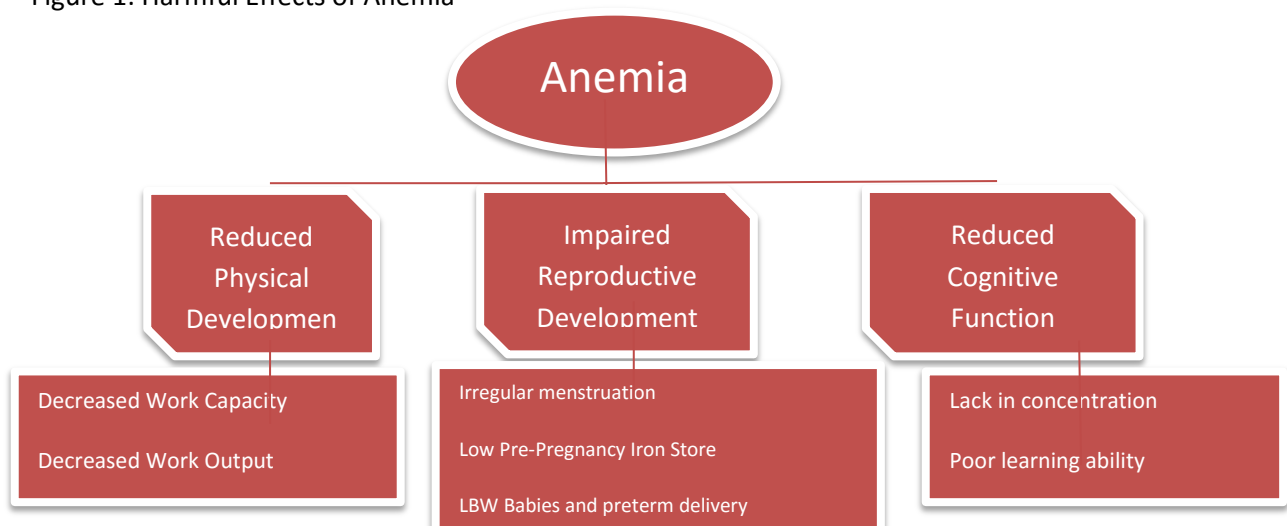
Anemia

Anemia, also spelled aneamia, is usually defined as a decrease in the amount of red blood cells (RBCs) or hemoglobin in the blood. It can also be defined as a lowered ability of the blood to carry oxygen. According to the World Health Organization (WHO), anemia is defined as a hemoglobin level of less than 13 g/dL in men and less than 12 g/dL in women. The basis of this definition is the average hemoglobin level of healthy individuals

Main symptoms that may appear in anemia

Most commonly, people with anemia report feelings of weakness, or fatigue, general malaise, and sometimes poor concentration. They may also report dyspnea (shortness of breath) on exertion. In very severe anemia, the body may compensate for the lack of oxygen-carrying capability of the blood by increasing cardiac output. On examination, the signs exhibited may include pallor (pale skin, lining mucosa, conjunctiva and nail beds), but this is not a reliable sign. There may be signs of specific causes of anemia, e.g., koilonychias (in iron deficiency), jaundice (when anemia results from abnormal break down of red blood cells — in hemolytic anemia), bone deformities (found in thalassemia major) or leg ulcers (seen in sickle-cell disease).

Figure 1: Harmful Effects of Anemia



Prevalence of Anemia

The WHO Global Database on Anemia for 1993–2005, covering almost half the world's population, estimated the prevalence of anemia worldwide at 25%. Although the prevalence of anemia is estimated at 9% in countries with high development, in countries with low development the prevalence is 43%. Anemia affects 1.62 billion people globally. Children and women of reproductive age are most at risk, with global anemia prevalence estimates of 47% in children younger than 5 years, 42 per cent in pregnant women, and 30 per cent in non-pregnant women aged 15–49 years. Africa and Asia account for more than 85% of the absolute anemia burden in high-risk groups and India is the worst.

TABLE 3: Prevalence Of anemia in South Asian Countries

Country	Proportion of population with anaemia (Hb <11 g/dl)	Public health problem
Bangladesh	47.0	Severe
Bhutan	80.6	Severe
India	74.3	Severe
Nepal	78.0	Severe
Pakistan	50.9	Severe
Sri Lanka	29.9	Moderate

TABLE 4: Prevalence of Anemia among various age groups in India

Age groups	Prevalence of anaemia (%)
Children (6–35 months)	79
Children (6–59 months)	69.5
All women (15–49 years)	55.3
Ever married women (15–49 years)	56
Pregnant women (15–49 years)	58.7
Lactating women (15–49 years)	63.2
Adolescent Girls	
12–14 years	68.6*
15–17 years	69.7*
15–19 years	55.8

Source: NFHS-3

*National Nutrition Monitoring Bureau Survey (NNMBS), 2006

Types of Anemia

Anemia may present itself in various types which make it necessary to be diagnosed properly.

Aplastic Anemia is a blood disorder in which the body's bone marrow doesn't make enough new blood cells. Damage to the bone marrow's stem cells causes aplastic anemia. In more than half of people who have aplastic anemia, the cause of the disorder is unknown.

Hemolytic Anemia is a condition in which red blood cells are destroyed and removed from the bloodstream before their normal lifespan is up. A number of diseases, conditions and factors can cause the body to destroy its red blood cells. In inherited hemolytic anemia, the genes that control how red blood cells are made are faulty. Different types of faulty genes account for the different types of inherited hemolytic anemia. In acquired hemolytic anemia, the body makes normal red blood cells; however, some disease, condition, or factor destroys the cells too early. Examples include immune disorders, infections and reactions to medicines or blood transfusions.

Thalassemia is an inherited blood disorders which cause the body to make fewer healthy red blood cells and less hemoglobin (an iron-rich protein in red blood cells). The two major types of thalassemia are alpha- and beta thalassemia. The most severe form of alpha thalassemia is known as alpha thalassemia major, while the severe form of beta thalassemia is known as thalassemia major or Cooley's anemia. Thalassemia affects both males and females and occurs most often in people of Italian, Greek, Middle Eastern, Asian, and African descent.

Sickle cell anemia is a serious disease in which the body makes sickle-shaped ("C"-shaped) red blood cells. Normal red blood cells are disk-shaped and move easily through your blood vessels Sickle cells contain abnormal hemoglobin that causes the cells to have a sickle shape, which don't move easily through the blood vessels – they are stiff and sticky and tend to form clumps and get stuck in the blood vessels. The clumps of sickle cells block blood flow in the blood vessels that lead to the limbs and organs. Blocked blood vessels can cause pain, serious infections, and organ damage. In sickle cell anemia, a lower-than-normal number of red blood cells occur because sickle cells don't last very long. Sickle cells usually die after about 10 to 20 days and the body can't reproduce red blood cells fast enough to replace the dying ones, which causes anemia.

Pernicious anemia is a condition in which the body can't make enough healthy red blood cells because it doesn't have enough vitamin B12 (a nutrient found in certain foods). People who have pernicious anemia can't absorb enough vitamin B12 due to a lack of intrinsic factor (a protein made in the stomach). However, other conditions and factors can also cause vitamin B12 deficiency.

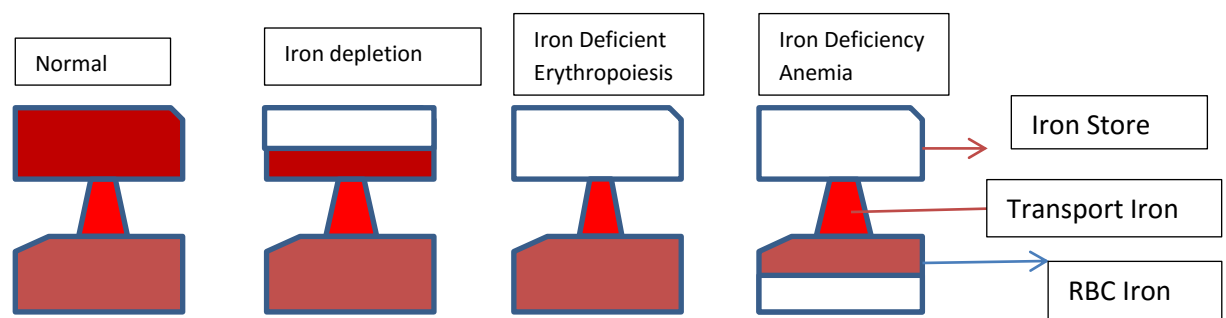
Fanconi anemia, or FA, is a rare, inherited blood disorder that leads to bone marrow failure. FA is a type of aplastic anemia that prevents the bone marrow from making enough new blood cells for your body to work normally.

Iron Deficiency Anemia

As the name implies, iron deficiency anemia is due to insufficient iron. Without enough iron, body can't produce enough of a substance in red blood cells that enables them to carry oxygen (hemoglobin). As a result, iron deficiency anemia may cause tiredness and shortness of breath.

Iron status can be considered as a continuum from iron deficiency with anemia, to iron deficiency with no anemia, to normal iron status with varying amounts of stored iron, and finally to iron overload which can cause organ damage when severe. Iron deficiency is the result of long-term negative iron balance. Iron deficiency anemia (IDA) should be regarded as a subset of iron deficiency, that is, it represents the extreme lower end of the distribution of iron deficiency

Figure 2: Iron levels in body at various stages



Causes of iron deficiency anemia include:

- **Blood loss.** Blood contains iron within red blood cells. So if you lose blood, you lose some iron. Women with heavy periods are at risk of iron deficiency anemia because they lose blood during menstruation. Slow, chronic blood loss within the body — such as from a peptic ulcer, a hiatal hernia, a colon polyp or colorectal cancer — can cause iron deficiency anemia. Gastrointestinal bleeding can result from regular use of some over-the-counter pain relievers, especially aspirin.
- **A lack of iron in your diet.** Your body regularly gets iron from the foods you eat. If you consume too little iron, over time your body can become iron deficient. Examples of iron-rich foods include meat, eggs, leafy green vegetables and iron-fortified foods. For proper growth and development, infants and children need iron from their diet, too.
- **An inability to absorb iron.** Iron from food is absorbed into your bloodstream in your small intestine. An intestinal disorder, such as celiac disease, which affects your intestine's ability to absorb nutrients from digested food, can lead to iron deficiency anemia. If part of your small intestine has been bypassed or removed surgically, that may affect your ability to absorb iron and other nutrients.

- **Pregnancy.** Without iron supplementation, iron deficiency anemia occurs in many pregnant women because their iron stores need to serve their own increased blood volume as well as be a source of hemoglobin for the growing fetus.

These groups of people may have an increased risk of iron deficiency anemia:

- **Women.** Because women lose blood during menstruation, women in general are at greater risk of iron deficiency anemia.
- **Infants and children.** Infants, especially those who were low birth weight or born prematurely, who don't get enough iron from breast milk or formula may be at risk of iron deficiency. Children need extra iron during growth spurts. If your child isn't eating a healthy, varied diet, he or she may be at risk of anemia.
- **Vegetarians.** People who don't eat meat may have a greater risk of iron deficiency anemia if they don't eat other iron-rich foods.
- **Frequent blood donors.** People who routinely donate blood may have an increased risk of iron deficiency anemia since blood donation can deplete iron stores. Low hemoglobin related to blood donation may be a temporary problem remedied by eating more iron-rich foods. If you're told that you can't donate blood because of low hemoglobin, ask your doctor whether you should be concerned.

Mild iron deficiency anemia usually doesn't cause complications. However, left untreated, iron deficiency anemia can become severe and lead to health problems, including the following:

- **Heart problems.** Iron deficiency anemia may lead to a rapid or irregular heartbeat. Your heart must pump more blood to compensate for the lack of oxygen carried in your blood when you're anemic. This can lead to an enlarged heart or heart failure.
- **Problems during pregnancy.** In pregnant women, severe iron deficiency anemia has been linked to premature births and low birth weight babies. But the condition is preventable in pregnant women who receive iron supplements as part of their prenatal care.
- **Growth problems.** In infants and children, severe iron deficiency can lead to anemia as well as delayed growth and development. Additionally, iron deficiency anemia is associated with an increased susceptibility to infections.

To diagnose iron deficiency anemia, your doctor may run tests to look for:

- Red blood cell size and colour. With iron deficiency anemia, red blood cells are smaller and paler in colour than normal.
- Hematocrit. This is the percentage of your blood volume made up by red blood cells. Normal levels are generally between 34.9 and 44.5 percent for adult women and 38.8 to 50 percent for adult men. These values may change depending on your age.
- Hemoglobin. Lower than normal hemoglobin levels indicate anemia. The normal hemoglobin range is generally defined as 13.5 to 17.5 grams (g) of hemoglobin per deciliter (dL) of blood for men and 12.0 to 15.5 g/dL for women. The normal ranges for children vary depending on the child's age and sex.
- Ferritin. This protein helps store iron in your body, and a low level of ferritin usually indicates a low level of stored iron.

Iron requirements are highest for pregnant women –1.9 mg/1,000 Kcal of dietary energy in the second trimester and 2.7 mg/1,000 Kcal in the third trimester. These are followed by iron requirements in infants (1.0 mg), adolescent girls (0.8 mg), adolescent boys (0.6 mg), non-pregnant women (0.6 mg), preschool and school age children (0.4 mg), and adult men (0.3 mg).

Other micronutrient deficiencies

Vitamin B12 is necessary for the synthesis of RBCs and its deficiency has been associated with megaloblastic anemia. Diets with little or no animal protein, as is often the case in our country, coupled with malabsorption related to parasitic infections of the small intestine, might result in Vitamin B12 deficiency and anemia.

Helminthic infestation

Helminthic such as hookworm and flukes cause chronic blood loss and consequently iron loss from the body, resulting in the development of anemia.

Malaria

Malaria, especially by the protozoa *Plasmodium falciparum* and *vivax*, causes anemia by rupturing RBCs and suppressing production of RBCs. Decreased RBC production results from marrow hypoplasia seen in acute infection.

Infections

Certain chronic diseases, such as cancer, HIV/AIDS, rheumatoid arthritis, Crohn's disease and other chronic inflammatory diseases, can interfere with the production of RBCs, resulting in chronic anemia.

TABLE 5: Hemoglobin concentration to diagnose anemia

Age groups	No Anaemia	Mild	Moderate	Severe
Children 6–59 months of age	≥11	10–10.9	7–9.9	<7
Children 5–11 years of age	≥11.5	11–11.4	8–10.9	<8
Children 12–14 years of age	≥12	11–11.9	8–10.9	<8
Non-pregnant women (15 years of age and above)	≥12	11–11.9	8–10.9	<8
Pregnant women	≥11	10–10.9	7–9.9	<7
Men	≥13	11–12.9	8–10.9	<8

Source: Haemoglobin concentration for the diagnosis of anaemia and assessment of severity. WHO

Iron Deficiency Anemia in Pregnancy

According to world Health Organization estimates, up to 56% of all women living in developing countries are anemic. In India, National Family Health Survey -2 in 1998 to 99 shows that 54% of women in rural and 46% women in urban areas are anemic. According to WHO, hemoglobin level below 11gm/dl in pregnant women constitutes anemia and hemoglobin below 7gm/dl is severe anemia. The Centre for Disease Control and Prevention (1990) defines anemia as less than 11gm/dl in the first and third trimester and less than 10.5gm/dl in second trimester. Serum Ferritin of 15microgm/L is associated with iron deficiency anemia.

About 1000 mg of iron is required during pregnancy. 500-600mg for RBC expansion. 300 mg for fetus and placenta and the rest for the growing uterus. As a result of amenorrhea there is a saving of about 150 mg of iron and therefore, about 850 mg of extra iron is required during pregnancy. Diet alone cannot provide the extra iron and stores which have around 500 mg of iron get depleted. But if iron stores are already deficient, iron deficiency anemia manifests. Iron deficiency anemia (IDA) is the commonest type of anemia in pregnancy.

Table 6: Classification of anemia according to center for disease control

Category	Anemia severity	Haemoglobin level (g/dl)
1	Mild	10.0 - 10.9
2	Moderate	7.0 - 10.0
3	Severe	< 7.0
4	Very severe (decompensated)	< 4.0

Maternal consequences of anemia

Mild anemia

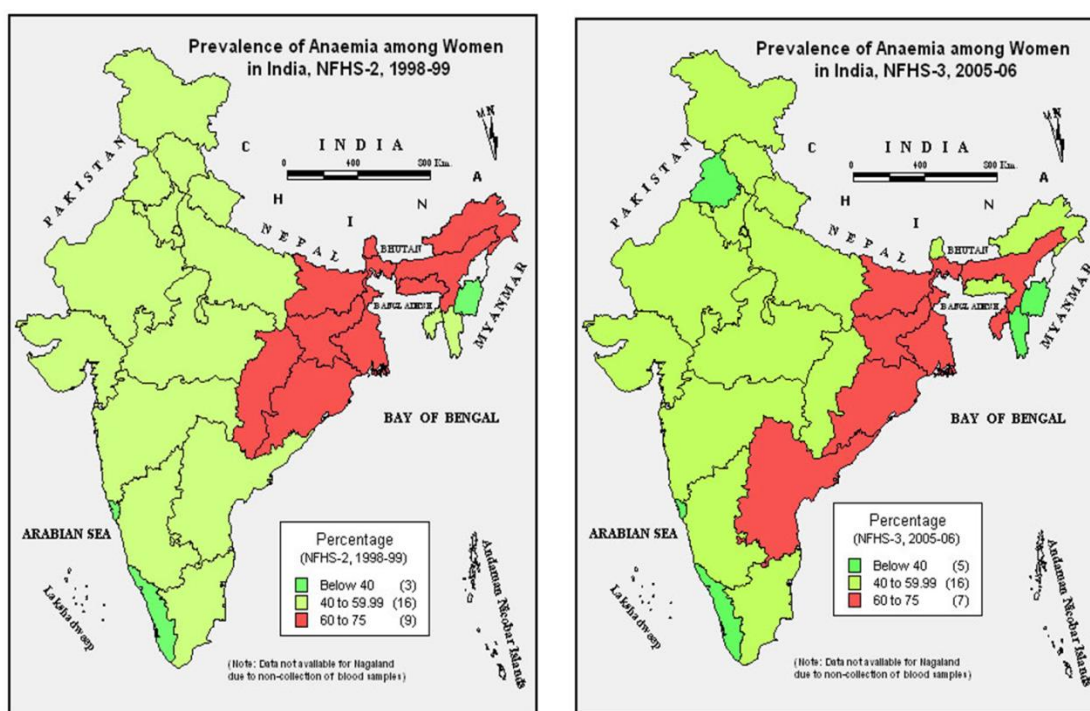
Women with mild anemia in pregnancy have decreased work capacity. They may be unable to earn their livelihood if the work involves manual labor. Women with chronic mild anemia may go through pregnancy and labor without any adverse consequences, because they are well compensated.

Women with moderate anemia have substantial reduction in work capacity and may find it difficult to cope with household chores and child care. Available data from India and elsewhere indicate that maternal morbidity rates are higher in women with Hb below 8gm/dl²¹. They are more susceptible to infections and recovery from infections may be prolonged. Premature births are more common in women with moderate anemia. They deliver infants with lower birth weight and perinatal mortality is higher in these babies. They may not be able to bear blood loss prior to or during labor and may succumb to infections more readily. Substantial proportion of maternal deaths due to antepartum and post-partum hemorrhage, pregnancy induced hypertension and sepsis occur in women with moderate anemia.

Severe anemia

Three distinct stages of severe anemia have been recognized - compensated, decompensated, and that associated with circulatory failure. Cardiac decompensation usually occurs when Hb falls below 5.0 g/dl. The cardiac output is raised even at rest, the stroke volume is larger and the heart rate is increased. Palpitation and breathlessness even at rest are symptoms of these changes. These compensatory mechanisms are inadequate to deal with the decrease in Hb levels. Oxygen lack results in anaerobic metabolism and lactic acid accumulation occurs. Eventually circulatory failure occurs further restricting work output. Untreated, it leads to pulmonary edema and death. When Hb is <5 g/dl and packed cell volume (PCV) below 14, cardiac failure is seen in a third of cases. A blood loss of even 200 ml in the third stage produces shock and death in these women. Even today women in the remote rural areas in India reach to the hospital only at this late decompensated stage. Available data from India indicate that maternal morbidity rates are higher in women with Hb below 8.0 g/dl. Maternal mortality rates show a steep increase when maternal Hb levels fall below 5.0 g/dl. Anemia directly causes 20 percent of maternal deaths in India and indirectly accounts for another 20 per cent of maternal deaths.

FIGURE 3 -NFHS data: Prevalence of Anemia among women in India



Prevention of iron deficiency

As most women start their pregnancy with anemia or low iron stores, so prevention should start even before pregnancy. As a public health approach, prolonged oral supplementation beginning before the woman becomes pregnant may be a better strategy to benefit the majority of the population. Twelve by twelve initiative is one such initiative aiming to have Hb of 12 g/ dl by 12 year of age using prophylactic iron therapy and advising consumption of iron rich food. Iron supplementation by 30 doses administered weekly over 7 months was as effective as 90 doses consumed daily for 3 months. Hence, women of child-bearing age in developing countries should receive a 2-4 months course of 60 mg of iron daily. In addition, concomitant use of folate will prevent neural tube defects in the new-born.

The Ministry of Health, Government of India has now recommended intake of 100 mg of elemental iron with 500 mg of folic acid in the second half of pregnancy for a period of at least 100 days. Women who receive daily antenatal iron supplementation are less likely to have iron deficiency anemia at term²⁶. Even two injection of iron dextran (250 mg each) given intramuscularly at 4 week intervals along with tetanus toxoid injection have been recommended for better compliance and adequate results.

As worm infestation is very common and given the safety of the deworming drugs, oral antihelminthic treatment can also be given to pregnant and lactating women. Single albendazole (400 mg) or mebendazole (100 mg) doses twice daily for 3 days with iron supplementation should be given to all anemic pregnant; women in the second and third trimesters for better results.

Table 7: Guidelines for Iron supplementation to pregnant women (W.H.O.)

Prevalence of anemia in pregnancy	Dose	Duration
<40%	60 mg iron + 400 µg folic acid daily	6 months in pregnancy
≥40%	60 mg iron + 400 µg folic acid daily	6 months in pregnancy, and continuing to 3 months postpartum

Notes:

- If 6 months duration cannot be achieved in pregnancy, continue to supplement during the postpartum period for 6 months or increase the dose to 120 mg iron in pregnancy.
- Where iron supplements containing 400 µg of folic acid are not available, an iron supplement with less folic acid may be used. Supplementation with less folic acid should be used only if supplements containing 400 µg are not available.

TREATMENT GUIDELINES

ORAL IRON THERAPY

The dosage of elemental iron required to treat iron deficiency anemia in adults is 120 mg per day for three months; the dosage for children is 3 mg per kg per day, up to 60 mg per day. An increase in hemoglobin of 1 g per dL after one month of treatment shows an adequate response to treatment and confirms the diagnosis. In adults, therapy should be continued for three months after the anemia is corrected to allow iron stores to become replenished. Adherence to oral iron therapy can be a barrier to treatment because of GI adverse effects such as epigastric discomfort, nausea, diarrhoea, and constipation. These effects may be reduced when iron is taken with meals, but absorption may decrease by 40 percent. Medications such as proton pump inhibitors and factors that induce gastric acid hypo secretion (e.g., chronic atrophic gastritis, recent gastrectomy or vagotomy) are associated with reduced absorption of dietary iron and iron tablets.

PARENTERAL IRON THERAPY

Parenteral therapy may be used in patients who cannot tolerate or absorb oral preparations, such as those who have undergone gastrectomy, gastrojejunostomy, bariatric surgery, or other small bowel surgeries. The most common indications for intravenous therapy include GI effects, worsening symptoms of inflammatory bowel disease, unresolved bleeding, renal failure induced anemia treated with erythropoietin, and insufficient absorption in patients with celiac disease.

Policies and Strategies in India for Iron Deficiency Anemia

A National Nutrition Policy was adopted in 1993, with the objective of operationalizing multi sectorial strategies to address the problem of under-nutrition/malnutrition. Based on this, the National Plan of Action on Nutrition 1995 laid out the sectorial Plan of Action for 14 Ministries and Departments of the Government of India. A National Nutrition Mission has been set up to address nutrition issues through a mission mode approach under the oversight of the Ministry of Women & Child Development (MWCD). One of the goals for the 12th Five Year Plan is to reduce anemia in girls and women by 50 per cent.

Table 8: Supplementation Interventions by Ministry of Health and Family Welfare (MoHFW)

	Children		Adolescents 10–19 years (recently introduced)	Pregnant and lactating women
	0–5 years	6–10 years		
IFA supplementation.	20 mg elemental iron and 100 microgram (mcg) folic acid per ml of liquid formulation and age appropriate de-worming for 100 days	30 mg elemental iron and 250 mcg folic acid per child per day for 100 days in a year	Weekly dose of 100 mg elemental iron and 500 mcg folic acid with biannual de-worming	100 mg of elemental iron and 500 mcg of folic acid daily for 100 days during pregnancy. Followed by same dose for 100 days in the post-partum period
Long Lasting Insecticide Nets (LLINs)/Insecticide Treated Bed Nets (ITBNs) are also provided to pregnant women.				

National Iron+ Initiative

Taking cognizance of ground realities discussed above the Ministry of Health and Family Welfare took a policy decision to develop the National Iron+ Initiative. This initiative will bring together existing programs (IFA supplementation for: pregnant and lactating women and; children in the age group of 6–60 months) and introduce new age groups.



Thus National Iron+ Initiative will reach the following age groups for supplementation or preventive programming:

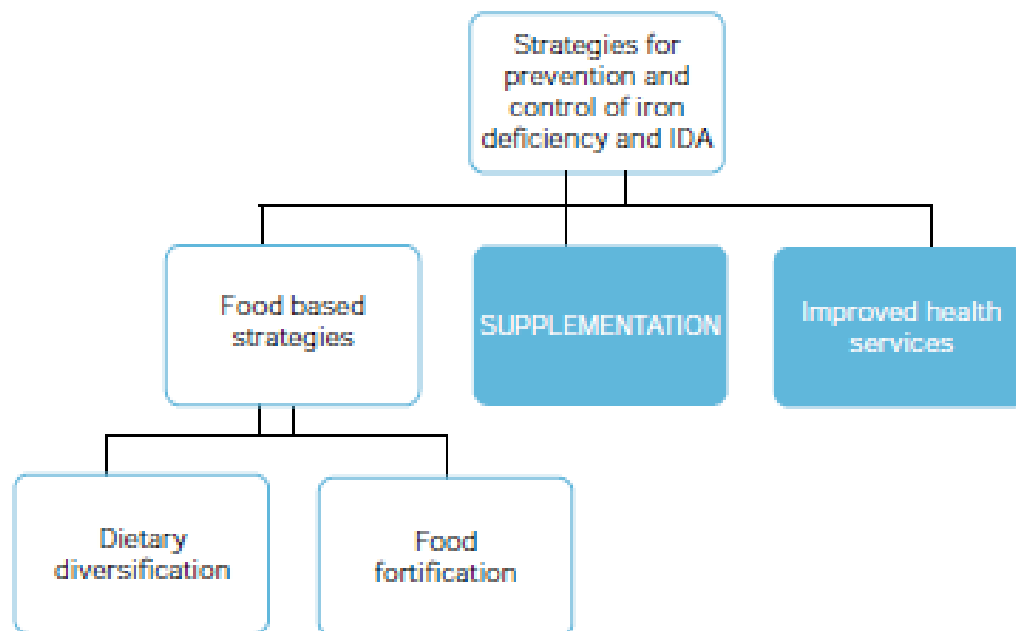
- Bi-weekly iron supplementation for preschool children 6 months to 5 years
- Weekly supplementation for children from 1st to 5th grade in Govt. & Govt. Aided schools
- Weekly supplementation for out of school children (5–10 years) at Anganwadi Centers

- Weekly supplementation for adolescents (10–19 years)
- Pregnant and lactating women
- Weekly supplementation for women in reproductive age

Establishing a continuum of care, the National Iron+ Initiative also defines a minimums service of packages for treatment and management of anemia across levels of care

Platforms and services at each level have also been mapped out and service providers' roles and responsibilities detailed.

Figure 4: Intervention to prevent and correct Iron Deficiency Anemia



Source: *Iron deficiency anaemia: assessment, prevention and control. A guide for Programme Managers*; WHO 2001- WHO/NHD/01.3

TYPES OF IRON COMPOUND

TABLE 9: GRAS Substance, SCOGS (Select Committee on GRAS Substances), US-FDA

Iron Compounds	Elemental Iron %(w/w)	Comments
Carbonyl Iron	100	• Provides the highest amount of elemental iron. • Dissolves in gastric secretion and is converted to hydrochloride salt prior to absorption in the stomach. • Absorption rate is slow, which permits continued release of iron for 1 to 2 days. • Less toxic than iron salts. • Requires much higher dosage to cause toxicity compared to ferrous sulfate.
Ferric ammonium citrate	18	• Most commonly used ferric salt. • Requires reduction to ferrous form in the intestinal lumen. • Less bioavailable than ferrous salts. • Less poisoning potential since the GI tract has limited capacity to reduce it to ferrous form.
Ferric pyrophosphate	10.5-12.5	It is a water-insoluble Fe compound used to fortify infant cereals and chocolate-drink powders as it causes no organoleptic changes to the food vehicle. It is only of low absorption in man
Ferrous ascorbate	14	Synthetic molecule of ascorbic acid and iron. Ascorbic acid enhances absorption of iron. Ascorbic acid reduces ferric iron to ferrous iron, which remains soluble even at neutral pH.
Ferrous carbonate(anhydrous)	48	

Ferrous citrate			
		• Similar efficacy and tolerability as ferrous sulfate. • Moderately soluble in water. • Almost tasteless.	
Ferrous fumarate	33		
Ferrous gluconate	12	Similar efficacy and tolerability as ferrous sulfate.	
Ferrous sulfate(dried)	20	Formulation of choice for treatment of iron-deficiency anemia given its general tolerability, effectiveness, and low cost.	
Ferrous tartrate			
Ferrous succinate	35		
		An iron-amino acid chelate. • Relatively high bioavailability. • Theoretically, the conjugation of ferrous iron with amino acid prevents the iron from forming insoluble ferric hydroxide in the small intestine. • May be less likely to cause GI intolerance than ferrous sulfate, ferrous gluconate, or ferrous fumarate.	
Ferrous bis glycinate	20		
Sodium ferric EDTA	14		
Iron peptonate	17		

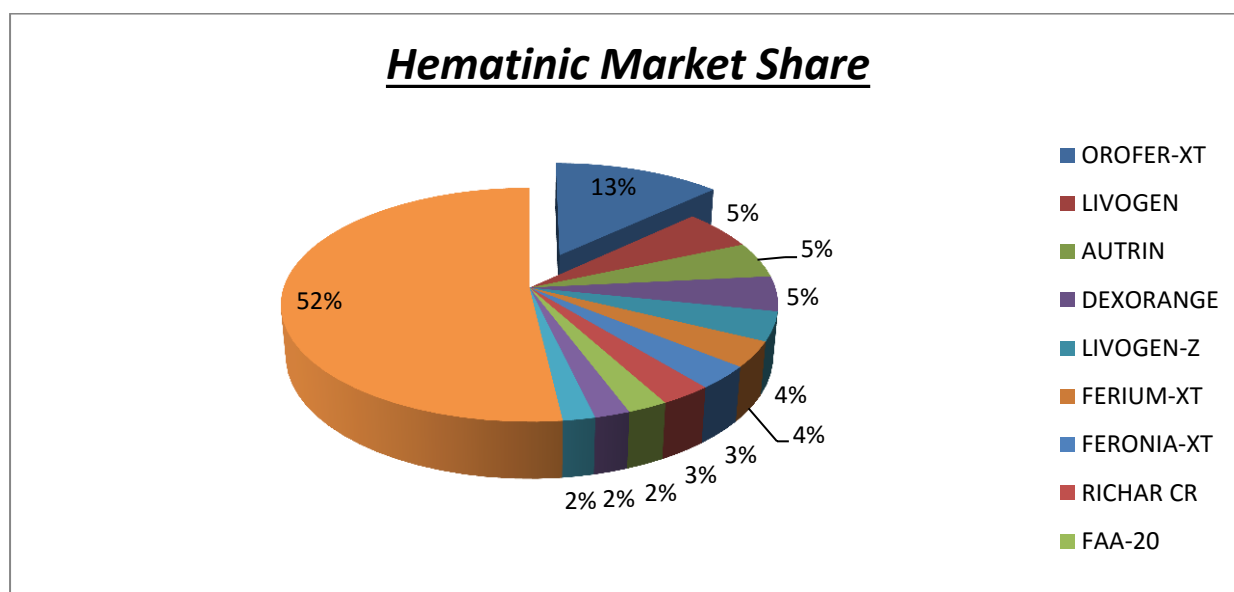
Hematinic Market

Table 10: Hematinic Market Size

Hematinic	MAT APR -2014	MAT APR -2015	MAT APR -2016	Growth % Over 15-16
CONV.IRON SOLIDS	653	709	796	12
IPC ORAL SOL.	9	10	9	-3
CARBONYL IRON SOL.	43	39	48	22
Grand Total	705	758	853	13

The above table represents the moving annual total for the haematinic's excluding parental haematinic's. The total market of haematinic's is 796 crs, which is growing at the rate of 12 % per annum.

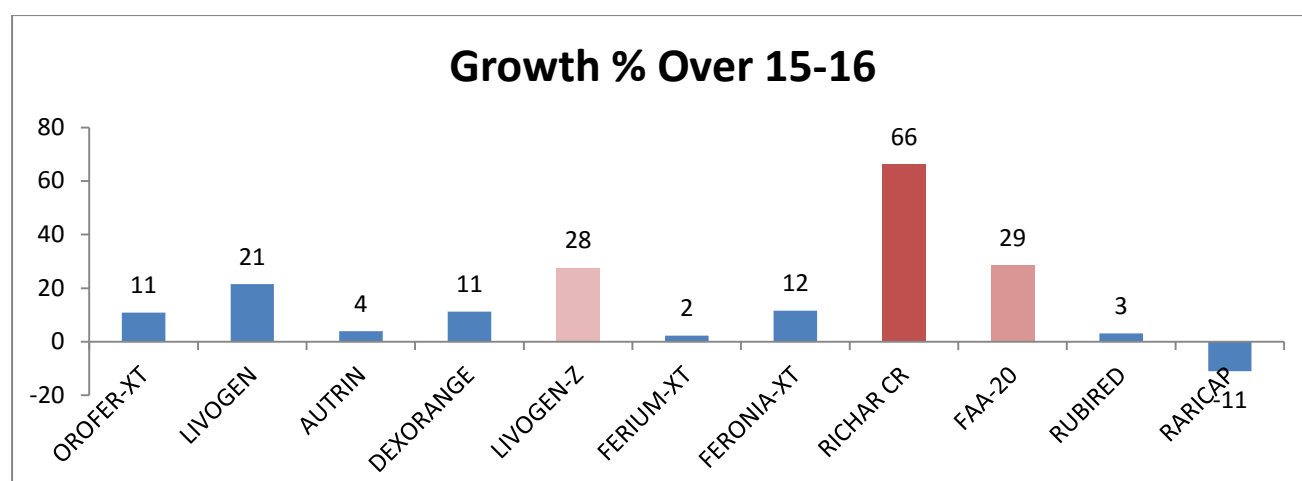
Figure 5: Hematinic Market Share



The pie chart represents the market share of the various brands of haematinics available in the country; the top 10 brands are mentioned.

Orofer-xt, a brand of Emcure is leading the market with a 13% market share which is 111 crs followed by livogen and autrin with 5% share of 47 crs each.

Figure 6: Growth Percentage 2015-2016



The percentage growth of the top brands of hematinic market is shown in the graph above, richer –cr is showing an overall growth of 66% over the year 15-16.

FAA-20 and livogen-z have the second and the third highest growth percentage of 29 and 28 percent respectively.

Table 11: Cost of the top brands and formulations

	Pack	Price	Formulation
Orofer XT	10'S	Rs 102.40	Ferrous ascorbate
Dexo-O	30's	Rs 80.40	Ferrous ascorbate
Ferium XT	10'S	Rs 93	Ferrous ascorbate
C PINK	15's	Rs 225	Ferrous ascorbate
Autrin	30's	Rs 84.60	Ferrous Fumarate
Livogen/ Z (Zinc)	50'S	Rs 102.40	Ferrous Fumarate

Ferrous ascorbate is used by most of the top brands as active ingredient in hematinic formulation, the cost of the formulations can also be seen the table with dexorange providing with the lowest market price among the top brands with ferrous ascorbate formulation and livogen in the ferrous fumarate.

Rationale

IDA is a condition in which the number of red blood cells or their oxygen-carrying capacity is insufficient to meet physiologic needs. During pregnancy these needs are way further more high, if these needs are not meet consequences such as low birth weight, premature delivery and intrauterine growth retardation may occur

- ❖ The study provides insights on
 - Decision making process For the treatment of IDA
 - The line of treatment of IDA by gynaecologists
 - Trusted molecules
 - Selection of formulation
 - Challenges faced by the gynaecologists in the treatment
 - Need for change in therapy
 - Top hematinic brands
 - Reasons for brand preference

Objectives

- ✓ To explore the decision making process in the treatment of Iron Deficiency Anemia by gynaecologist
 - To identify the need gaps in the treatment of IDA
 - To identify the most suitable iron molecule/salt in clinical practice
 - To identify the choice of brand of gynaecologists

Methodology

Sample Design:

Descriptive study

Sampling:

Cluster Sampling

Sample population:

Gynecologist and Obestritions

Sample Size:

Respondents: 75

Sample area:

Mumbai (Borivali, Kandivali,Dahisar,Andheri,Vile Parle)

Tool:

Questionnaire to collect primary data

Microsoft Excel to carry out analysis

Data Collection:

Primary- Through questionnaire and meeting with respondents

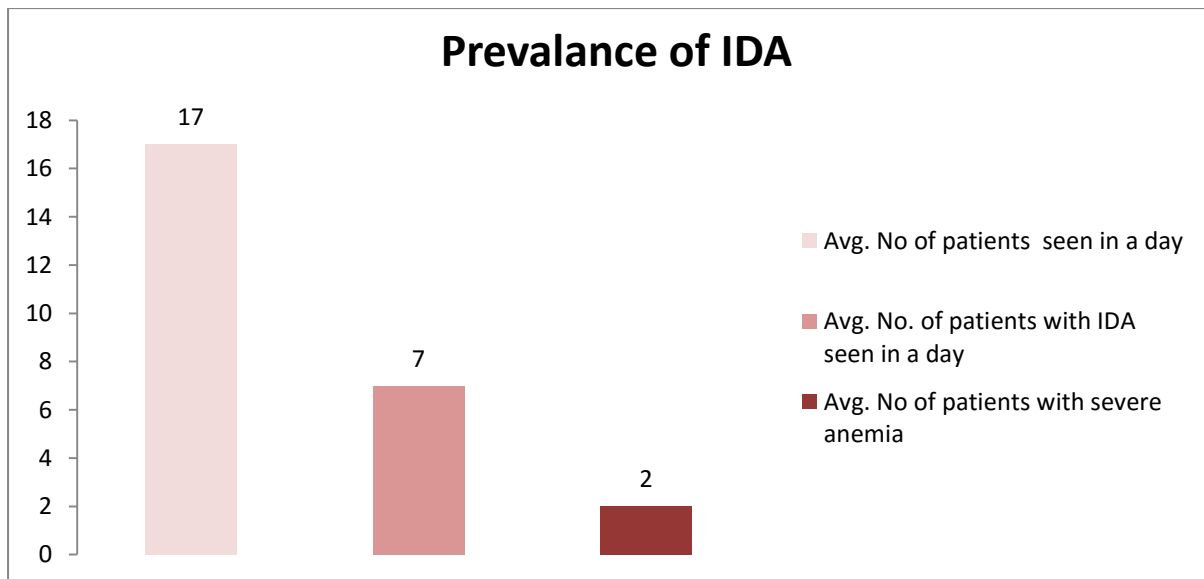
Secondary- To understand study topic and objectives information from various sources like articles, journals, reference books, previous relevant studies was collected. IMS and SMRC Data from Sun Pharma.

Study duration:

Two (2) months

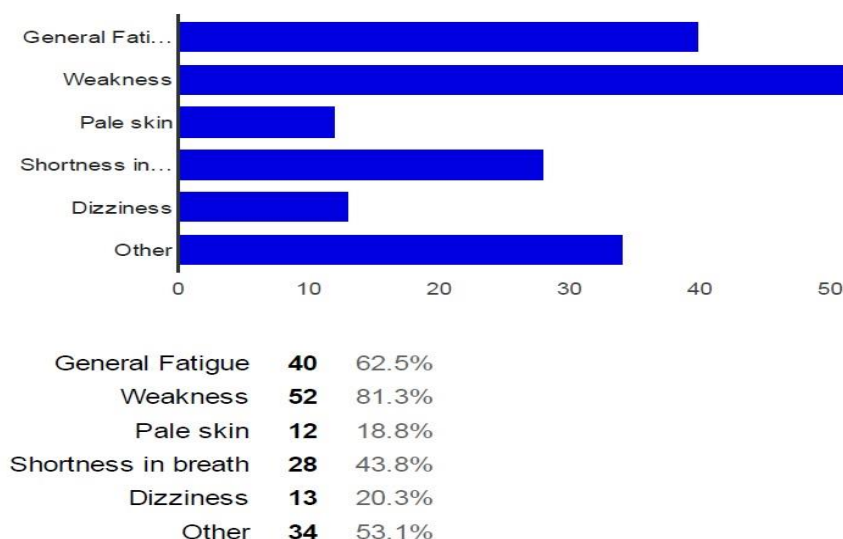
Findings and Interpretation

Figure 7: Avg. No of Patients per Day



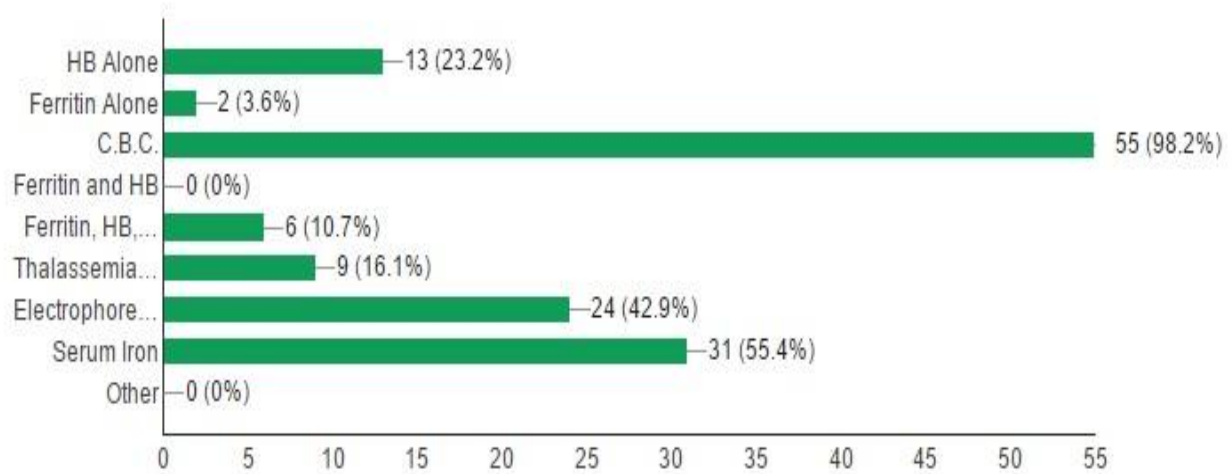
The above bars represent the average no of patients seen by a gynaecologist in a day and the average no of patients with IDA , the data suggests that the prevalence of IDA in pregnant women is about 41.17% , the graph also represents the number of pregnant women with severe IDA ,the value is represented as a per month value.

Figure 8: Common Symptoms Associated with IDA



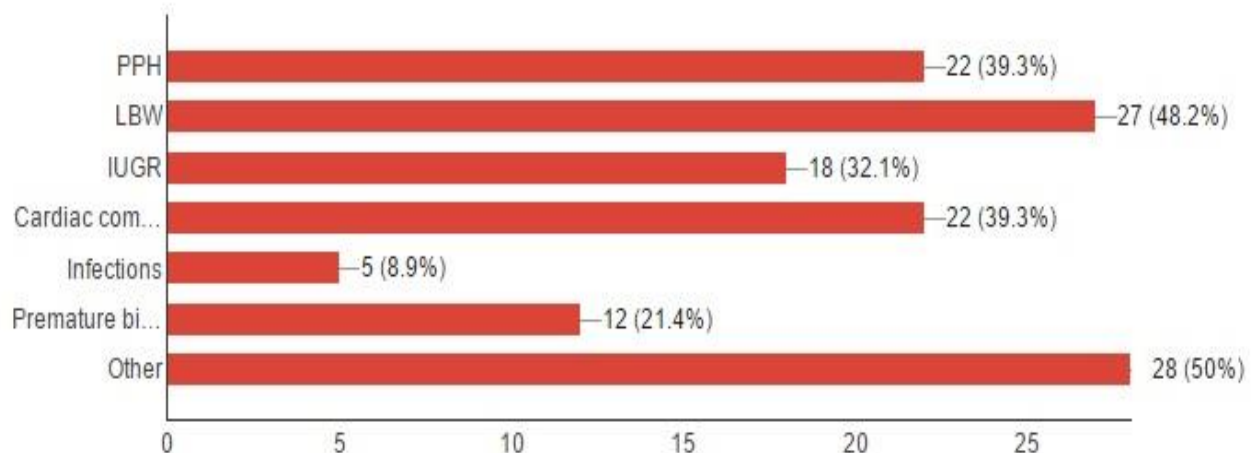
The Above graph shows the common symptoms that the gynaecologist look for in the diagnosis of IDA , weakness and general fatigue being the most common symptoms . The other symptoms associated with IDA are heavy menstrual bleeding and palpitation (a noticeably rapid, strong, or irregular heartbeat due to agitation, exertion, or illness).

Figure 9: Diagnostic Tests performed



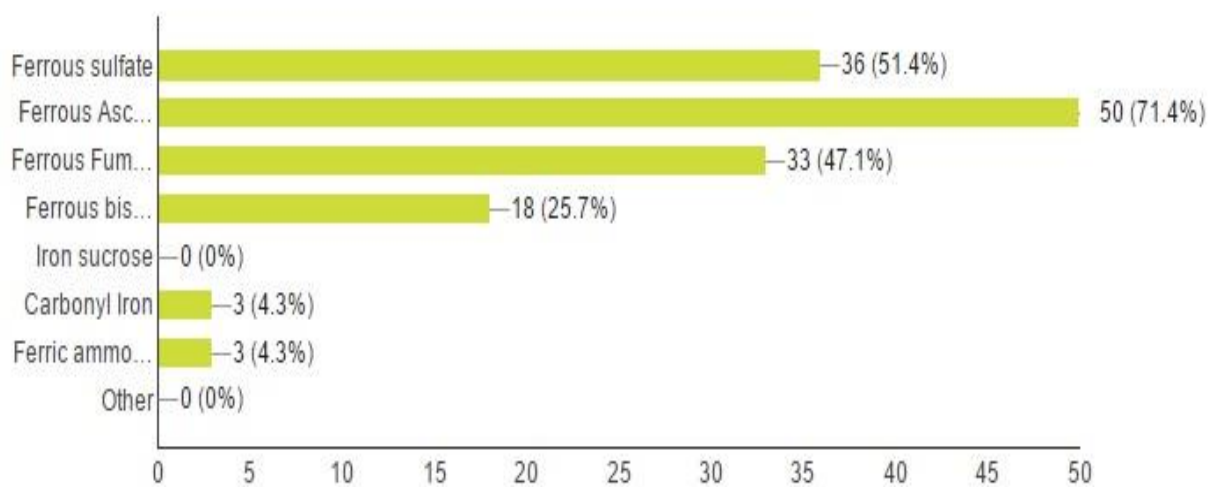
The most common test used to confirm IDA is C.B.C. (Complete Blood Count), other tests like thalassemia tests are carried out to rule out thalassemia. Serum ferritin tests are not done on a general basis. Depending upon severity and requirement the serum iron studies are carried out. These studies give a clearer picture of serum iron concentration, ferritin (iron reserves), transferrin (required for iron transport).

Figure 10: Consequences of depleting Iron Levels



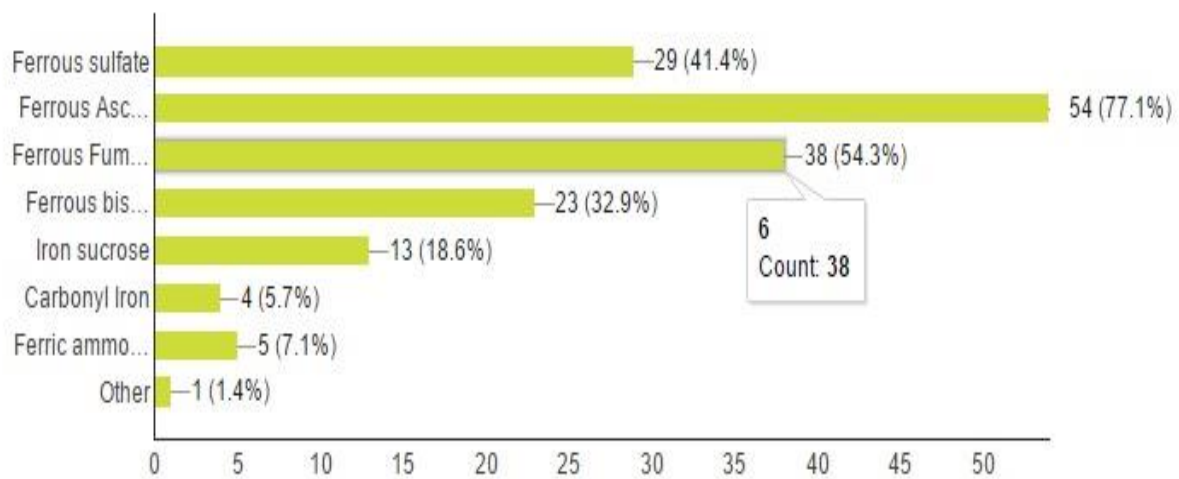
As the iron levels deplete the consequences that are generally observed are L.B.W. (low birth weight) babies, the iron reserves are required to be significantly high to meet the needs of the mother and the baby, low levels of iron result in I.U.G.R. (intrauterine growth retardation). Premature birth can be one of the consequences of depleting iron levels. Mother and child both are susceptible to infections. In severe cases cardiac complications may lead to cardiac arrest. Other complications like kidney problems may also present and there is further weakness leading to inability to work.

Figure 11: Line of treatment for mild IDA in pregnant women



Mild anemia according to WHO is 10-10.9 gm/dl in pregnant women, the most trusted molecules for the treatment according to the graph is Ferrous Ascorbate , Ferrous Sulphate and Ferrous Fumarate.

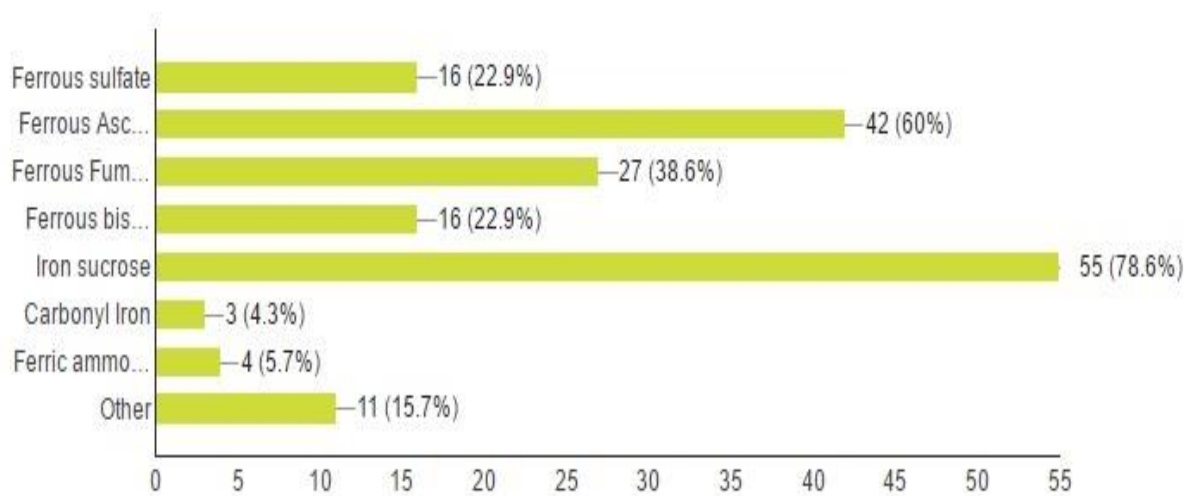
Figure 12: Line of treatment for moderate anemia in pregnant women



Moderate anemia according to WHO is 7-9.9 gm/dl in pregnant women. The molecules used in the treatment of moderate anemia according to this graph are Ferrous Ascorbate, Ferrous Fumarate and Ferrous Sulphate.

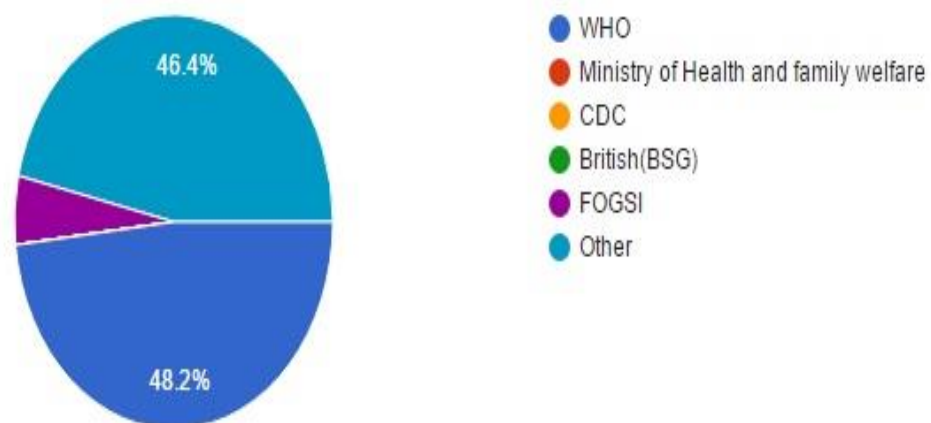
The two graphs can be compared to see that there is a shift from ferrous sulphate to ferrous fumarate for the treatment of moderate anemia in pregnant women.

Figure 13: Line of treatment for severe anemia in pregnant women



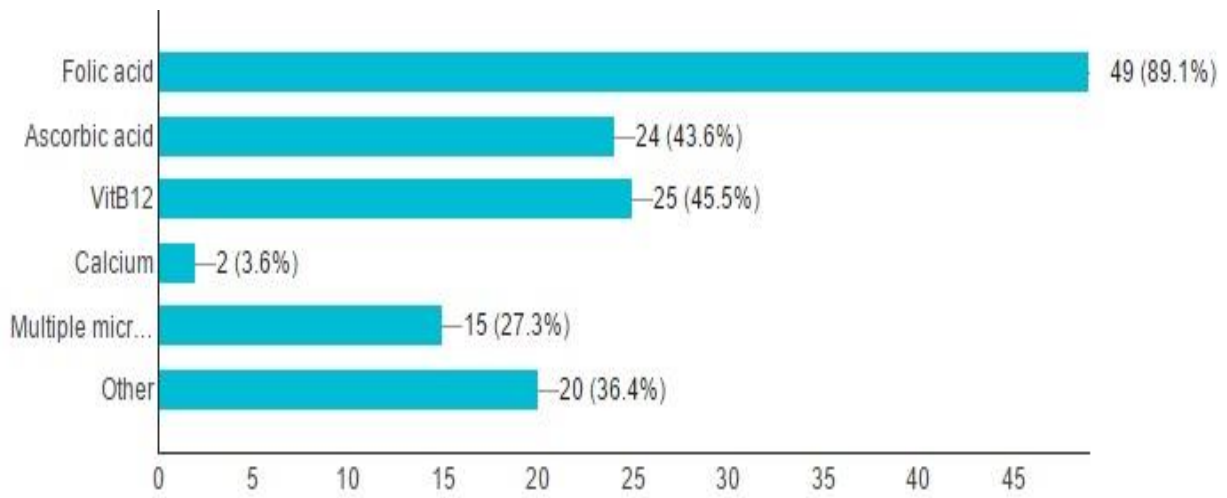
Severe anemia in pregnant women according to WHO is less than 7gm/dl of Haemoglobin in pregnant women. The preferred line of treatment is I.V.(intravenous) iron sucrose injections along with ferrous ascorbate. For further increase in severity other options include blood transfusion.

Figure 14: Guidelines followed by gynaecologists in treatment of IDA



Various guidelines are established for the diagnosis and treatment of IDA, according to this research 48.2% gynaecologists follow the WHO guidelines, 46.4% gynaecologist follow the medical textbook in the treatment of IDA while 5.4% follow FOGSI (Federation of Obstetric and Gynaecological Societies of India) guidelines.

Figure 15: Formulation used along with Iron in the treatment of mild anemia in pregnant women



The above formulation are generally used in the treatment of mild anemia in pregnant women, folic acid, vitamin B12 and ascorbic acid are the most commonly used. Other formulation generally used is zinc, protein and other trace elements.

Figure 16: Formulation used along with Iron in the treatment of moderate anemia in pregnant women

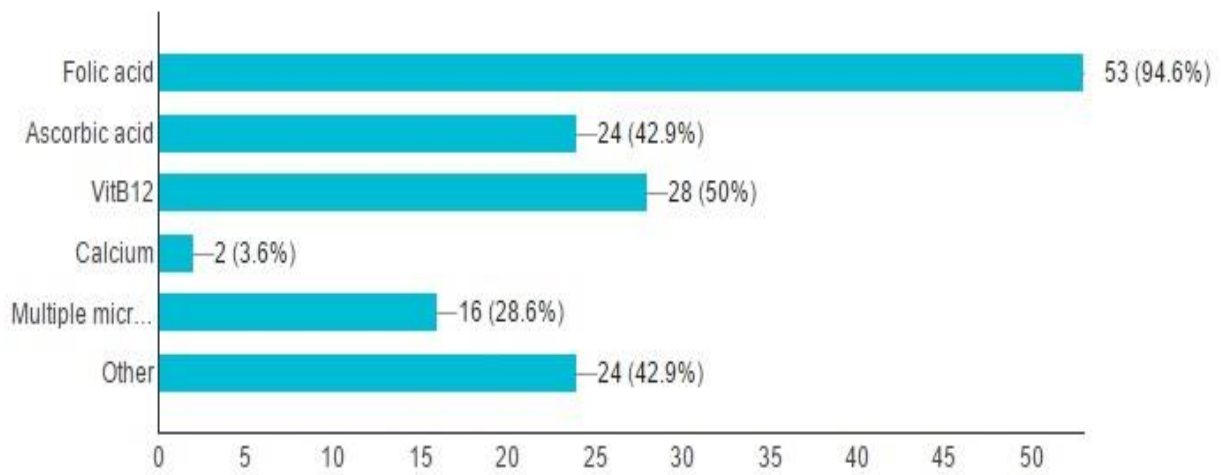
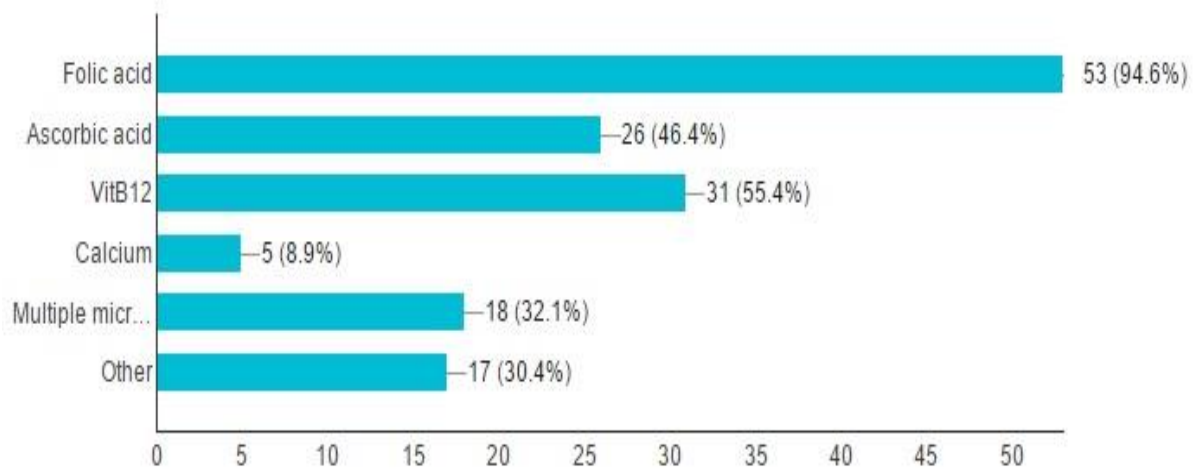


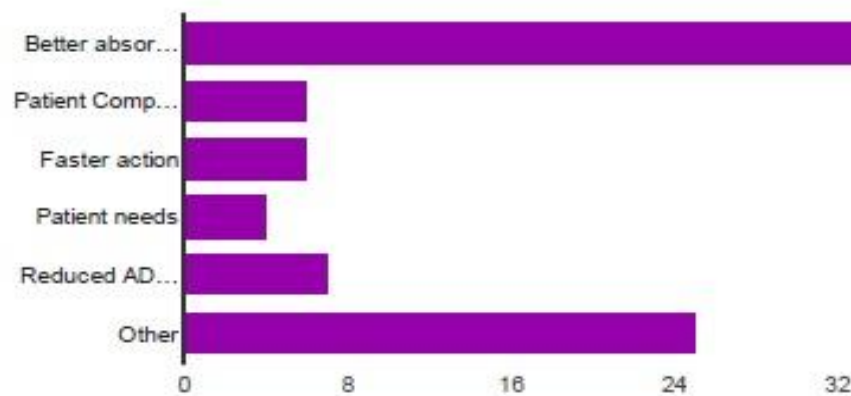
Figure 17: Formulations used along with Iron in the treatment of severe anemia in pregnant women



The graph shows very less difference in selection of combination for moderate and severe anemia in pregnant women with respect to mild, with a slight increase in number of folic acid combinations.

Hence the selection of combination is independent of severity of anemia.

Figure 18: Selection of combinations

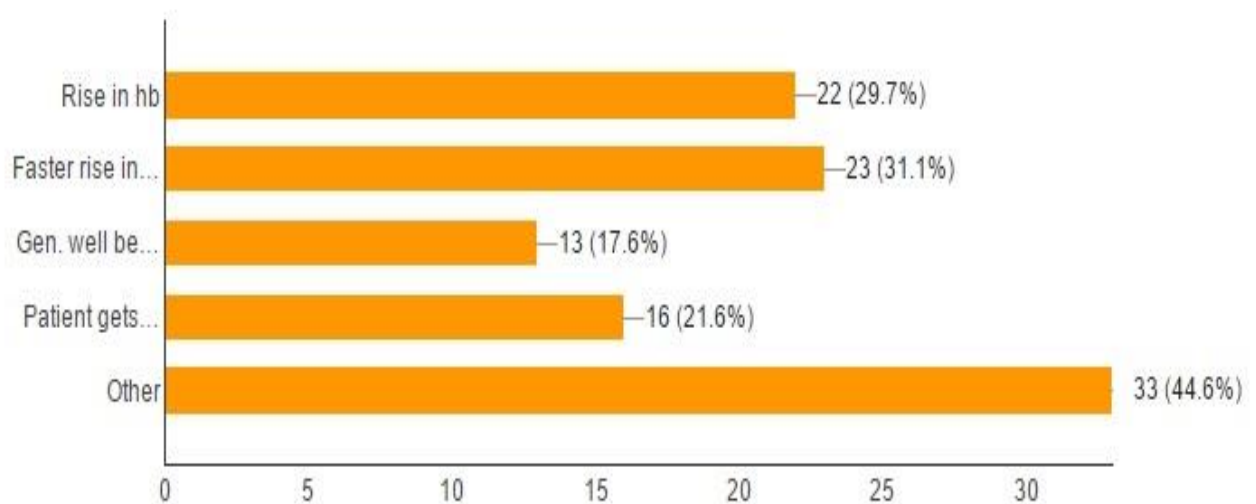


Better absorption	34	66.7%
Patient Compliance	6	11.8%
Faster action	6	11.8%
Patient needs	4	7.8%
Reduced ADR's	7	13.7%

The above graph brings about the insight on the selection of combinations; the most common reason is better absorption, other factors like decreased adverse drug reaction and faster action are also contributing factors for selection of combination.

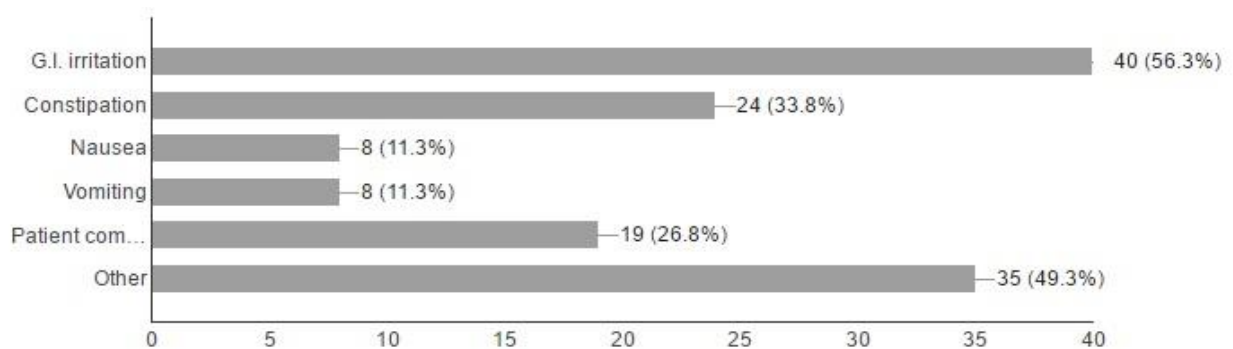
Other factors include general well being of patient and better results due to increase in absorption.

Figure 19: Advantages of iron therapy



Various advantages were mentioned by the doctors out of these the rise in haemoglobin is the primary advantage along with general well being of the patient. Other reasons include ease of administration, non invasive, better patient compliance.

Figure 20: Disadvantages of iron therapy



Iron therapy has certain disadvantages associated with it , the most common disadvantage of iron therapy is that it causes gastric irritation and results in constipation, diarrhoea, nausea, vomiting.

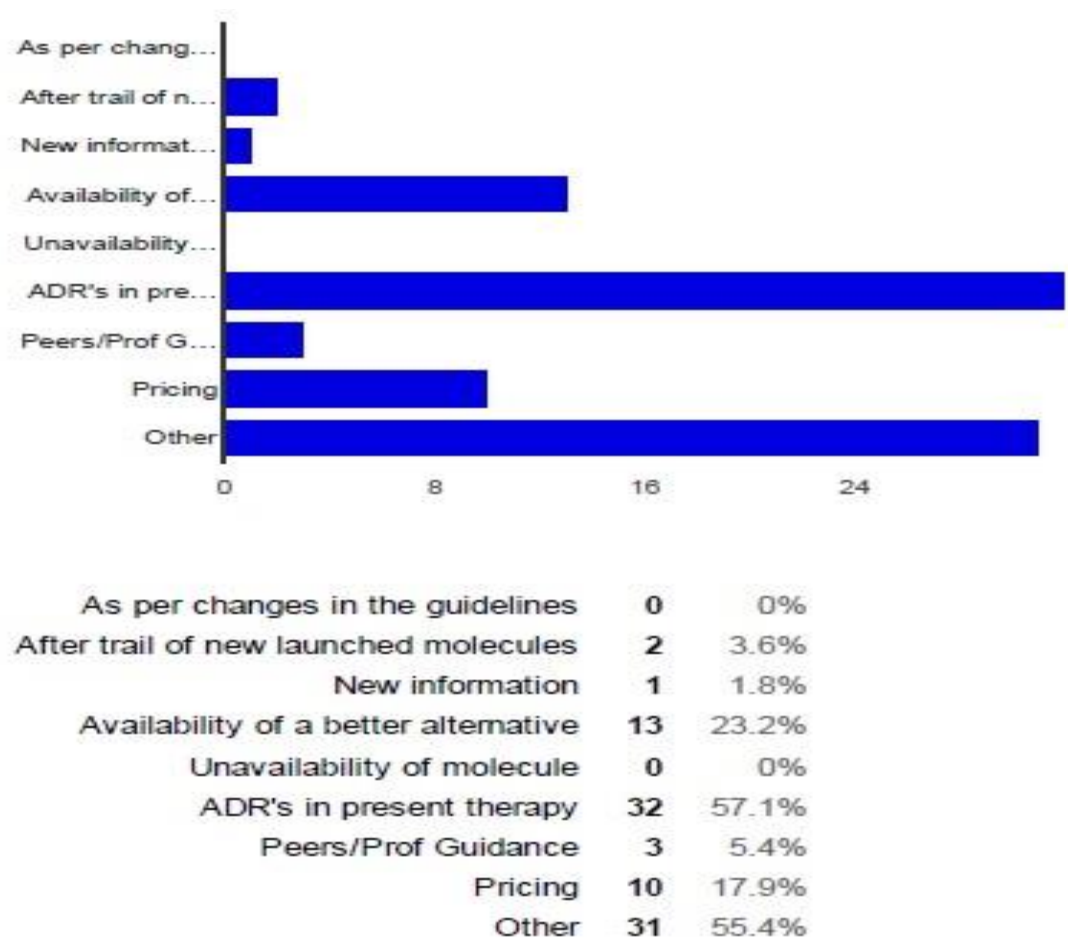
Iron therapy also has a low compliance with patients, according to the gynaecologists the patients would drop out of the treatment.

Other disadvantages associated with the therapy are side effects like blacking of stool, discoloration of teeth, cost and length of treatment were also considered as the factors.

Table 12: Average length of treatment

	Mild IDA	Moderate IDA	Severe IDA
Term of treatment (months)	5	6	Till recovery

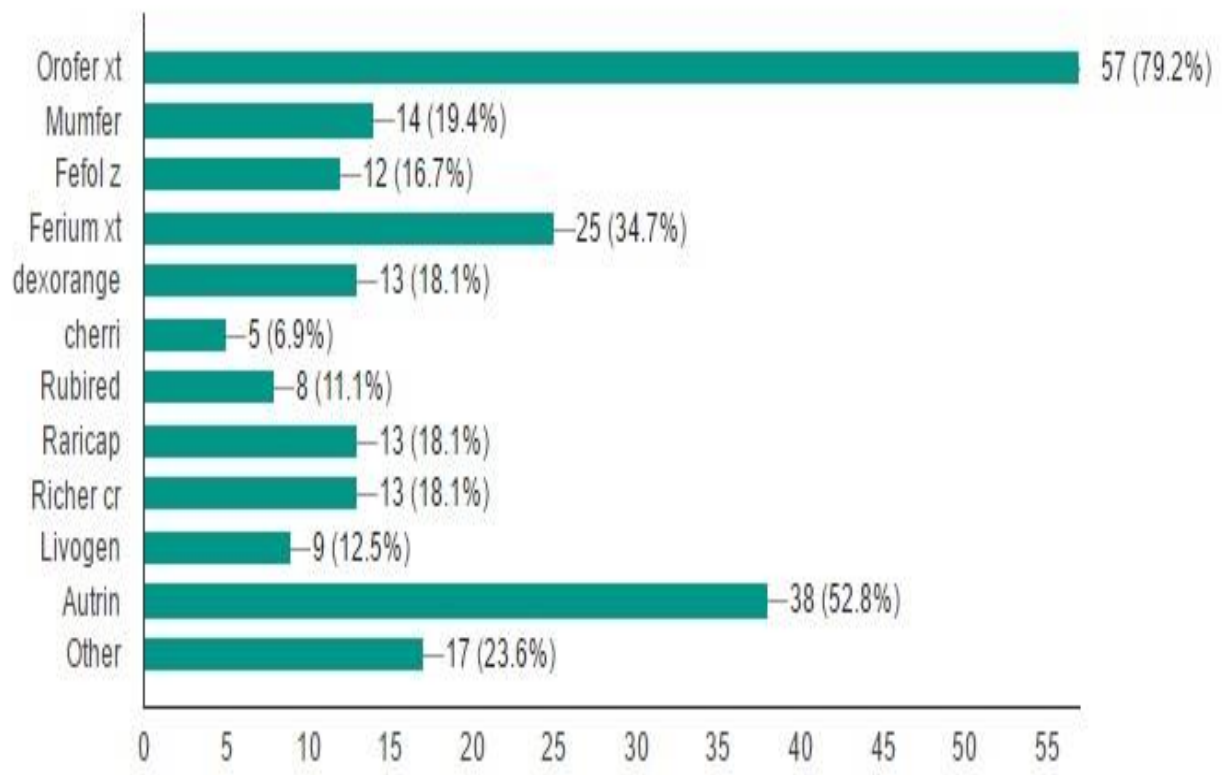
Figure 21: Need for changing the therapy



The change in the line of treatment of IDA by gynaecologists is brought about by the various adverse drug reactions in the present therapy and when there is no rise in haemoglobin after the treatment within one month.

23.2% of doctors considered the availability of a better alternative in terms of absorption and rise in haemoglobin as a factor for the change in therapy.

Figure22: Top brands of Iron supplements

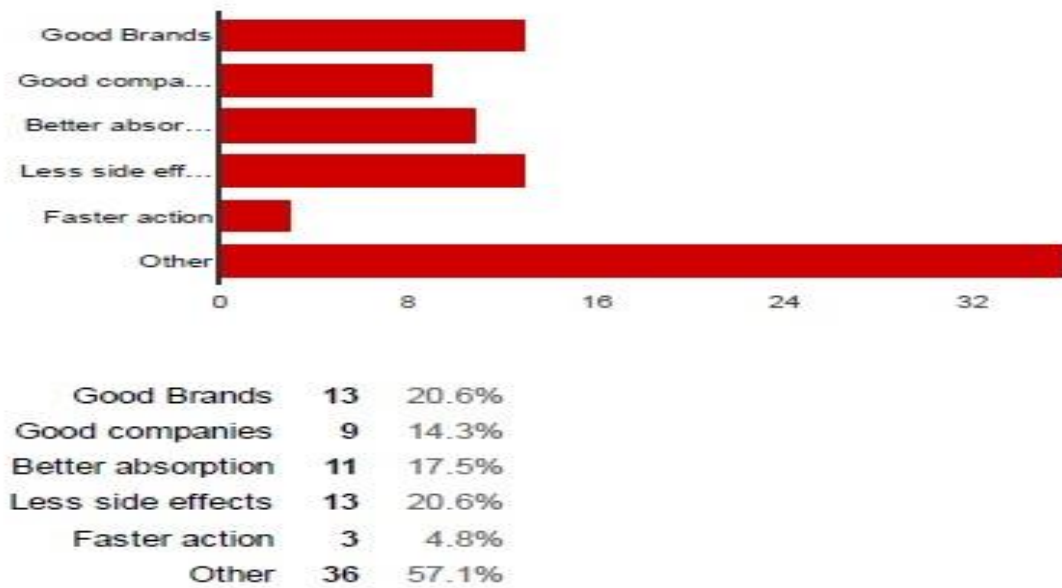


The Hematinic market is flooded with various brands, iron and iron combinations are available in various varieties of dosage forms.

In the oral iron therapy Orofer-xt (brand of Emcure) is the most commonly prescribed iron supplement followed by Autrin (brand of Wyeth) and Ferium-xt (Emcure)

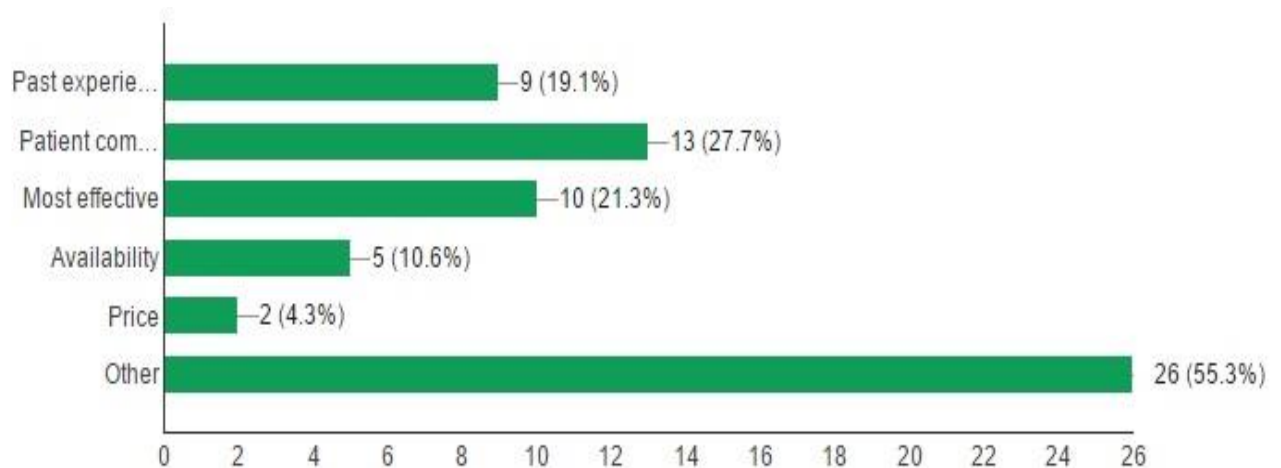
The other brands include faa20, c-pink, c-pink total.

Figure 23: Reasons for brand selection



The brand selection process by gynaecologist is based on better absorption and fewer side effects for the top brands and certain brands already have an image of being good brands of good companies.

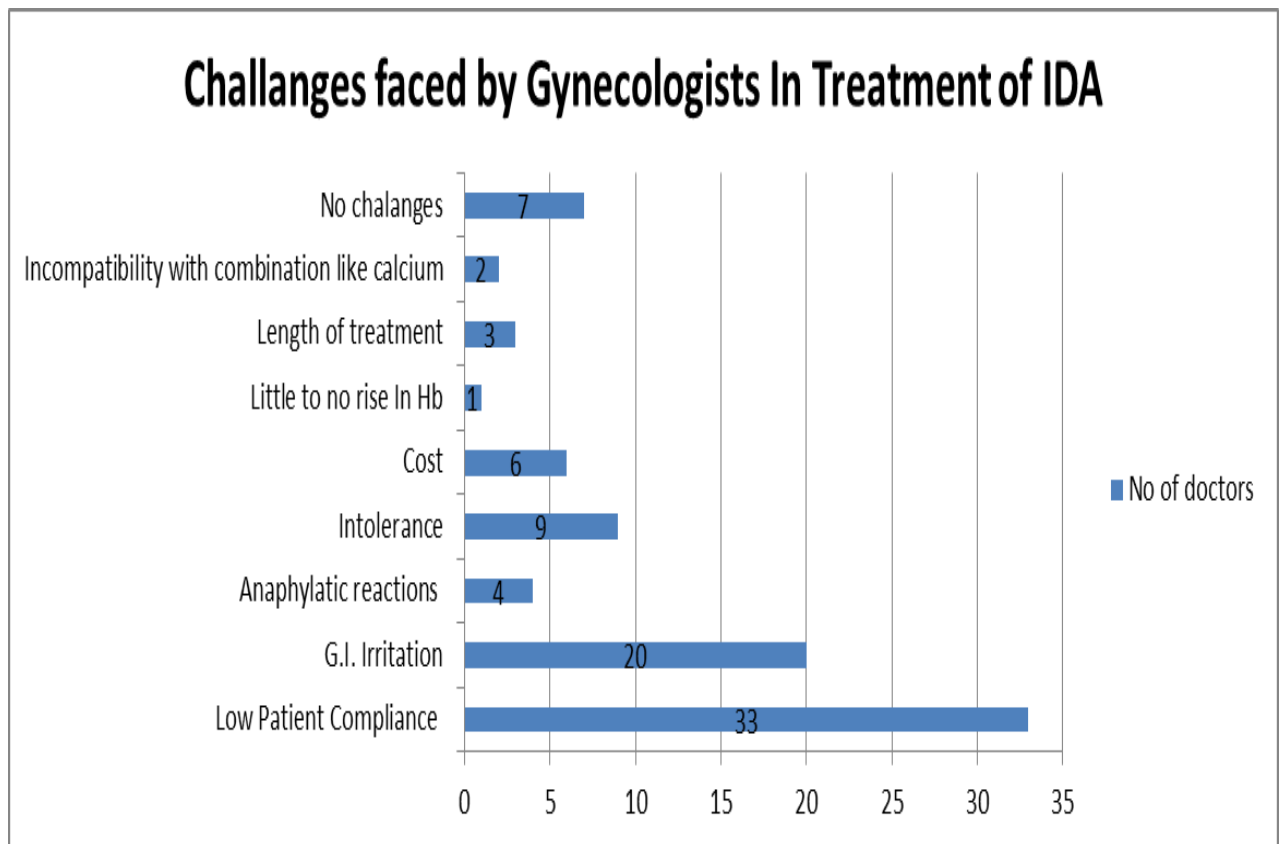
Figure 24: Unique advantages by brands



Over the years certain brands have created their brand image in various ways. The clinical data, case control studies shown by pharma companies. According to 27.7 % of gynaecologists these brands have better patient compliance while 21.3% believe that these brands have been the most effective in treatment of IDA in pregnant women.

The other unique advantages that the brands have created over the years include the content and quality of iron present in the formulation.

Figure 25: Challenges faced by gynaecologists in the treatment of IDA



Gynaecologists face the above challenges in the treatment of IDA in pregnant women.

The Iron therapy tends to have a very low patient compliance which is due to the fact that the treatment is of long term, from the earlier table 7 it is clear that the length of treatment for mild and moderate anemia is 5 and 6 months respectively.

Patients stops taking medicine and thus lead to low patient compliance.

The second biggest challenge in the therapy is gastric irritation caused by the iron which leads to various gastric disturbances and further causes' patients to leave the medicine and leading to low compliance and hence ineffective therapy.

Conclusion

- To market a hematinic brand, it is crucial to understand the decision making process of the gynecologists for the treatment of IDA.
- The prevalence of IDA was found to be 41.17%.
- A hematinic formulation with a Ferrous Ascorbate molecule is more preferred due to better absorption, followed by Ferrous fumarate, ferrous sulphate...
- The line of treatment for severe IDA in pregnant women is Iron sucrose injection.
- Iron formulations with - folic acid , ascorbic acid and zinc are preferred due to enhancement in absorption & added advantages of folic acid and zinc
- The main challenges faced by gynecologist is “NON- COMPLIANCE”
- The other main challenge is “INTOLERANCE OF IRON CAUSING GI IRRITATION”
- Shape and size of the solid dosage formulation should also be small.
- The length of the treatment is long.

Recommendations

Implications

The study gives quite a clear picture about the decision making process for the selection of haematinic's in the treatment of IDA. It provides complete information about

- The line of treatment of IDA by gynaecologists
- Trusted molecules
- Formulation Preferred
- Challenges faced by the gynaecologists in the treatment
- Need for change in therapy
- Top hematinic brands
- Reasons for brand preference

Way ahead

- A hematinic formulation which has “Ferrous Ascorbate” molecule should be considered as the active ingredient.
- Folic acid , ascorbic acid B12 and zinc should be part of iron formulation
- NDDS like liposomal iron can be considered to increase absorption and decrease the GI irritation which will help to increase the compliance
- A control release formulation could enhance the compliance ~ once a day
- Shape and size of the solid dosage formulation should also be small to enhance compliance
- Focus could be given on a better packing of drug making it patient compliant. For example a calendar /days based packing of tablets.
- Strong promotional activities along with the clinical data support is required to influence gynecologists in the decision making process for the treatment of IDA.

Annexure

Questionnaire 1

Respondent Details	
Name:	
Specialty :	
Years of Experience:	

1) Doctor, please tell me in your clinical experience.

Parameters	No. of patients
1)How many patients do you see in a day	
2)No. of patients with IDA seen in a day	
3)Avg. No. of patients with severe anemia	

2) What are the common symptoms of anemia or IDA that you look for?

-General fatigue - Weakness -Pale skin -Shortness of breath -Dizziness -Others _____

3) Doctor, what are the diagnostic tests that you perform to confirm IDA?

Parameters	HB alone	Ferritin alone	C.B.C.	Ferritin and HB	Ferritin, HB, Transferrin	Hemoglobin electrophoresis	Serum Iron	Others
Tests								

4) Doctor, in your opinion what are the consequences of depleting iron Levels?

--

5) What is your line of treatment for IDA in the following group?

Parameters	Pregnant Women		
Type of anemia	Mild	Moderate	Severe
HB levels			
Procedure			
Molecule			
Dose and duration			
Parameters	Other anemic Females		
Type of anemia	Mild	Moderate	Severe
HB levels			
Procedure			
Molecule			
Dose and duration			

6) In your opinion what are the advantages and disadvantages of putting patients on above mentioned treatment?

Advantages	Disadvantages

7) What all challenges you come across with regards to the above mentioned Iron therapy?

--

8) Are there any guidelines that you follow for the treatment of IDA?

-WHO guidelines -Ministry of Health Guidelines -CDC Guidelines -British (BSG) Guidelines -Others _____

9) What Iron molecule is your preferred Line of Treatment?

Salts/Molecules	Pregnant Women		
	Mild	Moderate	Severe
Ferrous Ascorbate			
Ferrous Sulphate			
Iron Sucrose injection			
Carbonyl Iron			
Ferrous Fumarate			
Ferrous Bis Glycinate			
Others			
Salts/Molecules	Other Anemic Females		
	Mild	Moderate	Severe
Ferrous Ascorbate			
Ferrous Sulphate			
Iron sucrose injection			
Carbonyl Iron			
Ferrous Fumarate			
Ferrous Bis Glycinate			
Others			

10) What combination of Iron are most commonly used in the therapy?

Combinations	Pregnant Women		
	Mild	Moderate	Severe
Conventional Iron			
Ascorbic Acid			
Folic Acid			
Vit-B complex			
Calcium			
Multiple micro nutrients			
Others			
Combinations	Other Anemic Females		
	Mild	Moderate	Severe
Conventional Iron			
Ascorbic Acid			
Folic Acid			
Vit-B complex			
Calcium			
Multiple micro nutrients			
Others			

11) What information do you look for the selection of a combination?

-Better absorption -Patient Compliance -Faster action -Patient needs -Reduced ADR -Others _____

12) When do you feel the need of changing the therapy?

- As per changes in the guidelines -After trial of new launched molecules -New Information - Availability of better alternative

-Unavailability of molecule -ADR's in present therapy - Peers/Prof Guidance -Pricing -Others _____

13) What all brands do you prescribe regularly?

Brands	Reasons for Preference over others

14) Over the period of time how has the brand created unique advantages in your mind?-Past experiences - Patient compliance

-Most effective -Availability -Price -Others _____

Questionnaire 2

Iron Supplements / Hematinic Market Survey

We would like to understand the usage of iron supplements/ hematinic in your practice. Kindly spare a few minutes of your time to give us the feedback in the prescribed format.

We appreciate your help!

Doctor's Name: _____

City: _____ State: _____ Pin code: _____

1] Which term do you prefer for products used to treat iron deficiency? (Put a ✓ against your preferred term)

Iron supplement _____ Hematinic _____ Other (Pls specify) _____

2] Which of the diagnostic criteria do you use to measure iron levels in your patient? (Put a ✓)

Hemoglobin _____ Hematocrit _____ any other (Pls specify) _____

3] How many Rx of an iron supplement/ hematinic do you write every month?

_____ Rx

5] List top 3 indications/ diagnosis for which you prescribe these products. Mention % of your avg. monthly Rx for each diagnosis & avg. duration of treatment (in months)

No.	Indication / Diagnosis	% of Avg. Monthly Rx for an iron supplement	Duration of Rx (in months)
1.			
2.			
3.			

6] List top 3 iron salts prescribed by you (E.g. Ferrous sulphate etc.). Mention % of your avg. monthly Rx for each diagnosis

1. _____ %
2. _____ %
3. _____ %

7] Please state reasons (clinical & others) for prescribing your no. 1 preferred iron salt

1. _____
2. _____
3. _____

8] List names of top 3 brands of iron supplement / hematinic prescribed by you. Mention % of your avg. monthly Rx for each diagnosis

- | | |
|----------|---|
| 1. _____ | % |
| 2. _____ | % |
| 3. _____ | % |

9] Please state the key benefits of prescribing iron supplements/hematinic for your patients?

1. _____
2. _____
3. _____

10] Please state the key concerns with currently prescribed iron supplements/hematinic?

1. _____
2. _____
3. _____

11] According to you, what are the main limitations of iron salts/ formulations currently available in the market?

1. _____
2. _____
3. _____

12] Is it true that the iron uptake is hampered during inflammatory conditions in the body?

Yes _____ No _____ Not aware _____

13] An iron supplement / hematinic can be administered with or without food. Is this an important advantage? (Put a ✓ against your answer)

Very Important _____	Important _____	Somewhat Important _____
Not Important _____	Don't know _____	

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