FOGSI
FEDERATION OF OBSTETRICS AND GYNAECOLOGICAL SOCIETIES OF INDIA

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FACT CONCLAVE

FOGSI's Audit of Clinical Techniques

Dr. Hrishikesh Pai, National Coordinator, 2019

Dr. Nandita Palshetkar, President FOGSI, 2019

science integra®

IN THREATENED MISCARRIAGE &
RECURRENT PREGNANCY LOSS

TRUST THE EVIDENCE

DOSAGE IN **TM**

40 mg **STAT** followed by 20/30 mg per day until symptoms remit*

IF IT'S ***ORALLY*** EFFECTIVE, IT'S†

Duphaston®

Dydrogesterone Tablet IP 10 mg

BACKED BY ***EVIDENCE***

DOSAGE IN **RPL**

10 mg **twice daily** until 20th week of pregnancy*

GLOBAL GUIDELINES BACK THE **WORLD'S NO. 1** PROGESTOGEN‡§

1 MISCARRIAGE RANZCOG 2013

2 MISCARRIAGE FOGSI 2015

3 RPL ESHRE 2017

Duphaston® 60 YEARS§ OF DELIVERING INFINITE JOY

Pictures are for representation purpose only and not of actual patients.

TM: Threatened miscarriage. **RPL:** Recurrent pregnancy loss. **RANZCOG:** Royal Australian and New Zealand College of Obstetricians and Gynaecologists. **FOGSI:** Federation of Obstetrics & Gynaecological Societies of India. **ESHRE:** European Society of Human Reproduction and Embryology.

† Schindler AE. Progestational effects of dydrogesterone in vitro, in vivo and on human endometrium. Maturitas. 2009;65 (1):S3–S11. * Prescribing information of Duphaston®. Version: 6.0, dated 27th June, 2018. ‡ Internal calculations based on Quintiles IMS database, IMS Health Analytics Link MAT03 2017. § Data on file.

References: 1. Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) 2013. http://www.ranzcog.edu.au/doc/progesterone-support-of-the-luteal-phase-and-early-pregnancy.html. Last accessed March 2014. **2.** Information available at http://www.fogsi.org/fogsi-gcpr/Accessed on 7th September, 2016. **3.** Recurrent pregnancy loss. Guideline of the European Society of Human Reproduction and Embryology November 2017. ESHRE Early Pregnancy Guideline Development Group.

Abbreviated Prescribing Information: Dydrogesterone Tablets IP Duphaston®. LABEL CLAIM: Each film coated tablet contains: Dydrogesterone IP 10 mg. Excipients q.s. Colour: Titanium dioxide IP. INDICATION: Progesterone deficiencies: Treatment of dysmenorrhoea; Treatment of endometriosis; Treatment of secondary amenorrhoea; Treatment of irregular cycles; Treatment of dysfunctional uterine bleeding; Treatment of pre-menstrual syndrome; Treatment of threatened miscarriage; Treatment of habitual miscarriage; Treatment of infertility due to luteal insufficiency; Luteal support as part of an Assisted Reproductive Technology (ART) treatment and Hormone replacement therapy. DOSAGE AND ADMINISTRATION: Dysmenorrhoea: 10 or 20 mg dydrogesterone per day from day 5 to day 25 of the menstrual cycle. Endometriosis: 10 to 30 mg dydrogesterone per day from day 5 to day 25 of the cycle or continuously. Dysfunctional uterine bleeding: When treatment is started to arrest a bleeding episode, 20 or 30 mg dydrogesterone per day is to be given for up to 10 days. Secondary amenorrhoea: 10 or 20 mg dydrogesterone per day, to be given daily for 14 days during the second half of the theoretical menstrual cycle to produce an optimum secretory transformation of an endometrium that has been adequately primed with either endogenous or exogenous estrogen. Pre-menstrual syndrome: 10 mg dydrogesterone twice daily starting with the second half of the menstrual cycle until the first day of the next cycle. The starting day and the number of treatment days will depend on the individual cycle length. Irregular cycles: 10 or 20 mg dydrogesterone per day starting with the second half of the menstrual cycle until the first day of the next cycle. The starting day and the number of treatment days will depend on the individual cycle length. Threatened miscarriage: An initial dose of up to 40 mg dydrogesterone may be given followed by 20 or 30mg per day until symptoms remit. Habitual miscarriage: 10 mg dydrogesterone twice daily until the twentieth week of pregnancy. Infertility due to luteal insufficiency: 10 or 20 mg dydrogesterone daily starting with the second half of the menstrual cycle until the first day of the next cycle. Treatment should be maintained for at least three consecutive cycles. Luteal support as part of an Assisted Reproductive Technology (ART) treatment: 10 mg Dydrogesterone three times a day (30 mg daily) starting at the day of oocyte retrieval and continuing for 10 weeks if pregnancy is confirmed. Hormone replacement therapy: Continuous sequential therapy: An estrogen is dosed continuously and one tablet of 10mg dydrogesterone is added for the last 14 days of every 28-day cycle, in a sequential manner. Cyclic therapy: When an estrogen is dosed cyclically with a treatment-free interval, usually 21 days on and 7 days off. One tablet of 10 mg dydrogesterone is added for the last 12 -14 days of estrogen therapy. **CONTRAINDICATIONS:** Known hypersensitivity to the active substance or to any of the excipients. Known or suspected progestogen dependent neoplasms (e.g. meningioma). Undiagnosed vaginal bleeding. Treatment for luteal support as part of an Assisted Reproductive Technology (ART) treatment should be discontinued upon diagnosis of abortion /miscarriage. Contraindications for the use of estrogens when used in combination with dydrogesterone. **WARNINGS & PRECAUTIONS:** Before initiating dydrogesterone treatment for abnormal bleeding the etiology for the bleeding should be clarified. Breakthrough bleeding and spotting may occur during the first months of treatment. If breakthrough bleeding or spotting appears after some time on therapy, or continues after treatment has been discontinued, the reason should be investigated, which may include endometrial biopsy to exclude endometrial malignancy. If any of the following conditions are present, have occurred previously, and/or have been aggravated during pregnancy or previous hormone treatment, the patient should be closely supervised. It should be taken into account that these conditions may recur or be aggravated during treatment with dydrogesterone and ceasing the treatment should be considered: Porphyria, Depression and Abnormal liver function values caused by acute or chronic liver disease. **PREGNANCY & LACTATION:** It is estimated that more than 10 million pregnancies have been exposed to dydrogesterone. So far there were no indications of a harmful effect of dydrogesterone use during pregnancy. Dydrogesterone can be used during pregnancy if clearly indicated. Breastfeeding: No data exist on excretion of dydrogesterone in mother's milk. Experience with other progestogens indicate that progestogens and the metabolites pass to mother's milk in small quantities. Whether there is a risk to the child is not known. Therefore, dydrogesterone should not be used during the lactation period. Fertility: There is no evidence that dydrogesterone decreases fertility at therapeutic dose. **ADVERSE REACTIONS:** The most commonly reported adverse drug reactions of patients treated with dydrogesterone in clinical trials of indications without estrogen treatment are migraines/headache, nausea, menstrual disorders and breast pain/tenderness. Undesirable effects in adolescent population: Based on spontaneous reports and limited clinical trial data, the adverse reaction profile in adolescents is expected to be similar to that seen in adults. Undesirable effects that are associated with an estrogen-progestogen treatment (see also 'Warnings and Precautions' and the product information of the estrogen preparation): Breast cancer, endometrial hyperplasia, endometrial carcinoma, ovarian cancer; Venous thromboembolism; Myocardial infarction, coronary artery disease, ischemic stroke. Issued on: Date (27/06/2018). Source: Prepared based on full prescribing information (version 6) dated 27/Jun/2018. * Registered Trademark of the Abbott Products Operations AG.

For full prescribing information, please contact: Abbott India Limited, Floor 16, Godrej BKC, Plot C-68, 'G' Block, Bandra-Kurla Complex, Near MCA Club, Bandra East, Mumbai-400 051. www.abbott.co.in

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Dr. Hrishikesh Pai
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Dear FOGSIANs,

FOGSI has always been the custodian of women's health and hygiene in India, but this year we took on the onus of going beyond healthcare and supporting women to achieve much more.

FOGSI this year has played prominent multidimensional roles ranging from advocacy, science generation, and even social activism. All this wouldn't have been possible without all the support and encouragement extended by each and every FOGSI member.

This year, FOGSI was privileged and pleased to bridge new collaborations and cement old ones with most importantly the Ministry of Health and Family Welfare Govt of India. Both FOGSI and Government realized that it is imperative for any health initiative to make a significant and successful impact a public private partnership is absolutely essential. The spectacular FOGSI Aarogya Mahila Summit in August 2019 at New Delhi where strategic planning and methodology of implementation on various health issues in women's health was discussed and the way forward was proposed.

Various joint strategies, position statements, pledges and health awareness campaigns were launched with professional associations like IAP, FPAI, and IMA etc., and across the country, which will ensure that the community is made aware on the importance of health-related issues and accessibility of healthcare. We strongly believe that women's health needs multidisciplinary care so that different perspectives and comprehensive approach is obtained.

FOGSI's Audit of Clinical Techniques (FACT) is an important part of our organizational responsibilities toward the key issues of the day. Senior FOGSIans, key opinion leaders, clinical practitioners and government officials have collaborated together in brainstorming sessions during the FACT Conclave held on 22nd November 2019 in Mumbai to deliver the key practice points and position statements drafted by the FOGSI leadership on PCPNDT Act, Caesarean section, Hysterectomy and Respectful Maternal Care. These are being released and disseminated to all 37,000 FOGSIans. We thank all the thought leaders for contributing their valuable time and expertise to these consensus documents.

We believe in healing through action, strength through diversity, and power through collaboration. Everyone deserves the opportunity to live a healthy, happy, and productive life. We urge every FOGSIan to change their mindsets from being just a FOGSI member to a proud FOGSI member and more importantly a passionate member selflessly committed towards the betterment of women's health in India.

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President FOGSI 2019

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National Coordinator, FOGSI 2019

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AAROGYA MAHILA SUMMIT

The Aarogya Mahila Women's Health & Empowerment Summit 2019 was organized by FOGSI under the leadership of Dr. Nandita Palshetkar President FOGSI at Hotel Hyatt in New Delhi on 28th and 29th August 2019. Dr. Hrishikesh Pai and Dr. Meera Agnihotri were the conveners of the summit.

The Aarogya Mahila Summit was a health summit in which FOGSI invited all the stakeholders namely the Ministry of Health and Family Welfare, Government of India, various NGOs and stakeholders committed to and actively participating in the upliftment of women's health. This health summit involved Key Opinion Leaders and senior FOGSI leadership who attended and participated in discussions on various issues related to women's health. The summit consisted of talks, lectures, key notes, and panel discussions on issues pertaining to women's health in India.

The health summit was inaugurated by the Honourable Minister of Health Dr. Harshvardhan and the Minister of Health - State Shri. Ashwini Chaubey in the presence of FOGSI President Dr. Nandita Palshetkar and the conveners for the health summit Dr. Hrishikesh Pai and Dr. Meera Agnihotri. Various senior FOGSI leaders & numerous participants from FOGSI and various stakeholders were present for the grand inauguration ceremony. The health minister thanked FOGSI for its role in the upliftment of women's health and said that the health ministry looks forward for further collaboration with FOGSI. Shri Ashwini Chaubey, the Minister of Health also emphasized the importance of women's health and that it was a priority of the Government of India. Various officials from the Department of Health And Family Welfare, Government of India were present. Other collaborators of FOGSI talked about the various roles and initiatives where their organizations were collaborating with FOGSI. At the time of the inauguration a pledge was taken by the senior FOGSI leaders and all attendees for Beti Bachao Beti Padhao Slogan of Government of India, and FOGSI pledged its unanimous support for this noble initiative. The academic partners who helped in the support of this summit included Abbott and FOGSI was grateful to Abbott.

The FOGSI Vision document which summarize the Vision, Mission, and historical contributions of FOGSI and its Office Bearers was released by the dignitaries on this occasion and was distributed to all the attendees.

In the evening of 28th August 2019 there was an award ceremony in which the prestigious We for Stree Awards were presented acknowledging and appreciating efforts of individuals and organizations for the upliftment of women's health. These awards were presented by the Honourable Minister of State Shri. Faggan Singh Kulaste along with FOGSI President Dr. Nandita Palshetkar, the FOGSI Office Bearers and the conveners for Aarogya Mahila Women's health & Empowerment Summit, Dr. Hrishikesh Pai and Dr. Meera Agnihotri. This was followed by an entertainment programme for the recreation of all the delegates and attendees.

Dr. Nandita Palshetkar
President FOGSI

Dr. Hrishikesh Pai
Convenor

Dr. Meera Agnihotri
Convenor


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PC-PNDT

The conclusions were as follows.

1. **What are the documents required to register a GCC, GL or GC?**
   - Form-A in duplicate
   - Affidavit on 100 Rs. Stamp Paper
   - D.D. or Online transaction
   - Premises details with occupancy proof
   - Details of Machine – Make, Model and Serial no.
   - Details of employee with Degree, Council Registration, and Experience certificate.

2. **Who can do a sonography – Can Gynecologists do USG?**

   Any post graduate diploma or degree holder which is recognised by MCI can do USG. Gynecologists are allowed to do USG.

3. **Categories of Registration under PC-PNDT Act**

   There are only five categories of Registration under PC-PNDT Act.
   - Genetic Counselling Centre
   - Genetic Laboratory
   - Genetic Clinic which includes USG clinic
   - Ultrasonography Clinic
   - Imaging Centre
   - There is no category like ART Centre – ART centre is to be registered in the category of Genetic Clinic.

4. **What are the PC-PNDT Procedures and Tests? The status of following procedures as per Section 2(i), (j), (k) of PC-PNDT Act.**

   a. Follicular Study - NO

   b. Ovum pick-up - NO

   c. Embryo transfer - NO

d. Semen analysis - NO

e. Semen wash - NO

f. IUI-H - NO

g. IUI-D - NO

h. NIPT - YES

i. PGD - YES

j. PGS - YES

k. Fetal Reduction - NO

5. Buying new machine, Replacing machine, Installing machine – Whether to intimate or take permission – What is period of intimation?

- Intimation is to be done 30 days in advance.
- No provision of permission.
- If change is sudden – to be intimated within seven day of change.

6. What do you mean by portable machine?

Every machine is portable if put on trolly with wheels.

Portable means USG machine used in vehicle which is registered as Genetic Clinic.

i. Can you move machine inside registered premise - YES

ii. Can you move USG machine outside registered premise - NO

iii. Should machine be kept in lock and key – Not necessary –but should not be used by unauthorized person

iv. How many doors in USG room – Nothing specified

v. Size of room – Attached bathroom – Not specified

vi. Should machine be wall mounted – Not necessary

7. How early you accept renewal?

Provision is at least 30 days in advance.

Concluded that - We recommend that renewal application should be accepted 90 days in advance.

8. Procedure to change or add a category

There is no provision of adding category in PC-PNDT Act and Rules: Not true

Concluded that – Fresh application to be done by depositing full amount

9. In the certificate of registration, i.e. PNDT CERTIFICATE FORM B, what should you write?

It should be uniform as per PC-PNDT Rules.

Form-B should contain -

i. Name of A. A. approving

ii. Name of centre and Category under which centre is registered

iii. Model and make of equipment

iv. Registration No. allotted

v. Validity period of earlier certificate for renewal

Names of doctors, photographs of doctors and name of embryologists not to be mentioned on Form-B as there is no provision.

How do you incorporate changes in certificate? – New certificate to be issued and no additional paper is to be issued to display.

10. What do you mean by conspicuous Place?
Where should the certificate of Registration be displayed?

Conspicuous place means place, which is easily visible to passer by.

Certificate should be displayed in waiting area of USG room.

11. What should be the writing on Notice Board – Size, Colour, Colour of text?

- Local language and in English – Both
- We do not do Sex determination here. It is a crime as per law.
- (Local Language)
- 3X2 Feet
- Blue colour
- White Text

12. A copy of PC-PNDT Act and Rules

A copy of latest (Which contains all amendments) - PC-PNDT Bare Act and Rules should be available in the centre.

In English only.

In local language not mandatory by law.

13. Can machine be taken out of hospital to take it to other hospital? – NO. One machine cannot be registered at two places.

14. Monthly reporting

i. What documents are to be submitted? Only form F? all refer chit and reports? I. D. Proof? – One copy (Xerox or carbon copy) of Form-F is to be submitted. Rest of the things (Reference chit I. D. Proof, Reports and Prints if taken) to be kept at center - should be made available for inspection at all reasonable time.

ii. How many Form-F to be filled?

Form-F to be filled in duplicate – One for A. A. and original to be kept in centre

iii. How many Form-G to be filled?

Form-G in triplicate – One for patient, One for A. A., and one original for centre

iv. Xerox? Or Original?

Xerox or carbon copy to be submitted – Original to be kept in registered centre

v. If filling online then?

If filling on-line: Need to keep printed copy of online submitted form.

vi. Need for register for non-obstetric sonography?

There is no need to fill any kind of form for non-obstetric sonography.

15. Is print compulsory? What if somebody do not have printer or camera?

If somebody do not have printer then there is no need to take print.

If patient is given print then a copy of print to be preserved with report.

16. Format of Reference Chit

Is there any fix proforma of reference chit - YES

Can't Ayurvedic or Homeopathic doctors or non-medico person refer somebody for USG:

- There is no fix proforma of reference chit in PC-PNDT Act and Rules. Views were divided for the proposal of developing and distributing common proforma.
- AYUSH doctors can recommend USG with their council registration no.
- In case of doubt, register patient as self-reference and do needful. (Means making the case paper, preserving it with full history and clinical examination)

17. How many Form-F to be filled - TWO
How many Form-G to be filled - THREE

18. Is I. D. of patient compulsory?

It is not compulsory by law.

19. Format of USG Register - When to complete?

It should be as per PC-PNDT Rule – Rule 9(1) – Five column register containing – Serial No., Name of patient, Name of Spouse, Address with mobile number, and date.

Entries in register should be completed at the end of the day.

20. Trifling clerical error – Chance to prove contrary should be given to the accused before taking action. [Section 4(3) of PC-PNDT Act]

21. At how many places sonologist can register his or her name in one district

As there is stay on this amendment granted by three high courts. As UOI was party in case stay is considered valid in all over India and Anuradha Vemmuri circulated the same so till date a doctor can be registered in any number of registered centres in one district.

22. What do you mean by Objectionable Material. Taking action for keeping Radha Krishna Murti or pic, Ajanta's handle in USG room and Colour of dress: These all are abuse of law.

23. Role of Police under PC-PNDT Act - Section – 28 of PC-PNDT Act and Rule 18A – (3) (iv)

Conclusion - As far as possible police is not to be involved.

24. Who can amend PC-PNDT Act and Rules?

Only Central Government can amend PC-PNDT Act and Rules. (Section – 32 & 33 of PC-PNDT Act).

25. Rule 13 – Intimation of change –

In usual case 30 days in advance.

If some change is done in emergency then within seven days of change.

26. Is wearing Apron compulsory?

No. But name plate should be displayed on dress worn with designation.

27. Renewal pending case –

As here are so many judgments, now it was concluded that renewal should be done pending case.

28. ART CLINIC

i. How will they register? – To be registered as Genetic Clinic

ii. What category should they register? – Genetic Clinic with permission to do invasive procedures. In any other specify column one may write ART procedures.

iii. If already register then what to do? – Apply afresh to change the category as there is no provision of changing category in PC-PNDT Act or Rules.

iv. What forms should ART specialist fill while doing different procedures?

a.	Follicular Study	-	No Form
b.	Ovum pick-up	-	No Form
c.	Embryo transfer	-	No Form
d.	Semen analysis	-	No Form
e.	Semen wash	-	No Form
f.	IUI-H	-	No Form
g.	IUI-D	-	No Form
h.	NIPT	-	Form-F (Section – A, C & D) and Form-G
i.	PGD	-	Form-F (Section – A, C & D) and Form-G
j.	PGS	-	Form-F (Section – A, C & D) and Form-G
k.	Fetal Reduction	-	No Form
l.	Obstetric sonography	-	Form-F (Section – A, B & D)
m.	Amniocentesis	-	Form-F (Section–A,B,C & D) and Form-G
n.	Chorionic villus biopsy	-	Form-F (Section–A,B,C & D) and Form-G
o.	Cordocentesis	-	Form-F (Section–A,B,C & D) and Form-G
p.	Fetal skin biopsy	-	Form-F (Section–A,B,C & D) and Form-G

29. Who can de-seal the machine once sealed by A. A. – No discussion on this point was done.

30. Can A. A. cheque check MTP records?

There were disputed opinions. A few thought that it will amount to breach of confidentiality of women while other thought that A. A. is also in many places authority of MTP Act so he should be allowed to see MTP Register. Question remained inconclusive.

Abbreviations:

A.A.: Medical Officer of Health of the ward; ART: assisted reproductive technology; GC: genetic clinic; GCC: Genetic Counselling Centres; GL: genetic laboratories; IUI-D: intra uterine insemination with donor semen; IUI-H: intra uterine insemination with partner semen; MCI: Medical Council of India; NIPT: noninvasive prenatal testing; PCPNDT: Pre-Conception and Pre-Natal Diagnostic Techniques; PGD: pre-implantation genetic diagnostics; PGS: pre-implantation genetic screening; UOI: Union of India; USG: ultrasonography.

LOWER (UTERINE) SEGMENT CESAREAN SECTION (LSCS)

Cesarean rates and the confusion that surrounds them

There is a surprising lack of clarity amongst various organizations on cesarean rates. It is altogether surprising that rhetoric has replaced - sometimes even dangerously - what is best for the woman, her baby and the family. We believe that a rational evidence based approach to this issue is vital rather than the lazy narrative of the commercialization of medicine in general and birthing in particular.

The question which begs to be answered is therefore:

"Is there a recommended rate for Cesarean Section?"

The short answer is NO.

However, confusion abounds in this aspect and it is worthwhile to take some time to understand the genesis of the canard of 10% to 15% Cesarean rates:

In 1985 the World Health Organization (WHO) stated: "There is no justification for any region to have cesarean section rates higher than 10%-15% " (World Health Organization. Appropriate technology for birth. Lancet. 1985; 2 (8452): 436-7).

The studies on which the WHO based the 15% recommendation 30 years ago were "limited by either having incomplete data or relying on averaged cesarean delivery rates from multiple years without accounting for year-to- year variation in these estimates" (Molina G, Weiser TG, Lipsitz SR, et al. Relationship between cesarean delivery rate and maternal and neonatal mortality. JAMA. 2015; 314: 2263-70). Although the methodology of arriving at these rates was not robust - to say the least - and the methodology has come under scrutiny in several publications (Betran AP, Torloni MR, et al for the WHO Working Group on Caesarean Section. WHO Statement on Caesarean Section Rates. BJOG 2016;123:667–70), this document has provided fodder to several studies which based the utility of cesarean sections using these figures as a basic assumption.

What is almost always overlooked is that the WHO document looked upon reflected a correlation only with mortality. The rates were never meant to assess cesarean rates at the level of an individual facility or individual physician or patient. These rates were an indicator of accessibility, availability and utilization of this facility, and is of use to policymakers as an indicator of maternal/perinatal health. *(Betran AP, Merialdi M, Lauer JA, et al. Rates of caesarean section: Analysis of global, regional and national estimates. Pediatric and Perinatal Epidemiology. 2007;21: 98-113)*

Morbidity both fetal and maternal was not taken into account for these rates. This was and is an infirmity which has not been addressed even now, adequately, to arrive at a uniform cesarean rate. It is also true that what is not considered are the longer term effects of birth on women; in particular, pelvic organ prolapse, anal sphincter injury, sexual dysfunction, fistulae, urinary incontinence (UI), and others.

It is therefore not surprising to see data where the 10% to 15% cesarean rate has been found repeatedly wanting. None of the countries with a stillbirth rate of 2-4 /1000 have a Cesarean Section rate between the WHO recommended 10%-15% threshold. (Leddy MA, Power ML, Schulkin J. The impact of maternal obesity on maternal and fetal health. Rev Obstet Gynecol. 2008; 1: 170-178).

An elegant report cites that previously recommended national target rates for cesarean deliveries may be too low. The same report goes on to say that the focus of discussion about cesarean section rates should be on "supporting safe and appropriate provision of cesarean delivery. with the intent of reducing maternal and neonatal mortality without causing overuse of procedures". (Molina G, Weiser TG, Lipsitz SR, et al. Relationship between cesarean delivery rate and maternal and neonatal mortality. JAMA. 2015; 314: 2263-70) However, it was also clear that there is a "complex interplay between overall maternal health resources, emergency obstetrical services, and other factors".

Not surprisingly the WHO issued a new statement in 2015 with the headline "Every effort should be made to provide cesarean sections to women in need, rather than striving to achieve a specific rate" WHO. (WHO Statement on Caesarean Section Rates. Geneva: World Health Organization; 2015 (WHO/ RHR/ 15.02).

A very recent commentary from the authors involved in the WHO statements notes- "mortality is normally the only outcome considered in the analyses. Maternal and newborn morbidity (eg, obstetric fistula, birth asphyxia), or psychological and social well-being (eg, maternal– infant relationship, women's psychological health or ability to successfully initiate breast feeding) as well as long-term pediatric outcomes should be considered when estimating a rate that would achieve optimal outcomes. However, since there are practically no morbidity data at the population level, it has not been possible to assess the ecological relationship between cesarean section and these other outcomes. The statement also consolidates the shift in the focus of attention from the search for an optimal cesarean section rate that provides little basis for action, to a practical and feasible proposal: the use of the classification as a standard system to monitor and compare cesarean section rates at the facility or other levels. (Ana Pilar Betrán, Jun Zhang, Maria Regina Torloni, A Metin Gülmezoglu Evid Based Med December 2016, volume 21, number 6, 237)

Thus, to conclude, the current studies and recommendations have two fallacies, one is trying to extrapolate population level data to facility level and two is focussing on mortality with the exclusion of morbidity either neonatal or maternal.

Indian Data

As per the latest data (National Family Health Survey 2015-16 (NFHS-4), the cesarean rates at population level in India seem to be 17.2 %. The same document goes on to look at cesarean rates in the private and public sector and whilst the discrepancy in the rates in these two sectors has been commented upon, there is no mention in the commentaries of the fact that the private sector delivers more babies than the public sector in the urban areas and absolutely no indication of morbidity rates either maternal or neonatal in either sector. There is also no acknowledgement of the fact that the lower rates in public sector could simply be a reflection of the paucity of capacity, both infrastructure and human resource.

To reiterate and quote from the WHO working group on cesarean section - "The time has come to put the debate about the preferable rate of cesarean section on hold. Let's start to collect data uniformly so that in the near future we will be able to move our focus from cesarean section rates at population level to monitoring and discussing cesarean section rates and outcomes in each group of the Robson classification. Only then will we

have the data and evidence that will lead us more clearly to actions to improve care". (Betran AP, Torloni MR, et al, for the WHO Working Group on Caesarean Section. WHO Statement on Caesarean Section Rates. BJOG. 2016;123:667–70)

FOGSI recommends the setting up of a cloud based registry linked to its website, which will collect anonymous data at hospital level using the WHO recommended Robson's ten group classification system.

We would like to emphasise that the hallmark of labor management in the 21st century should be individualized care for the laboring woman with the expectation of a successful and safe vaginal delivery, together with the ability to intervene with a cesarean delivery, if needed, to prevent morbidity and mortality. (Adapted from Caughey A B BIRTH 41:3 September 2014)

(Drafted by Jaydeep Tank with inputs from Team FOGSI)

Modified Robson's Criteria

1. Nullipara, singleton cephalic, ≥ 37 weeks, spontaneous labor
   a. On demand
   b. In vitro fertilization conceptions
   c. Antepartum complications cord prolapse
   d. 2nd stage complication, shoulder dystocia, deep transverse arrest
2. Nullipara, singleton cephalic, ≥ 37 weeks
   a. Induced
   b. Cesarean section before labor
3. Multipara, singleton cephalic, ≥ 37 weeks, spontaneous labor
4. Multipara, singleton cephalic, ≥ 37 weeks
   a. Induced
   b. Cesarean section before labor
5. Previous cesarean section, singleton cephalic, ≥ 37 weeks
   a. Spontaneous labor
   b. Induced labor
   c. Cesarean section before labor
   d. >1 lower segment cesarean section
   e. Morbidity adherent placenta
6. All nulliparous breeches
   a. Spontaneous labor
   b. Induced labor
   c. Cesarean section before labor
   d. Preterm breech
7. All multiparous breeches (including previous cesarean section)
   a. Spontaneous labor
   b. Induced Labor
   c. Cesarean section before labor
   d. Preterm breech
8. All multiple pregnancies (including previous cesarean section)
   a. Spontaneous labor
   b. Induced labor
   c. Cesarean section before labor
9. All abnormal lies (including previous cesarean section butexcluding breech)
   a. Spontaneous labor
   b. Induced labor
   c. Cesarean section before labor
10. All singleton cephalic, ≤ 36 weeks (including previous cesarean section)
    a. Spontaneous labor
    b. Induced labor
    c. Cesarean section before labor
    d. Medical disorders hypertensive disorders of pregnancy, gestational diabetes mellitus, and anemia
    e. Preterm premature rupture of membranes, bad obstetric history

Key take away points

Cesarean section should be offered where indicated

Continuous audit and research to be encouraged

Identify high risk factors on admission

Be aware of the newer definitions of labor

Consent for cesarean section

Consent for cesarean section must be requested after providing the pregnant women with evidence based information in a manner that respects the woman's privacy, views, and culture whilst taking into consideration the clinical situation.

1.8.1 Consent should be taken in the language understood by the patient and never implied. Patient should be explained that though techniques of anesthesia and surgery are advanced, yet there may be complications due to anesthesia , procedural complications like hemorrhage, infection, soft tissue injuries and injury to the baby. However, all possible precautions will be taken by the performing team of doctors to minimize the complications.

1.8.2 In case a patient is unable to sign, a left thumb impression is taken. If the patient is not in a position to give a consent and consent should be obtained from relatives. In case of minors < 18 years, guardian consent is necessary. A 100 % favorable outcome of the mother and the baby is never guaranteed.

1.8.3 Patient may opt for refusal of cesarean section being oblivious of benefits to her and her baby's health. She has to be counseled again. Despite this If there is a refusal of consent it must be documented on paper. If the procedure is life saving, cesarean section is performed without valid consent.

Annexure 1: Pre op checklist: do & confirm

(When the patient is on op table before starting anesthesia)

- Name, diagnosis, procedure
- Pre op instructions followed – NBM, medicines to be taken (Inhalers, Betnesol, Antihypertensive, Thyroid medicine, Misoprost), medicines to be withheld (low dose Aspirin, Hypoglycemics, Heparin)
- Pre op investigations done & checked
- Pre op check by Physician, Anesthetist done
- Consent checked– informed/high risk/tubal ligation/NICU/stem cell
- X match & blood group – blood (component) kept ready
- Risk factors social/medical/allergies considered
- Pre op antibiotics given
- Usual drugs which are contraindicated considered -NSAIDs/Scoline/Prostaglandins/ Methylergometrine
- Additional equipment kept ready - drains, epidural catheter
- Trolley check. Mop/ instrument count before and after
- Baby preparation done – resuscitation equipment / warmer / baby label/ baby record/neonatologist / NICU call

Annexure 2 : Post Op checklist for doctors (Before the patient is shifted out of the OT)

- Sponge & instrument count checked
- Pulse/BP/PPH/O2 saturation
- Urine output/Colour
- Lab sent – HPE/cord blood
- Baby – warmer/label
- Anesthetist permission for shifting the patient out of the OT

Obstetricians fees should be irrespective of route and mode of delivery

Encourage implementation publication

BP: blood pressure; NBM: nil by mouth; NICU: neonatal intensive care unit; NSAIDS: Nonsteroidal anti-inflammatory drugs; OT: operation theatre; PPH: postparandial hyperglycemia.

RESPECTFUL MATERNITY CARE

Clinical philosophy in respectful maternity care

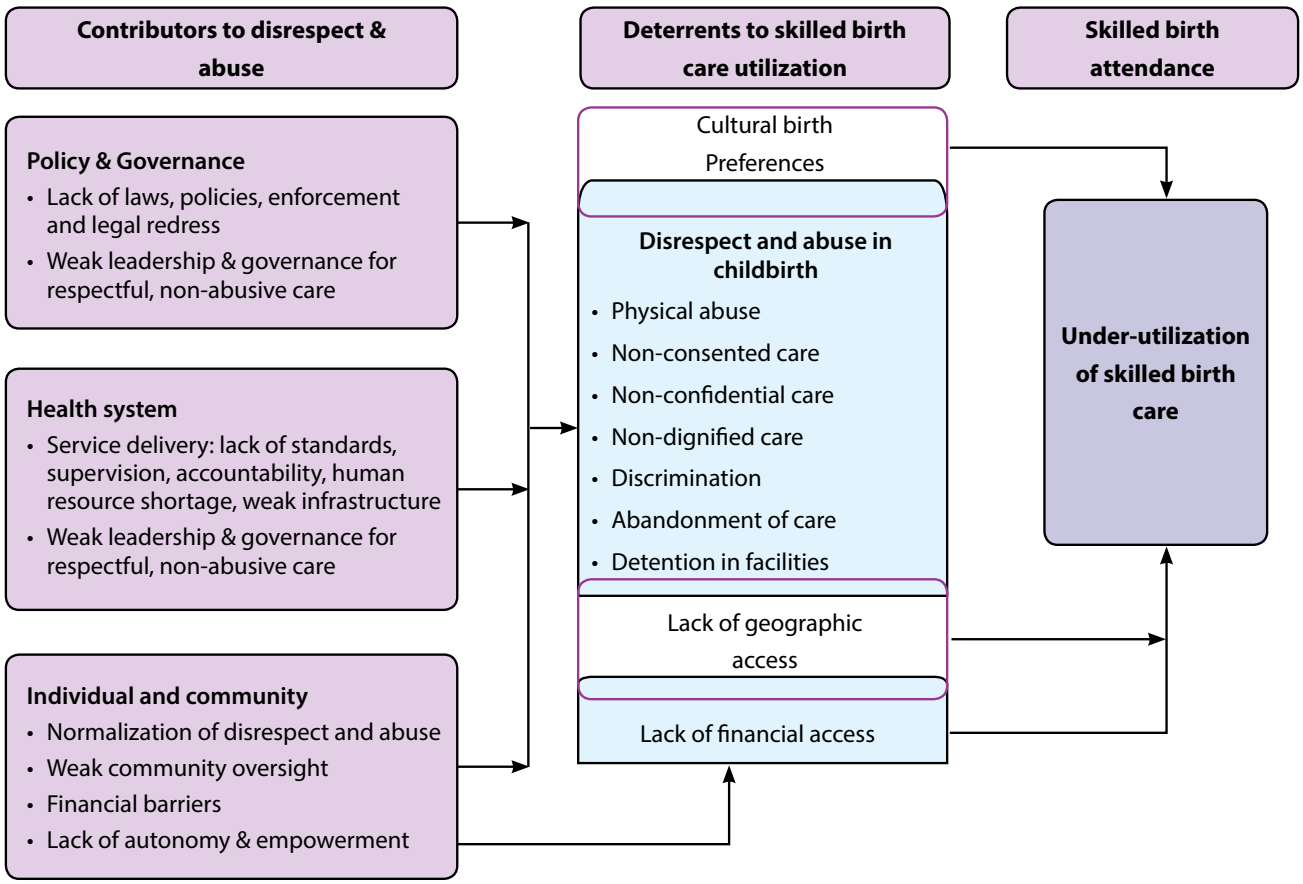
All the times when babies are delivered and life-saving operations are performed, rarely is the pregnancy experience of the woman considered. In the line of duty, we routinely separated women from their families by asking them to deliver alone in an 'unknown' labor room. The focus is on uterus and birth canal, and the woman is separated from her reproductive organs, overlooking that a birthing woman may be anxious in reaction to some uncertainties that she may be facing. Respectful maternity care is based on philosophy of respect for women's basic human rights, including respect for the woman's autonomy, dignity, feelings, choices, religion, and preferences, including companionship during maternity care.

The WHO has called for the prevention and eradication of disrespect and abuse during childbirth. It has been stated that, "every woman has the right to the highest attainable standard of health, including the right to dignified, respectful care during pregnancy and childbirth."

Need for respectful maternity care

There has been a significant reductions in the global rate of maternal mortality, which are however, uneven between and within countries. Higher rates of maternal deaths have been shown to be often concentrated within more vulnerable,

Contributors to disrespect and abuse in childbirth on skilled utilization[4]



marginalized communities. In India extensive efforts have been put to reduce maternal mortality and to increase access to reproductive health care, with good progress being made in some of the areas. However, the progress has been uneven and inequitable, and many women still lack access to maternal and reproductive health care.[1]

The World Health Organization (WHO) has recognized that there is a need for systematic elimination of mistreatment during pregnancy and childbirth which is critical in global health.[2] Furthermore, the WHO's 2016 Standards for Improving Quality Maternal and Newborn Care in Health Facilities emphasizes the significance of women's and newborns' experience of care, which should provide emotional support, dignity, and personal choice for mothers.[3] There is a general agreement that respectful maternity care is a fundamental human right and an significant component of quality intrapartum care that every pregnant woman should receive, but the effectiveness of proposed policies remains uncertain.

Tackling Disrespect and Abuse: Seven Rights of Childbearing Women	
Physical abuse	**Freedom from harm and ill treatment**
Non–consented care	Right to information, informed consent and refusal, and respect for choices and preferences, including companionship during maternity care
Non–confidential care	Confidentiality, privacy
Non–dignified care (including verbal abuse)	Dignity, respect
Discrimination based on specific attributes	Equality, freedom from discrimination, equitable care
Abandonment or denial of care	Right to timely healthcare and to the highest attainable level of health
Detention in facilities	Liberty, autonomy, self–determination, and freedom from coercion

Respectful Maternity Care

Respectful Maternity Care is an approach that focuses on the interpersonal aspect of maternity care that emphasizes the fundamental rights of the mother, new-born and families, including protecting the mother-baby from pain. Respectful Maternity Care also recognizes that all childbearing women need and deserve respectful care and protection of the women's right to choice and preferences.[5]

Standardizing Respectful Maternity Care

What constitutes Respectful Maternity Care for implementation is often variable. A multi-component Respectful Maternity Care policy may reduce women's overall experiences of disrespect and abuse, and some components of this experience.[6] The principles of care and respect during childbirth, and of women's rights during childbirth, are universal.[7] The relationship between women and the doctors, midwives, and other birth attendants who care for pregnant woman is important in upholding these principles.

Characteristics of health care to be avoided and promoted

The characteristics of health care that should be avoided are being impersonal, and being centred on profession and not on woman or family. The healthcare that disempowers woman and separates her from her family during labor and birth should be avoided.

A Respectful Maternity Care respects a woman's beliefs, traditions, and culture while empowering the woman and her family to be active participants and continue to support woman during labor. Also, women should have the choice of companion during labor and birth, and also should have the right to information, privacy and have freedom of movement during labor.

Towards Respectful Maternity Care professional and communities should collaborate in all planning, implementation, and evaluation of respectful maternal care. Knowledge, skills and attitudes that supports Respectful Maternity Care must be

Proposed Respectful Maternity Care components[11]

	Governance	Technical support	Championing change makers	Participatory action research processes	Facility environment changes
Input	Work with policy makers and leaders to strengthen RMC	Conduct training and sensitize supervisors, provides, students on RMC	Identify and support RMC champions to guide and lead training and mentorship	Discuss RNC experiences, drivers, interventions with providers and families	Pilot test stakeholders-driven intervention to promote RMC (respectful communication/ privacy curtains/birth companions)
Process	Recognition of RMC as a principle of service	Knowledge, skills, attitudes of providers/ students is updated	RMC core team, advocates, mentors and serves as role model for RMC	Strategies to promote RMC during child birth are collectively identified	Women's preferences are respected and the facility environment is improved
Out put	RMC increases and D and A decreases	RMC increases and D and A decreases	Providers observe RMC in action; RMC increases and D and A decreases	Increased ownership and sustainability of intervention; RMC increases and D and A decreases	Women are less stressed and more comfortable during the childbirth
Outcome	Quality of service improves	Quality of service improves	Quality of service improves	Quality of service improves	Reduction in complications during childbirth
Impact	More deliveries conducted at facilities with skilled birth attendant. Reduction in maternal morbidity and mortality				

D and A: Disrespect and Abuse; RMC: Respectful Maternal Care.

required in all education and training programs that involve healthcare workers. It is important to mobilize resources to support implementation of Respectful Maternity Care.[5] The principles of respectful care need to be extended to newborns, who are also at risk of disrespectful and abusive care.[9]

Dignity of the mother

A women's birth experiences stay with her for lifetime, this may influence her decisions on where to seek care in future. Despite this there is silence over disrespect and abuse in India as elsewhere in the work. There is a need to promote respectful, dignified care, which is now widely viewed as an essential component to improve care seeking. We must empower women to know their rights, be it regarding companion in the room or agreeing to medical intervention, so that they make an informed decision. Over all, women must be asked about their experiences, listened, and responded.[6]

Going forward

The mapping of review of peer-reviewed and gray literature to examine whether gender inequality is a determinant of mistreatment during childbirth has indicated that

Domains of Respectful Maternity Care[8]

- Being free from harm and mistreatment
- Maintaining privacy and confidentiality
- Preserving women's dignity
- Prospective provision of information and seeking informed consent
- Ensuring continuous access to family and community support
- Enhancing quality of physical environment and resources
- Providing equitable maternity care
- Engaging with effective communication
- Respecting women's choices that strengthens their capabilities to give birth
- Availability of competent and motivated human resources
- Provision of efficient and effective care
- Continuity of care

there have been important advances in documenting mistreatment at the health facility, but less attention has been paid to addressing the associated structural gender inequalities.[10] A modest but growing body of research has demonstrated that interventions to foster Respectful Maternity Care can enact change. Implementing multi-factored policies and practices to increase respectful maternal care can be successful in low resource settings (see table below). Creating functional networks among the wider body of stake holders and involving community and

media at every step of the process can also be useful. Studies should be carried out to determine the preferences and choices related to respectful maternity care. A political commitment at national and local levels should be obtained to create appropriate policies and standards for respectful maternal care.[5]

Some of the factors that may be beneficial in supporting the efforts to incorporate Respectful Maternal Care into a broader maternal and newborn health program include:[10]

- Obtaining published literature on the experience of disrespect and abuse within our societal context to show if it existed
- Creating a theory of change among the team. Foster agreement within the team to unravel this complex health problem and kept the team focused throughout implementation
- Slow the implementation process if there is rigidity, discomfort and pushback, this allows more time to understand, refocus, and move forward
- Speaking with grassroots-level stakeholders regarding RMC, their enthusiasm may provide us the boost to continue upholding RMC
- Partnering with allies within our organization, which will allows obtaining benefits from pre-existing knowledge to deal with foreseen challenges
- Link with women's rights groups and those who implement gender programming, these may be the drivers to women's rights to respectful care

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HYSTERECTOMY

The Federation of Obstetrics and Gynaecological Society of India (FOGSI's - fogsi.org) response to the articles in the Newspapers and other media on Hysterectomy rates in Beed (Maharashtra)

Recently a spate of articles discussing the purported high rates of hysterectomy in Beed district were published in newspapers and other media. It is a given that all surgery, procedures, and tests should be indicated.

It is also equally true that the best judge for the need of hysterectomy is the Health care provider who has to work with the patient to arrive at an informed decision after due counselling. We are happy to work with the Government and local authorities to spread awareness on Women's health in general and on this issue in particular.

We have taken the Governments advisory to the AMOGS ((dated 1/5/19) to heart and initiated several measures to optimize the use of Hysterectomies, including CME's and outreaches to our members. Among these –

FOGSI and AMOGS have initiated a unique campaign called as "Save the Uterus" for its members this year. As a part of this campaign we are organizing a CME highlighting the various conditions especially Menstrual Disorders that affect the Uterus. Various treatment options medical and surgical are highlighted during these CMEs especially emphasizing the need to judiciously use Hysterectomy as a treatment option. In addition, patient education sessions giving a simplified understanding of gynecological problems and the treatment options available are discussed with community members and especially women with through counselling of the various pro and cons of each treatment modality. Such successful meetings have already been conducted in Beed, Aurangabad, Solapur, Latur and Osmanabad. Further meetings have been planned in Nanded, Sangli, Amravati, Gondia, Jalna, Pune and Mumbai.A total of 500 plus doctors and women have attended these programs. After looking at the sincere participation of doctors and women in these programs, we are certain that optimal treatment will be provided to the women and will improve the health of women.

However we also would like to draw your attention to the below facts:

We have written to the organization (Tathapi) on the 16th of May seeking a copy of the report which forms the basis of these news reports and government action and have as yet to receive a reply from them. It is quite difficult to assess the scientific veracity and methodology of the report for us as we do not have access to it, and it does not seem to be available in the public domain. We would be happy to study the report if provided to us.

A collation of facts seem to be as under (source material is newspaper articles as no scientific community level data is available to us).

1

A 2018 survey of 200 women in Beed by Maharashtra State Commission for Women revealed that 36% had undergone hysterectomy. A more recent survey this year by the public health department of 271 women showed that 21% had undergone hysterectomies. Both surveys revealed that nearly 85% of the procedures were at private hospitals. "The National Family Health Survey data shows that across Maharashtra, 2.6% hysterectomies are performed, while the national average is 3.2%. The Beed numbers are 14 times more. It's alarming," said Dr Abhay Shukla of SATHI (Support for Advocacy and Training to Health Initiatives).

https://timesofindia.indiatimes.com/city/mumbai/beed-sees-14-times-more-hysterectomies-ngosseek-action-against-pvt-hospitals/articleshow/69763004.cms (1)

2

A study, commissioned by the Maharashtra State Commission for Women in 2018, indicates that the rate of hysterectomies in Beed stands at 36%. According to data from the National Family Health Survey, this figure is a sharp contrast to the rate of hysterectomies conducted in Maharashtra, which stands at 2.6%. Not only that, it is also much higher than the rate across India, which is 3%. In 2018, out of the 200 women surveyed in Beed, 72 had undergone a hysterectomy. In 2019, out of of 271 surveyed, 56 had undergone the procedure.

https://indianexpress.com/article/cities/mumbai/maharashtra-hysterectomies-in-beed-districtunusually- higher-compared-to-state-india-5777912/ (2)

3

Dr Abhay Shukla, co-convenor, Jan Swasthya Abhiyan, said the government conducted two surveys. Of the 200 women surveyed in 2018, in Beed district, 72 had hysterectomies. The rate of uterus removal in Beed was 36%, compared to 2.6% in Maharashtra and 3.2% in India.

In 2019, Dr Shukla said 271 women were surveyed of whom 56 had hysterectomies, that is 21% of them — again a high number. According to figures provided by the Beed administration, 11 hospitals conducted most of the surgeries and 85% of the surgeries in 2018 and 2019 were in private hospitals. One hospital which did not have a gynecologist conducted 24 hysterectomies which is grossly high, he added.

https://www.firstpost.com/india/beed-high-hysterectomy-rate-among-sugarcane-cutters-signalsunethical- medical-practices-poor-work-conditions-6807101.html (3)

4

"Of the total 271 cases surveyed in Beed district during 2018, 72 were hysterectomies. In India the standard hysterectomy rate is 3 while in Maharashtra it is just 2.5. On this backdrop the rate in Beed in 2018 comes to 36 which is 14 times higher than the normal," said Achyut Borgaonkar.

https://www.deccanherald.com/national/hysterectomies-among-women-sugarcane-workersrocks- beed-740121.html (4)

5

Shinde is among the thousands of women from Beed who have have had their wombs removed. Figures suggest that over 4,500 women from the district have undergone hysterectomies in the last three years.

http://timesofindia.indiatimes.com/articleshow/69763004.cms? utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst (5)

6

Women in Vanjarwadi, where 50% of the women have had hysterectomies, say that it is the "norm" in villages to remove the uterus after having two or three children.

https:// www.thehindubusinessline.com/economy/agri-business/why-half-the-women-in-maharashtrasbeed- district-have-no-wombs/article26773974.ece (6)

The articles thus seem to say:

A

Two surveys are reported (we are unable to locate them and therefore can only comment on what the media has reported). One had a sample size of 200 women and the other had a sample size of 271. The target population of the women surveyed has not been indicated in the media however the findings have been extrapolated to the entire district. The population of beed as per the 2011 census was 25,85,000 (25.89 Lakhs).

https://www.census2011.co.in/census/district/361-bid.html

It is plainly obvious that at a community level this sample size is grossly inadequate, this is either a deeply flawed survey or that there has been deliberate obfuscation of facts and the findings, which should have been restricted to a particular population have been incorrectly and deliberately extrapolated to the entire district.

B

We would encourage a community level survey to determine accurately what the population level rates for Hysterectomy actually, and we would be happy to work with the authorities to bring this to fruition.

C

The findings of the survey reported in one article say - "In 2018, out of the 200 women surveyed in Beed, 72 had undergone a hysterectomy. In 2019, out of of 271 surveyed, 56 had undergone the procedure". (2)

Again it is plainly obvious that hysterectomy rates have actually fallen over the two years

D

One of the article claims that 4500 women have undergone hysterectomies in three years (5). This would mean 1500 Hysterectomies annually.

At the 2011 population level - this would mean an annual hysterectomy rate of 0.005 at population level.

E

One of the articles seems to suggest that 50% of women (no qualification regarding age is given so one presumes it is at population level) in a given village have had Hysterectomies (6) The population of Vanjarwadi was 989 in the 2011 census.

https://www.census2011.co.in/data/subdistrict/4218-georai-bid-maharashtra.html

Assuming that half of this population is female (494) this would mean 247 Hysterectomies in Vanjarwadi alone!! Quite clearly unless the surveys were conducted in Vanjarwadi alone there is a problem with these numbers.

Further, we also believe that this issue has been reported in a knee jerk manner by evoking suspicion about the practice of doctors. It is unfortunate the lazy narrative of commercialization of medicine in general and this procedure in particular are made the overarching theme rather than looking at the social, economic, and other local factors as driving practices.

We would not like to presume that Hysterectomy rates do not need attention.

However, it is equally clear that more accurate data is needed and is indeed imperative to draw any suitable conclusions both about Hysterectomy rates as well as the role of the private sector in them. e.g. although the reports speak to the fact that most hysterectomies occur in the private sector no attention is given to wether the public sector in the area under consideration has the capacity to preform Hysterectomies throughout the district. Is it simply the paucity of resources in the public sector which compels these women to go to the private sector, thus skewing the rates between private and public sector.

To that end we would respectfully like to propose:

1

A detailed multidimensional community level survey to understand the issue in all its complexity in partnership with the authorities.

2

Awareness and close liaison between FOGSI and the Government and concerned authorities to approach the problem in a systematic and scientific manner with a proper mechanism to determine trends.

3

A series of public awareness programs to reach out to the community and educate them about their options. Working with cane and sugar factory owners and mukadams to give women a choice in the matter of their menstrual hygiene.

4

Increasing awareness levels amongst all health care providers including community level workers, physics from other specialities and family practitioners regarding women's health and rights in general (like family planning, respectful maternal care, avoiding gender preferences, etc) and this issue in particular.

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2. https://indianexpress.com/article/cities/mumbai/maharashtra-hysterectomies-in-beeddistrict-unusually-higher-compared-to-state-india-5777912/
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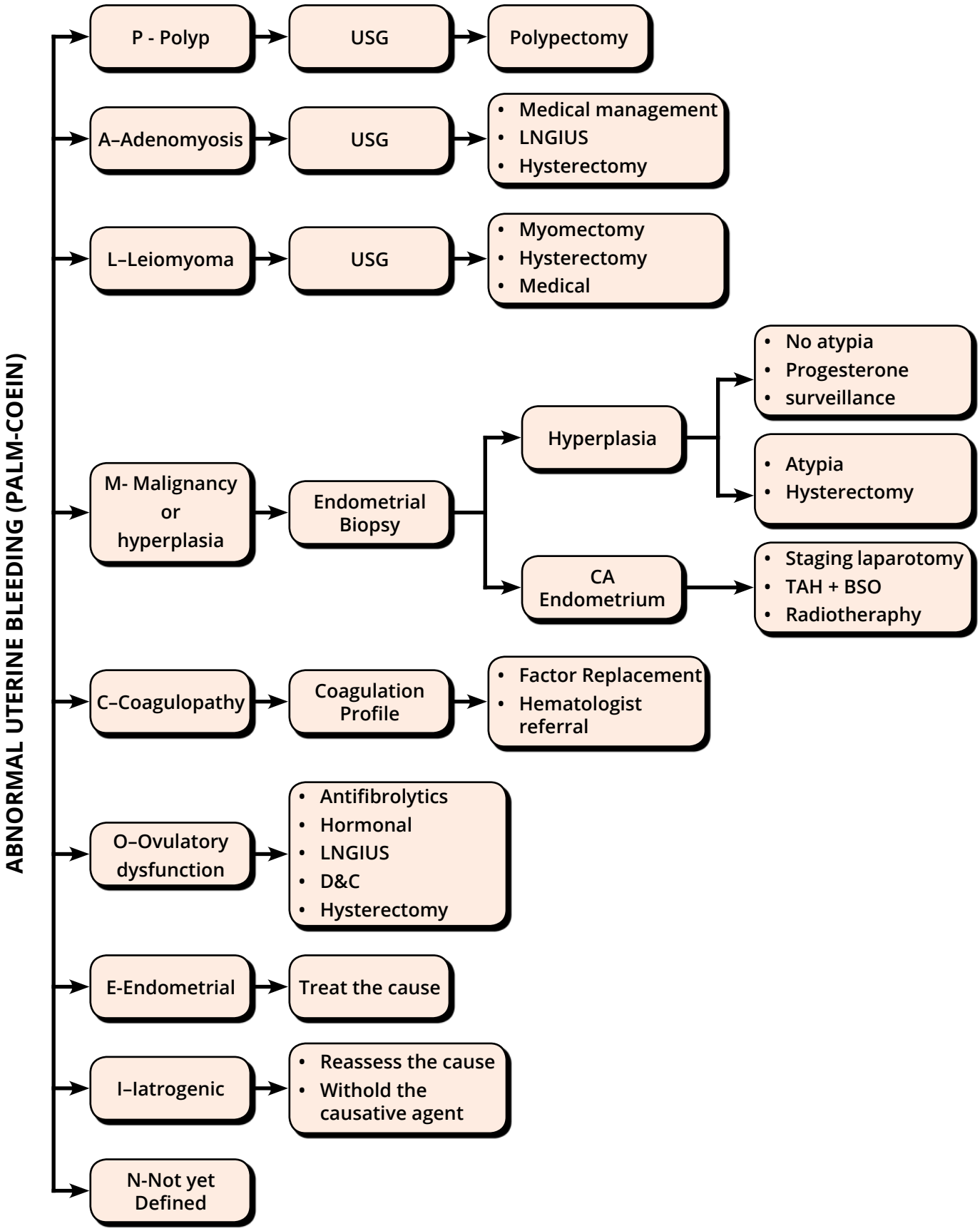

BSO: bilateral salpingo-oophorectomy; CA: cancer; D&C: Dilation and curettage; LNG-IUS: levonorgestrel-releasing intrauterine system; TAH: total abdominal hysterectomy; USG: ultrasonography.

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† Schindler AE. Progestational effects of dydrogesterone *in vitro, in vivo* and on human endometrium. Maturitas. 2009;65 (1):S3-S11. *Prescribing information of Duphaston®. Version: 6.0, dated 27th June, 2018.‖ 30 refers to dosage of Duphaston in LPS as a part of ART treatment: 30 mg per day starting at day of oocyte retrieval and continuing upto 10 weeks (as per Duphaston PI). ‡ Internal calculations based on Quintiles IMS database, IMS Health Analytics Link MAT03 2017. § Mirza F, et al. Dydrogesterone use in early pregnancy. Gynecol Endocrinol.2016;32(2):97-106. # Data on file.

Abbreviated Prescribing Information: Dydrogesterone Tablets IP Duphaston®. LABEL CLAIM: Each film coated tablet contains: Dydrogesterone IP 10 mg. Excipients q.s. Colour: Titanium dioxide IP. INDICATION: Progesterone deficiencies: Treatment of dysmenorrhoea; Treatment of endometriosis; Treatment of secondary amenorrhoea; Treatment of irregular cycles; Treatment of dysfunctional uterine bleeding; Treatment of pre-menstrual syndrome; Treatment of threatened miscarriage; Treatment of habitual miscarriage; Treatment of infertility due to luteal insufficiency; Luteal support as part of an Assisted Reproductive Technology (ART) treatment and Hormone replacement therapy. DOSAGE AND ADMINISTRATION: Dysmenorrhoea: 10 or 20 mg dydrogesterone per day from day 5 to day 25 of the menstrual cycle. Endometriosis: 10 to 30 mg dydrogesterone per day from day 5 to day 25 of the cycle or continuously. Dysfunctional uterine bleeding: When treatment is started to arrest a bleeding episode, 20 or 30 mg dydrogesterone per day is to be given for up to 10 days. Secondary amenorrhoea: 10 or 20 mg dydrogesterone per day, to be given daily for 14 days during the second half of the theoretical menstrual cycle to produce an optimum secretory transformation of an endometrium that has been adequately primed with either endogenous or exogenous estrogen. Pre-menstrual syndrome: 10 mg dydrogesterone twice daily starting with the second half of the menstrual cycle until the first day of the next cycle. The starting day and the number of treatment days will depend on the individual cycle length. Irregular cycles: 10 or 20 mg dydrogesterone per day starting with the second half of the menstrual cycle until the first day of the next cycle. The starting day and the number of treatment days will depend on the individual cycle length. Threatened miscarriage: An initial dose of up to 40 mg dydrogesterone may be given followed by 20 or 30mg per day until symptoms remit. Habitual miscarriage: 10 mg dydrogesterone twice daily until the twentieth week of pregnancy. Infertility due to luteal insufficiency: 10 or 20 mg dydrogesterone daily starting with the second half of the menstrual cycle until the first day of the next cycle. Treatment should be maintained for at least three consecutive cycles. Luteal support as part of an Assisted Reproductive Technology (ART) treatment: 10 mg Dydrogesterone three times a day (30 mg daily) starting at the day of oocyte retrieval and continuing for 10 weeks if pregnancy is confirmed. Hormone replacement therapy: Continuous sequential therapy: An estrogen is dosed continuously and one tablet of 10mg dydrogesterone is added for the last 14 days of every 28-day cycle, in a sequential manner. Cyclic therapy: When an estrogen is dosed cyclically with a treatment-free interval, usually 21 days on and 7 days off. One tablet of 10 mg dydrogesterone is added for the last 12 -14 days of estrogen therapy. **CONTRAINDICATIONS:** Known hypersensitivity to the active substance or to any of the excipients. Known or suspected progestogen dependent neoplasms (e.g. meningioma). Undiagnosed vaginal bleeding. Treatment for luteal support as part of an Assisted Reproductive Technology (ART) treatment should be discontinued upon diagnosis of abortion /miscarriage. Contraindications for the use of estrogens when used in combination with dydrogesterone. **WARNINGS & PRECAUTIONS:** Before initiating dydrogesterone treatment for abnormal bleeding the etiology for the bleeding should be clarified. Breakthrough bleeding and spotting may occur during the first months of treatment. If breakthrough bleeding or spotting appears after some time on therapy, or continues after treatment has been discontinued, the reason should be investigated, which may include endometrial biopsy to exclude endometrial malignancy. If any of the following conditions are present, have occurred previously, and/or have been aggravated during pregnancy or previous hormone treatment, the patient should be closely supervised. It should be taken into account that these conditions may recur or be aggravated during treatment with dydrogesterone and ceasing the treatment should be considered: Porphyria, Depression and Abnormal liver function values caused by acute or chronic liver disease. **PREGNANCY & LACTATION:** It is estimated that more than 10 million pregnancies have been exposed to dydrogesterone. So far there were no indications of a harmful effect of dydrogesterone use during pregnancy. Dydrogesterone can be used during pregnancy if clearly indicated. Breastfeeding: No data exist on excretion of dydrogesterone in mother's milk. Experience with other progestogens indicate that progestogens and the metabolites pass to mother's milk in small quantities. Whether there is a risk to the child is not known. Therefore, dydrogesterone should not be used during the lactation period. Fertility: There is no evidence that dydrogesterone decreases fertility at therapeutic dose. **ADVERSE REACTIONS:** The most commonly reported adverse drug reactions of patients treated with dydrogesterone in clinical trials of indications without estrogen treatment are migraines/headache, nausea, menstrual disorders and breast pain/tenderness. Undesirable effects in adolescent population: Based on spontaneous reports and limited clinical trial data, the adverse reaction profile in adolescents is expected to be similar to that seen in adults. Undesirable effects that are associated with an estrogen-progestogen treatment (see also 'Warnings and Precautions' and the product information of the estrogen preparation): Breast cancer, endometrial hyperplasia, endometrial carcinoma, ovarian cancer; Venous thromboembolism; Myocardial infarction, coronary artery disease, ischemic stroke. Issued on: Date (27/06/2018). Source: Prepared based on full prescribing information (version 6) dated 27/Jun/2018. ® Registered Trademark of the Abbott Products Operations AG.

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