FEMISA
Fibroid Embolisation: Information, Support & Advice

PRESS RELEASE
Embargoed until 14th March

PATIENT GROUP CONDEMNS NICE REVISED HEAVY MENSTRUAL BLEEDING GUIDELINES AS UNSAFE FOR WOMEN

MANY MORE WOMEN WILL DIE AND SUFFER SERIOUS COMPLICATIONS WHILE GYNAECOLOGISTS INCREASE SELF-REFERRALS

The revised NICE Clinical Guidelines on Heavy Menstrual Bleeding [HMB], (which includes fibroids) launched today is unsafe for women. Many more women will die or suffer serious complications and suffer symptoms for longer as a result of the changes. Informed choice for women and access to safer, less invasive alternatives to hysterectomy will be reduced and safeguards for women have been removed. These guidelines, run for NICE by part of RCOG *, promote the interests of and self-referral to gynaecologists at the expense of safety for women and greatly increased cost to the NHS.

- Hysteroscopy is recommended as a first line hospital diagnosis for heavy menstrual bleeding instead of ultrasound. 180 women a year die in the NHS in England from hysteroscopy [i] and a further 3,000 [ii] women suffer serious complications. If hysteroscopy is to be used as a first line hospital diagnosis these deaths and serious complications could double or triple to over 500 deaths and over 8,000 serious complications each year.[iii] It is also excruciatingly painful for some women and requires at least a day off work [iv] Ultrasound and MRI are much safer, cheaper and quicker and visualise the whole abdomen.
- Hysterectomy can now be used as a first-line treatment. The previous version of the NICE Guidelines stated "*Hysterectomy should not be used as a first line treatment solely for HMB".* It also advocated the least invasive approach e.g. vaginal rather than abdominal. In the new version this has been removed. Over 180 women die in the NHS in England from hysterectomy each year [mortality rate 0.6% HES] and over 2,000 suffer serious complications. These figures will rise significantly with the rise in hysterectomies. [v]
- Gynaecologists have no training or education in the safer less invasive treatment for fibroids uterine artery/fibroid embolisation [UAE/UFE] performed by Interventional Radiologists[vi] and these Guidelines have not

recommended multi-disciplinary fibroid clinics where gynaecologists and interventional radiologists work together so women can be fully informed about all treatments. Many will only be offered hysterectomy.[vii] Recommendations have also been removed that women should be sent information on all possible treatment before their outpatient appointment, further reducing informed choice for women.

- Healthy ovaries can now be removed. In the previous version of the NICE Guidelines it stated that *"Removal of healthy ovaries at the time of hysterectomy should not be undertaken".* This has been removed so many more women will be '*persuaded*' to have oophorectomy to save them from cancer and suffer many side effects including instantaneous menopause.[viii]
- The new Guidelines recommend endometrial ablation should be used to treat fibroids >3cm, when this has only been formally assessed for safety and efficacy for small fibroids <3cm.
- Magnetic resonance guided ultrasound [MRgFUS], a non-invasive interventional radiology treatment has been positively assessed by NICE for safety and efficacy, but has been completely left out, so women will have great difficulty accessing it.
- Diagnosis has been recommended only after pharmaceutical treatments have been tried. These should be given while diagnosis is taking place. For women with fibroids, medicines only offer temporary relatively short-term relief from symptoms and this will delay treatment and women will suffer for longer.

Ginette Camps-Walsh the co-ordinator of FEmISA said "***The previous NICE Guidelines on HMB [2007] made significant advances in giving women access to safer, less invasive treatments that enabled women to retain their fertility with alternatives to hysterectomy as a first line treatment for heavy menstrual bleeding and fibroids >3cm.***

The new recommendations are not patient centred, promote old, less safe, very invasive procedures, particularly hysterectomy, which have never been reviewed for safety or efficacy, have a higher complication and death rate and are more expensive to the women, their families, their employers and the NHS. This is a very regressive step for women and the NHS and we condemn it."

FEmISA estimates that the increased costs to the NHS, women and their families is unsustainable – an additional £60 million p.a. for increased hysteroscopy alone. These recommendations are not cost effective for the NHS and particularly not for women. [ix] On the other hand, £61 million p.a. could be saved if 60% of the hysterectomies for fibroids were replaced by UAE and a further £76 million savings from earlier return to work after UFE compared with hysterectomy. [x]

ENDS

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INFORMATION FOR EDITORS

***NICE Clinical Guidelines on Heavy Menstrual Bleeding**

NICE subcontracts the management of guidelines and other outputs to outside organisations and this is paid for by taxpayers. These guidelines were managed by the National Collaborating Centre for Women's and Children's Health, which is part of the Royal College of Obstetrics and Gynaecology and reports to their Board. Many clinical specialities are involved in the diagnosis and treatment of HMB and fibroids e.g. pathologists, radiologists, ultra-sonographers, radiographers, pharmacists, GPs, Interventional Radiologists etc as well as gynaecologists. Although two of the hospital treatments for fibroids are performed by Interventional Radiologists and not gynaecologists the review committee consisted of 1 GP and the rest were gynaecologists and gynae nurses. After protest from FEmISA and others an Interventional Radiologist was co-opted. No other clinical specialities were involved and this knowledge gap is quite apparent in the results - https://www.nice.org.uk/guidance/gid-ng10012/documents/committee-member-list-2

INCIDENCE OF FIBROIDS

Uterine fibroids or leiomyomata are the commonest benign tumours in women of reproductive age. Up to 80% of women develop uterine fibroids with 25-30% developing symptoms that need treatment. The peak incidence occurs between 35 and 40 years old.
64,500 women in England are diagnosed each year with fibroids and structural abnormalities of the cervix and other parts of the reproductive tract.

NICE CLINICAL GUIDELINES ON HEAVY MENSTRUAL BLEEDING

There are 4 in-patient treatments for fibroids –

Hysterectomy – removal of the uterus/womb either with or without the cervix. This is the least safe, most expensive and most common treatment. The women becomes infertile and has early menopause. It has never been formally reviewed for safety and efficacy.

Myomectomy – removal of the fibroid alone either abdominal or by hysteroscopic approaches. It allows a woman to retain her fertility. This has never been formally reviewed for safety and efficacy and the mortality and serious morbidity rate is unknown.

Uterine Artery/Fibroid Embolisation [UAE/UFE] – is newer treatment performed by Interventional Radiologists since 1980s. It has been formally, positively reviewed by NICE for safety and efficacy, is minimally invasive and has a very mortality rate – no reported deaths at all in recent years. A woman retains her fertility. The hospital stay is overnight and the return to work much sooner than hysterectomy or myomectomy.

Magnetic Resonance guided Focused Ultrasound [MRgFUS] - This is an Interventional Radiology minimally invasive treatment reviewed positively by NICE for safety and efficacy.

For more information see the FEmISA web site -
http://www.femisa.org.uk/index.php/about-fibroids

Old NICE Clinical Guidelines on Heavy Menstrual Bleeding 2007 -
https://www.nice.org.uk/guidance/CG44

Revised NICE Guidelines on HMB - https://www.nice.org.uk/guidance/indevelopment/gid-ng10012

***These links may be changed by NICE*.**

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REFERENCES

[i] NHS – HES ONS hospital mortality data

[ii] The incidence of fluid overload - 1.6% and 2.5% (Agostini A 2002a; Overton 1997), uterine perforation is 0.014%, and infectious complications account for 0.3% to 1.6% of cases (Bradley 2002) average 3.14%

[iii]

Hysteroscopy	No. Procedures p.a. [HES]	Mortality @ 90 days [i]	Mortality Rate [i]	No. Serious Complications - rate 3.14% [ii]
Current				
Diagnostic	55,377	148	0.3%	1,739
Therapeutic	31,573	32	0.1%	991
Total	86,950	**180**		**2,956**
Projected x 2				
Diagnostic	110,754	296	0.3%	3,478
Therapeutic	63,146	64	0.1%	2,147
Total	173,900	**360**		**5,913**
Projected x 3				
Diagnostic	166,131	444	0.3%	5,648
Therapeutic	94,719	128	0.1%	3,220
Total	260,850	**572**		**8,869**

[iv] Increased mortality and morbidity from hysterectomy as first line treatment for HMB

Hysterectomy	No. Procedures p.a.	Mortality @ 90 days	Mortality Rate	No. Serious Complications -	Serious Complication Rate Maresh
Current					
Abdominal	31,086	**176**	0.6%	**1,430**	4.6%
Vaginal	7,236	**6**	0.10%	**514**	7.10%
Projected +20%					
Abdominal	37,303	**211**	0.6%	**1,716**	4.6%
Vaginal	8,683	**7**	0.10%	**617**	7.10%
Projected +30%					
Abdominal	40,412	229	0.6%	**1,859**	4.6%
Vaginal	9,407	8	0.10%	**668**	7.10%

*Maresh et AL –The VALUE national hysterectomy study: description of the patients and their surgery 202

[iv] **PAIN FOR WOMEN FROM HYSTEROSCOPY**

Hysteroscopy as a first line diagnosis for fibroids and endometriosis is unacceptable. It is very painful for many and not appropriate as an outpatient treatment.
It has been described by Lyn Brown MP (West Ham) (Lab): in a parliamentary debate in 2013 from their women constituents experiencing it as 'absolute agony' and Ms Brown went on to say "*This procedure, without anaesthesia, is barbaric. It is absolute torture. It needs to be stopped. At the very least, the patient should be informed that it could be extremely painful and have options explained and open for her. That way, she can make an informed decision as to whether to go ahead without anaesthesia.*"

Another patient was given a hysteroscopy under local anaesthetic and commented - "the procedure was still very uncomfortable and painful. I have to say that I think offering a hysteroscopy without any form of anaesthetic is barbaric."

Another woman asked about the pain said" it was excruciating". There are many more such quotes directly from women who have experienced hysteroscopy.

Bob Stewart MP : May I ask what percentage of women feel no pain whatsoever?

There was no answer at the time, it is probably none – there are no women who do not suffer pain.

[vi] **FEmISA Report - Patient Choice and Nice Compliance for Fibroid Treatment -**
http://www.femisa.org.uk/images/femisa%20report%20on%20patient%20choice%20and%20nice%20compliance%209.17%20-%20final.pdf
[vii] **Women's Health APPG Report** -
https://static1.squarespace.com/static/5757c9a92eeb8124fc5b9077/t/58d8ca34f7e0ab027a19247c/1490602579808/APPG+Womens+Health+March+2017+web+title.pdf

[viii] The incidence of ovarian cancer is 2% (Cancer Research UK)

[ix] **COST – HYSTEROSCOPY IS NOT COST EFFECTIVE**

The NHS Tariff for an abdominal ultrasound is £40 for hysteroscopy is £340. This 'excruciatingly painful and 'barbaric' procedure as well as being very expensive to women also costs the NHS and taxpayer is 850% more expensive. There are currently 55,377 diagnostic hysteroscopy procedures and 31,573 therapeutic ones pa. with a total cost of **£29.5 million**. If all women with suspected structural abnormalities were given hysteroscopy instead of ultrasound this figure is likely to double or triple as per model in comment 3. **64,500 women are diagnosed each year with fibroids and structural abnormalities of the cervix and other parts of the reproductive tract.**

It would also be expensive for women, their families and employers, as ultrasound is a quick non-invasive procedure taking a few minutes, while hysteroscopy even in outpatients is likely to require a whole day off work and require a family member too escort them.

[x] See Cost comparison on the FEmiSA web site - http://www.femisa.org.uk/index.php/cost-comparisons