

**West London
Menopause and PMS Service**

**SERVICE DEVELOPMENT &
GUIDELINES**

June 2007

Mr Nick PANAY & Claire BELLONE

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Mr Panay works across two hospital sites: The Queen Charlotte's & Chelsea Hospitals and Chelsea & Westminster Hospital. The combined service has been called the '**West London Menopause and PMS Service**'. The philosophy of care is based on the principles outlined by the:

**International Menopause Society Position Statement:
Recommendations on Postmenopausal Hormone Therapy 2007¹**

Mission Statement

The aim of the West London Menopause and PMS Service will be to provide a tertiary referral service for patients from primary and secondary care. Over the next five years the service will develop to provide the following:

1. By collaborating with relevant specialists such as reproductive medicine specialists, breast surgeons, cardiologists, psychiatrists and rheumatologists and geriatricians, the service will function in a truly multidisciplinary fashion so that patients can receive the best advice possible.
2. Menopause Nurse Specialists will be involved with the running and development of the service, liaising with primary and secondary health care professionals. The CNS will attend and support outreach clinics as these are developed.
3. A truly professional clinical trials unit will run in parallel with the NHS service. This will enable the efficient running of trials under 'good clinical practice' (GCP). Revenue raised will be channelled into the funding of research fellows and nurses to conduct studies of true scientific merit.
4. Funding would be raised concomitantly from conventional sources such as the MRC and Wellbeing for Women (WoW), applications being supported by the strong reputation of the Queen Charlotte's, Hammersmith and Chelsea & Westminster Hospital's research facilities. Ultimately, the aim will be to produce a menopause and PMS unit of international standing and respect.

¹ Pines A, Sturdee DW, Birkhauser MH, Schneider HP, Gambacciani M, Panay N. IMS Updated Recommendations on postmenopausal hormone therapy. *Climacteric*. 2007 Jun;10(3):181-94.

Menopause and PMS Service at Chelsea & Westminster

1. Clinical Team and Personnel

1.1 Multi Disciplinary Team. Lead Clinician: Mr Nick Panay

Mr Nick Panay is Consultant Obstetrician and Gynaecologist at Queen Charlotte's and Chelsea Hospital, Chelsea & Westminster Hospital and Honorary Senior Lecturer at Imperial College London. He is also Director of the West London Menopause and PMS Centre. He qualified from University College London and trained under Professor Studd at the Chelsea and Westminster Hospital. He leads a medical team from primary and secondary care with a commitment to research particularly in the area of PMS, include the study of evidence based alternative treatments and the avoidance of progestogenic side effects in conventional treatments using tissue selective agents.

Clinics	Menopause clinic – 24 patients. 6NP:18FU (Thursday AM) PMS clinic – 12 patients 2NP: 10FU (Thursday PM) POF clinic – 4 patients 1NP: 3FU (Thursday PM) Implant clinics – average 20 patients/week. Clinics run by SpN
Team	Lead consultant, second consultant, research registrar, 2 registrars, SHO, GP attachment, Specialist Nurse. Links with a psychosexual counsellor, psychotherapist and dietician. Administrative and secretarial team
National targets	<ul style="list-style-type: none"> • NP:FU ratio - 1:0.96 • NP referral - currently max 11 weeks and 6 weeks by March 2008 • 18 week pathway to be implemented by May 2007

1.2 Nursing - The nursing service is currently run by a part time Clinical Nurse Specialist. The role is integral to the successful review and development of the service; ensuring innovative ideas are implemented to achieve best clinical practice and national targets.

The CNS requires advanced clinical knowledge, skills and competencies supported by ongoing training. The CNS manages her own caseload under the supervision of Mr Panay and runs nurse lead implant clinics. It is also expected that the CNS will review and prioritise all new referrals to the service, see the long standing menopausal patients who come for annual screening and liaise directly with other consultants, Annie Zunz ward and

patients regarding the management and support of women undergoing a surgical menopause.

1.3 Clerical & Secretarial Support - Clerical support is provided by the pre-existing staff who run the gynaecology out patient service. All new patient accesses the service via primary and choose and book or tertiary referral. The service has one dedicated secretary within a the gynaecology secretarial team.

2.0 Allied Health Care Professionals

2.1 Dietician at QC&H - This post was initiated to offer a specialist dietetic service to women attending the clinic. It is funded by Alpro UK Ltd.

2.2 Psychotherapist at QC&H - This post was initiated to offer counselling services to patients attending the clinic specialising in women's health, particularly in the area of young menopause and POF.

2.3 Psychosexual counselling at C&W. This post was initiated to provide psychosexual counselling to all women attending the GOPD, particularly for women undergoing fertility treatment

3. 0 Choose and Book & the 18 Week Treatment Patient Pathway

Referrals will be managed in line with the National targets and PCT agreements. Choose and Book is now live to most GPs. GPs and patients can view clinic service directory and find advice on management in the primary care setting including referral criteria / indicators.

PCT agreement has been obtained to continue long term management to complex cases until their conditions are stabilised and can be appropriately discharged back to primary care e.g.: osteoporosis, PMS, POF and GnRH analogues. Currently all implant patients are seen at C&W (1/3 of the patient activity) and the long term management of this group of patients remain undecided.

When referring for scan appointments patients have a choice to attend alternative providers if local facilities can not accommodate them. We will remain responsible for ensuring patient care is not compromised or delayed and reporting timescales will need to be addressed as part of the 18-week referral to treatment patient pathway.

Both Bone densitometry Dual Energy X ray Absorptiometry - DEXA) and Ultra Sound is currently provided at Chelsea & Westminster. Further Ultra Sound facilities are provided at the South Westminster clinic.

4.0 New Patient Referrals

With the implementation of each target the capacity of the clinic and management of patients within the service will have to be reviewed. It is proposed that the CN reviews all NP referrals to ensure the new referral target and 18 week pathway is optimised. Referrals can be from:

- Local GP's
- Other specialties via consultant referral within the trust
- Tertiary referrals from for the same referring condition
- Tertiary referral from non-trust hospitals e.g. Royal Marsden

Indication Information/ investigation if available to be included in referral letter

5.0 Referral Indicators to Menopause & PMS Service

While the majority of women can be managed in primary care, in the following situations referral may be necessary for investigation and specialist advice about the use of HRT.

5.1 Abnormal Bleeding

Non HRT users

- eg. a sudden change in menstrual pattern, intermenstrual bleeding, post coital bleeding or a postmenopausal bleed

HRT users

Sequential HRT:

- change in pattern of withdrawal bleeds or breakthrough bleeding.

Continuous combined or long cycle regimens:

- Break through bleeding persisting for more than 4-6 months after starting or which is not lessening.
- A bleed after amenorrhoea on a continuous combined regimen
- Ultrasound scan –Ideally transvaginal , reporting endometrial thickness / cervical smear report

5.2 Multiple Treatment Failure

- 3 or more regimens tried. List types of HRT and detail problems

5.3 Venous Thromboembolism (confirmed)

- Personal history, family history of unprovoked event in a first degree relative age <50
- Detail confirmation of history eg venogram, ultrasound, V/Q scan, anticoagulation history, circumstance of event, thrombophilia screen

5.4 Premature menopause / Premature Ovarian Failure (POF)

- Menopause <40. Reason for ovarian failure. FSH, TFTs, BMD, autoantibody screen

5.5 Osteoporosis (treatment and prevention)

- Confirmed or high risk eg early menopause, corticosteroids > 5mg prednisolone/day
- positive family history especially first degree relative
- low body mass index BMD- by DXA if available
- Reporting T & Z scores plus any non-traumatic vertebral fracture
- History of traumatic fracture

5.6 Previous or High Risk of Hormone Dependent Malignancy

- eg breast± ovarian/ endometrial cancer. Details of disease: stage, treatment, family history

5.7 Patient Preference

6.0 Follow-up Appointments

Visit outcomes:

- Discharge
- Patient declines treatment or intervention, eg: advice only and review at 3-6 months then discharge
- Period of watchful waiting, eg: POF, PMS review
- Referral for investigations, eg: USS, hysteroscopy, DEXA, hormone profile
- Addition to waiting list, eg: Treatment Centre hysteroscopy or Mirena IUD
- Decision to treat, eg: commence HRT, prescription, Mirena IUD
- Treatment commenced in clinic and ongoing, eg: implants, GnRH analogue injections or Mirena IUS

- **1st follow-up** should be conducted after **8 weeks** if investigations require review, or after **3 months** in patients starting a new menopausal preparation. Consider discharge if appropriate.
- **2nd follow-up** – consider discharge if established on effective treatment, not requiring further intervention or patient declines intervention. Only if required, subsequent follow-up should be conducted no less than six monthly unless special review is required.
- **Patients stabilised on a menopausal preparation can expect to be discharged back to their GP after 2nd follow-up (typically 9 months after 1st the first appointment)**

7.0 Hospital DNA Policy

In order to optimise capacity and achieve targets the hospital DNA policy will be enforced: 1 DNA and discharge. Patients for GnRH analogues and implants may be an exception to this rule due to the ongoing need for treatment.

8.0 Referral to Dieticians

The menopause brings a whole host of potential nutritional concerns to women, including heart health, bone health, weight management as well as specific menopausal symptoms such as hot flushes and night sweats (vasomotor symptoms), mood swings, irritability, fatigue and poor concentration.

All members of the team are able to refer menopause patients for dietetic counselling and women suffering from PMS, PCOS and infertility are also regularly seen. Women are seen in half hour appointments and can be offered an unlimited number of appointments.

- For specific dietary advice relating to the menopause and PMS – Refer to Nigel Denby at QC&H via dictated letter.
- For general dietary advice – refer to the C&W dietician on an internal request form. This is sent in internal post.

9.0 Referral for Counselling

The Menopause occurs at a time when many aspects of a woman's life are changing both in the home and at work where roles may be changing. Some may feel they can manage the transition themselves but for others this can be more problematic and all aspects of life can suffer.

Referrals can be made directly from clinic via dictated letter to the respective counsellor. They will be seen for as many sessions as are required, usually between 5 to 10 sessions

- **Counsellor at QC&H** - Dani Singer offers one to one counselling to any patient attending the clinic. Issues covered include stress management, relationship difficulties, bereavement, loss of fertility, conflict resolution & some psychosexual issues. In addition, the service offers a series of lunchtime forums for young women who are experiencing an early or premature menopause.
- **Psychosexual counsellor at C&W** - Sarah Porter offers one to one counselling for women attending the clinic and/or their partner. She specifically provides counselling on psychosexual problems. NB: Exclude any physical cause of problem prior to referral. Physical causes may require a gynaecology opinion prior to referral.

10.0 Referral for USS, Urgent Mammogram and Dexa scans

- Indications for DEXA scan are according to RCP / NICE guidelines. (appendix VIII)
- Mammograms are not routinely ordered. (appendix VI)
- USS eg for post menopausal bleeding, ovarian cysts, fibroids etc (Appendix IV)

11.0 Data Entry

Currently notes are being kept in a traditional manner. A proforma for implant & GnRH analogues patients is in place to ensure effective and consistent management of this patient group. It is anticipated to devolve a direct entry database, based on the proforma, to aid auditing of the service and clinical care. A similar model could be devised for management of POF patients, to link up with the existing POF database. Auditing of patient attendance and outcomes can be obtained via LASTWORD.

12.0 Service Development

Although the service is rapidly expanding, the national targets (NP:FU ratios and 18 week treatment pathway) significantly direct the future development of the service. The team is currently funded for a locum consultant, a registrar, and part time specialist nurse; in addition there is an unfunded GP, research fellow and registrar/GP undertaking special skills training. To ensure an ongoing effective and sustainable service, a full service review and subsequent business proposal reflecting best clinical practice guidelines (CPG) and national and local targets will be required and put forward to the trust. This will encompass the following:

- There has historically been a non-funded GP attachment post at Chelsea & Westminster. The GP attachment post offers excellent opportunities to provide a comprehensive community wide service and training for GPs with a specialist interest in menopause.

Menopause care could be equally provided within the community via appropriately supported specialist GPs. The objective will be to improve primary care intervention and management of women on HRT. Demand for a substantively funded integrated women's health/menopause community based service will be evidenced via audit of the referrals to the menopause service. The initial financial support for this GP led project will be sought from industry with a business case put forward to the Trust and PCTs to secure on going funding

- The aim is to have a dedicated Early Menopause Clinic across established at both sites with a national role for managing this group of patients. A small but significant number of patients referred to the menopause service have Premature Ovarian Failure (POF). This will involve discussion and close collaboration with the oncology and reproductive services exploring the possibilities of tissue cryopreservation and ovum donation for these patients.

The Assisted Conception Unit at the Chelsea & Westminster has an established and highly successful reproductive medicine service and experienced in conducting evidence based research. It is proposed to run a joint POF and fertility service with ACU and establish a centre of excellence for the management of POF, with the development of best practise guidelines via the Good Clinical Practice Forum (GCP). Future research and audit opportunities will be identified including widening the current POF research database at Hammersmith & Queen Charlottes Hospital to included women at Chelsea & Westminster.

- The effective management of the menopause and PMS requires the understanding of the complex problems this group of women. The aim of the service is to provide a comprehensive holist approach by developing a multi-disciplinary team of allied specialists with a special interest in the menopause and PMS. Currently available is a counsellor (Dani Singer) and dietician (Nigel Denby) at Queen Charlottes both with a special interest in the menopause, and psychosexual counsellor and dieticians at Chelsea and Westminster.

Other potential contributors include psychiatrists, rheumatologists, physiotherapists, physicians, and breast surgeons.

- With the support of the pharmaceutical industry and charitable links it is planned to develop the service to become a centre of academic and clinical excellence. Educational donations will be placed in the 'West London Menopause and PMS Fund'. The aim is to attract support from more than one sponsor to avoid any conflict of interest and bias towards one company's product(s). Sponsorship would support:

12.1 Research

Junior doctors and nurse specialists will be encouraged to perform quality research and audit within the department hopefully leading to publication and higher degrees.

Scope and requirements for research and audit:

- Funded projects – GP special attachment to develop links with PCT and initiate outreach clinics.
- Funding of research nurse / nurse specialist. To support ongoing research, audit, education and training
- Professional / public relations. Building relationships with other health care services, professionals, patients and the general public. Possible strategies include:
 - Questionnaire to GP's to determine degree of local interest in the menopause and scale of the problem i.e. are they happy with existing service, could they provide more patients and could they look after long term patients. e.g. shared care
 - Targeting of interested GP's as possible sites of associated/out-reach clinics
 - Determination of secondary centres prepared to use clinic as tertiary referral centre / collaborative research
 - Large meetings e.g. in local town hall where the public are invited for education purposes and volunteering for research projects

- Development of the West London Menopause and PMS patient library in collaboration with the volunteers' service.

Current projects include:

Cardiovascular System: Arterial Compliance Work - Collaboration with John Stevenson and Peter Collins at the Brompton Hospital and National Heart Institute

Alternatives to HRT - Isoflavones (Randomised study of Red Clover vs no hormonal treatment for the management of menopausal symptoms in women with a history of breast carcinoma).

Premature Ovarian Failure - The menopause and PMS clinic will focus particularly on women who have had a diagnosis of premature menopause (<40 years of age) as this is a poorly understood and poorly managed area. There will be collaborative links set up with the ovum donation service in the department of reproductive medicine across both sites for work into various aspects of iatrogenic and endogenous premature ovarian failure. Links with the Royal Marsden have already been set up. An MRC grant will be applied for work in this area.

Data base – we have established an POF database of >200 patients. It is aimed at facilitating the development of guidelines, local and national, for the management of these patients.

Endometrial Studies of Women on HRT - Work into bleeding problems on and off HRT will be carried out in liaison with the Institute of Reproductive and Developmental Biology at QCH.

12.2 Training

Mr Panay is the lead support for advanced menopause training within the service with support from the menopause nurse specialists. Clinical service provision aside, one of the primary aims of the tertiary level clinic will be to

provide an opportunity and facilities for training of both junior medical and nursing staff. It is expected that all such junior staff will be supernumerary to requirements for service provision to allow development of a full understanding of menopause and PMS prior to being allowed to interact unsupervised with patients.

Medical & Nurse Distance Learning Courses

- There is now a recognised degree level menopause course associated to the RCN. The menopause nurse will also require to the non medical prescribing course.
- There is the Family Planning module and RCOG modules in menopause available to primary and secondary medical clinicians and nurses. It is expected that all junior doctors attending the tertiary level clinic will have completed this two module course.
- Multidisciplinary learning. The BMS runs an advanced skills training course accessible to all allied clinicians in the field. It is expected that all members of the team attend this course.

In addition to distance learning there will be encouragement for all staff to attend workshops and major conferences such as the annual BMS meeting and clinics will be cancelled accordingly for the big conferences.

- Visitors / Attachments / Multidisciplinary Aspects - Formal links will be established with specialists and interested GP's in order to facilitate a seamless service provision for even the most complex of cases. Current links include:
 - Medical oncologist at the Royal Marsden
 - Consultants in Care of the Elderly, Hammersmith
 - Consultant Breast surgeon at Charing Cross and the Royal Marsden
 - Director of Academic Radiology (specifically interested in DEXA scans) at Queen Charlotte's & Hammersmith and Chelsea & Westminster

- Reproductive Medicine Hammersmith and Chelsea & Westminster

Visitors from other institutions will be encouraged to attend the clinics for their own education

14.0 Charitable Funds & Library

The 'West London Menopause Fund' has been established at Chelsea & Westminster with Nick Panay and Claire Bellone as joint fund holders. Cheques should be made to 'Chelsea & Westminster Health Charity'. The aim is to support on going research and training.

A menopause library has also been established to be an informative resource for patients. The service is supported by hospital volunteers with charitable donations to maintain the library

15.0 Service Aims for 2007 Onward

- Funding for at least one major menopause project to be secured
- Funding for WTE nurse specialist to include research component to role
- Secure substantive recurring funding for research fellow post
- Establish an identifiable Early Menopause clinic - POF clinic
- Audit patient satisfaction of the service via questionnaire
- Ensure sustainability of library service
- Establish substantive funding for GP with special interest & community clinic
- Develop research and audit

Further advice and support

menopause@chelwest.nhs.uk Menopause Nurse Specialist 020 8746 8590

www.menopausematters.co.uk

<http://www.thebms.org.uk> British Menopause Society

www.daisynetwork.org.uk for Premature Ovarian Failure

www.pms.org.uk NAPS – National Association for Premenstrual Syndrome

www.nos.org.uk National Osteoporosis Society

www.womenshealthlondon.org.uk Women's Health Concern

www.nhsdirect.nhs.uk 24hr helpline 0845 4647

www.niceguidance.org.uk/

www.rcplondon.ac.uk Royal College of Physicians

www.eguidelines.co.uk Good Clinical Practice (GCP)

Appendix I Taking a History

Periods, symptoms and contraception

- Date of last menstrual period (could she be pregnant?)
- Frequency, heaviness and duration of periods
- Hot flushes and night sweats
- Vaginal dryness
- Other symptoms
- Contraception

Personal or family medical problems

Breast, ovarian or bowel cancer in close family members

- Have any parents, sisters or brothers or the patient had such cancers?
- If so, at what age did they develop it?

Deep vein thrombosis or pulmonary embolism

- Have any parents, brothers or sisters or the patient had such conditions?
- If so, when and why did this happen?
- Was it after a hip or knee replacement?
- Was the person on the “pill” or pregnant?

Did they have any test to confirm the clot?

- Was the clinical suspicion confirmed?
- Were they treated with anticoagulants such as heparin or warfarin?

Risk factors for heart disease and strokes

- Has the patient already had a heart attack or stroke?
- Have her parents, brothers or sisters had a myocardial infarction or stroke, and, if so, at what age?
- Does the patient smoke, and, if so, how many cigarettes a day?
- Does the patient have hypertension or diabetes?
- Does the patient have a high cholesterol level?

Risk factors for osteoporosis

- Was the menopause before the age of 45 years?
- Has the patient taken systemic corticosteroids for six months or longer?
- Has the patient had anorexia or significant weight loss?
- Does the patient have a family history of osteoporosis (especially in her mother, grandmother or sister)?
- Has the patient had low calcium or vitamin D intake or deficiency, or malabsorption disorders?
- Has the patient already had a fracture? If so, was it from standing height, how did it happen and where was it?

Other

- Has the patient had migraines?
- What medicines are being taken, including herbal remedies and vitamin supplements?
- Is the patient at risk of pregnancy?

What does the patient want?

- Does she want to take HRT?
- If yes, what preparation would she prefer – and by what route?
- If not, what are her most important treatment endpoints?

It is a woman’s evidence-based patient choice to take or not to take HRT or any therapy, and her decision must be recorded in the notes.

Appendix II Investigations & Monitoring

New patients

- All new patients will undergo full gynaecological history (proforma). Physical examination, including breasts and pelvic examination is only performed when clinically indicated. Unnecessary examinations should be avoided as this increases patient anxiety
- Weight, Blood Pressure and BMI will be recorded for screening purposes.

Baseline investigations for new patients may include:

NB: No investigations are mandatory for new patients

- Hormone profile E2, FSH – where menopausal status is uncertain or to monitor response to therapy if patient is having problems which may be related to estradiol dosage (useless with conjugated estrogens)
- LFT's, U&E's – if from history or clinically, liver and / or renal disease are suspected
- Other hormonal investigations e.g. TFT's, prolactin – where clinically indicated
- Pelvic or vaginal ultrasound scan – if history of bleeding irregularities, pelvic pain etc or if indicated from clinical examination. (Appendix IV)
- Pipelle endometrium – where bleeding irregularities have are present. (Appendix IV)
- Hysteroscopy – as pipelle, but where index of suspicion is higher or if cavity abnormality is suspected on ultrasound scan - refer to Gynaecology Rapid Access Service - fax proforma in clinic. (Appendix IV)
- DEXA scans – if significant risk factors are identified according to RCP guidelines – (Appendix VIII)
- Mammograms – according to national guidelines or if clinical suspicion (breast ultrasound more appropriate if <40 years of age) – (Appendix VI)
- Thrombophilia screen - if personal or 1st degree family history of thrombo- embolic disorder. (Appendix V)
- Cardiovascular disease risk markers e.g. lipids, lipoproteins, insulin resistance etc; according to personal and family risk factors (Appendix V)

Follow-up Patients

- Weight, Blood Pressure and BMI will be recorded for screening purposes.
- Pelvic examination only if clinically indicated from patient history.
- Breast examination only if clinically indicated.
- Investigations will be performed according to need as for new patients.

New and Follow-up Research Patients

Examinations and investigations are performed according to requirements of protocol

Cervical Smears

Women between 25 and 64 will be on the national recall for cervical screening. Cervical screening does not need to continue after the age of 64 for women on HRT who have a normal smear history.

Appendix III Guidelines for Prescribing HRT

NB: see site specific pharmacy formulary for menopause products. Prescribing of menopause products will be carried out according to the needs of the individual patient. Patients not already on a menopause product will be counselled regarding the full range of available products which are suitable for them. Some products may not be appropriate e.g. continuous combined HRT for perimenopausal women.

Summary of some of the currently available menopause products:

HRT Grade A and B data for vasomotor symptoms, depression, GU and bone fracture data; preclinical and epidemiological data for cardiovascular and CNS⁶ (Alzheimer's) benefits. Epidemiological and RCT data for DVT risk.

- Sequential – suitable for the perimenopause
- Continuous combined – indications for use: >1 year since last menstrual period or after at least 1 year of sequential therapy

	Benefits	Disadvantages
Oral Estrogens	Compliance and tolerance	Increases LDL Increases SHBG Worse for migraine
Non-oral Estrogen	Reduces LDL Reduces SHBG Better for migraine	Compliance and tolerance
Oral Progestogen	Compliance Only oral natural progestogen is Urogestan	Higher incidence of progestogenic side-effects with synthetic progestogens
Non-oral Progesterone	Less adverse progestogenic side-effects than oral	Compliance and tolerance

Non-oral HRT avoids first pass metabolic effects and can monitor serum estradiol levels and is therefore better than oral HRT but it is more expensive. Patch / gel / implant is down to patient preference. Ultimately compliance is main issue – if oral HRT assures compliance of patient then should be first choice.

Local estrogens – Vagifem / estring / estriol (Premarin & dienestrol are absorbed systemically potentially causing endometrial hyperplasia if unopposed

Vaginal lubricants and dyspareunia

A variety of vaginal lubricants and bioadhesive moisturisers are available and can be bought without prescription eg Replens. Hypo-estrogenic vulva and vagina may be treated with topical estrogen.

Non-HRT products for bones

- **Bisphosphonates** - only afford bone protection (density & fracture data). Refer to NICE guidelines for osteoporosis (appendix XI). Alendronate, risedronate, etidronate, are used in the prevention and treatment of osteoporosis, and also corticosteroid-induced osteoporosis. Limited data suggest that in combination with estrogen when they appear to have a synergetic effect on bone density and gain in bone mineral density is greater than that achieved by either agent alone.
 - **Alendronate** is administered either daily (10mg) or (70mg) once weekly.
 - **Risedronate** is administered either daily (5mg) or (35mg) once weekly.
 - **Etidronate** is given intermittently (400mg, 14 out of every 90 days) with 1,250mg of calcium salts during the remaining 76.
 - **Ibandronate** is administered as a 150 mg film-coated tablet once a month. The tablet should preferably be taken on the same date each month.

The former two are the most potent. All bisphosphonates are poorly absorbed from the gastrointestinal tract and must be given on an empty stomach. Food or calcium containing drinks (except water) inhibit absorption which at best is only 5-10% of the administered dose. The principal side effect of all bisphosphonates is irritation of the upper gastrointestinal tract. Symptoms resolve quickly after drug withdrawal. The question of how long to prescribe a bisphosphonate has not yet been fully clarified since bone mass appears to be maintained after cessation of treatment. Five years treatment with a 2-years "holiday" have been proposed for alendronate, but there may be differences with individual bisphosphonates. This may not be applicable to glucocorticoid-induced osteoporosis.

- **Selective Estrogen Receptor Modulators (SERMs)** - Compounds that possess estrogenic actions in certain tissues and anti-estrogenic in others are called Selective estrogen Receptor Modulators or SERMs. Raloxifene is licensed for the prevention of osteoporosis-related vertebral fracture and is administered daily (60mg). Raloxifene does not treat menopausal symptoms and indeed may induce them and is therefore only suitable for asymptomatic post-menopausal women. It reduces CV markers and the risk of breast cancer in women with osteoporosis. It has no effect on endometrium

- **Parathyroid hormone (PTH)** - Teriparatide (human PTH (1-34) recombinant origin) is identical in amino acid sequence to the biologically active portion of the native hormone (1-34) and 20 mcgs are administered daily by subcutaneous injection. It will be used in cases of severe osteoporosis. No synergy between PTH and alendronate has been found. Indeed the results suggested that the concurrent use of alendronate may reduce the anabolic effects of PTH. Its cost has prevented its use in all but specialist referral centres.

- **Strontium ranelate** - stimulates bone formation and inhibits bone reabsorption. In randomised placebo-controlled trials vertebral and hip fracture were reduced. The most common side effects are nausea and diarrhoea.

- **Calcitriol** - This is the active metabolite of vitamin D and facilitates the intestinal absorption of calcium. Evidence of efficacy is conflicting and the need to measure calcium levels in those receiving therapy limit its use.

- **Calcitonin** - Parenteral calcitonin is expensive and produces side effects such as nausea, diarrhoea and flushing and results in the production of neutralising antibodies in some patients. Its analgesic properties are useful for the pain of acute vertebral collapse. Nasal calcitonin has also been shown to reduce vertebral fractures but is not available in all countries

- **Vitamin D & Calcium** - only afford bone protection (density & fracture data)

Tissue specific agents

- **Tibolone (Livial)** - As for SERMS but also benefits climacteric symptoms and mood/libido (androgenic effect). 10-15% incidence of breakthrough bleeding but no endometrial hyperplasia.

'Natural alternatives'

- **Progesterone cream (Wild Yam)** – RCT data for symptom relief only (not skeletal protection).
- **Red clover** – only in context of study (protocol to be decided) RCT data for favourable effect on climacteric symptoms and bone markers. Theoretical benefit for breast cancer protection.
- **Soya / tofu** – can be recommended as part of diet.
- **Reflexology / aromatherapy / acupuncture** – limited clinical data but useful for some patients.

Appendix IV Problems on HRT

1. Bleeding problems on HRT.

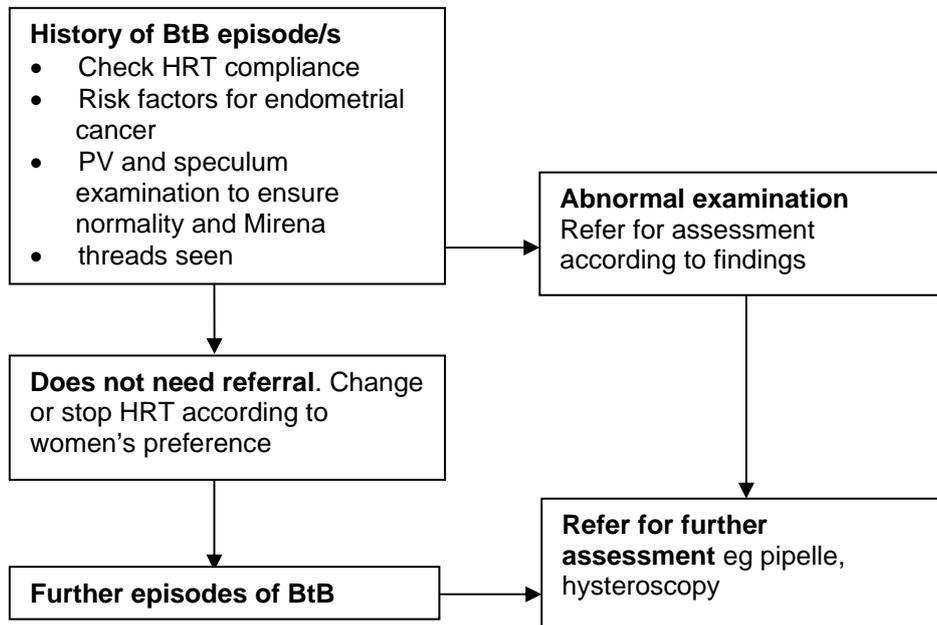
Sequential therapy: If heavy bleeding occurs:

- Increase duration of progestogen (from 12/14 to 18/21)
- Increase dose of progestogen (e.g. NET 5mg to 10mg)
- Change to a more androgenic (C19 eg. NET) from C21 progestogen
- Reduce dose of estrogen (e.g. from 2 to 1 mg)
- If persists > 6 months refer to menstrual disorders clinic for USS +/- OP hysteroscopy. (Appendix IV)

Continuous combined: If breakthrough bleeding (BTB) occurs:

- Allow minimum of 3 months before change in strategy and give reassurance
- After 3 months either continue for further 3 months with same preparation or switch to:
 - Continuous combined with more androgenic progestogen
 - continuous combined with less estrogen
 - tibolone (Livial)
 - sequential HRT

NB: If break through bleeding (BTB) continues for more than six months or if starts de novo when bleed free for 1 year, arrange for urgent ultra sound or urgent referral to Gynaecology Rapid Access clinic for hysteroscopy (fax proforma in OP2)



2. Progestogenic Side Effects

Progestogenic side effects are mainly PMS or androgenic

If "PMS – like" progestogenic side effects occur:

- Decrease duration of progestogen to 10 or even 7 days bearing in mind that the incidence of endometrial hyperplasia increases to 2% and 4% respectively. In this situation surveillance of breakthrough bleeding with USS +/- pipelle is necessary.

If androgenic side-effects occur:

- Decrease dosage of progestogen. In this situation surveillance of breakthrough bleeding with USS +/- pipelle is necessary.
- Use product with less androgenic progestogen ie.C21 rather than C19 progestogen
- Use natural progesterone as progestogenic opposition e.g. cyclogest or crinone
- Use local route; e.g. levonorgestrel releasing intrauterine system (Mirena). If using Mirena warn about breakthrough bleeding and progestogenic side effects in 1st 3 to 6 months.

Progestogens	+ve effects	-ve effects
Androgenic: C19: Levonorgestrel, Norethesterone	Increased libido Increased energy Increased metabolism	Increased hirsutism Increased aggression
Progestogenic: PMS symptoms C21: Dydrogesterone, Medroxyprogesterone	Less Bloating Less irritability Less acne	Increased Bloating Increased irritability Increased acne Increased depression

1. Estrogenic Side Effects

Estrogenic side effects are mainly breast tenderness & nausea

- Use non oral route to allow monitoring of estradiol levels
- Use lower dose of estrogen (especially in over 60's) i.e.1mg rather than 2 mg orally or 25mcg transdermally.

2. Weight Gain with HRT

- There is no evidence from research of increase in weight with HRT. Weight increases with age due to slowing down of basal metabolic rate. Weight distribution also naturally changes to the abdomen as age increases.
- Advice should be given on diet and lifestyle. Referral to the dietician may be of benefit.
- Including testosterone may help increase the basal metabolic rate and aid weight loss.

Appendix V Risks Associated with HRT

1. Breast Cancer Risks^{2,3}

The background risk for women with a mean age of 65 developing breast cancer is 15:1000 over the next 5 years

- For women on combined HRT: 4 extra cases in every 1000 women who use it for 5 years between the ages of 50 – 59 years.
- Estrogen only HRT protects women against developing breast cancer.
- There appears to be no increase in the risk for shorter term use of less than 3 years.
- Estrogen only has a lower risk than combined HRT. The risk with tibolone appears to be similar to that of estrogen only.
- Breast cancer associated with taking HRT diminishes when you stop and is no longer evident after 5 years.

Previously Diagnosed

- Not necessarily a contraindication for HRT- liaise with breast surgeons at CXH) and oncologists at Hammersmith for QCH patients and Royal Marsden for CW patients.
- Weigh benefits v risks according to: symptoms, risks of osteoporosis, cardiovascular disease and dementia v stage, ER status of tumour, node involvement, duration since diagnosis and treatment.

Family History

- Few data: Weigh up pros vs. no of relatives affected.
- Check BRCA 1 & 2 status though these are usually ER –ve and probably not related to increased risk with HRT

Benign Breast Disease

Not a contraindication, though may exacerbate symptoms

Estimated degree of breast cancer risk

High Risk >1 in 4	Action
Breast /ovarian cancer in > 3 relatives	REFER to specialist genetic counsellor
Breast cancer in 3 relatives <40	
average age breast cancer <60	
1 member of family with breast + ovarian cancer	

Medium Risk 1 in 4 - 1 in 8	Action
1st degree relative with breast cancer < 40	Counsel in clinic. No need to refer
2nd degree paternal female relative with breast cancer <40	
1st degree relative with bilateral breast cancer < 60	
2 x 1st / 2nd degree relative with breast cancer < 60 or ovarian cancer	
1st / 2nd degree relative with breast + ovarian cancer	
3 x 1st / 2nd degree relative with breast or ovarian cancer any age	
1st degree male relative with breast cancer	

² Writing group for the WHI Investigators. Risks and benefits of estrogen plus progestin in healthy menopausal women: principal results from WHI randomized controlled trial. JAMA 2002;288(3):321-33

³ The WHI Steering Committee. Effects of conjugated equine estrogen in postmenopausal women with hysterectomy: the WHI randomized controlled trial. JAMA 2004;291(14):1701-12

Low Risk 1 in 8 to 1 in 14	Action
No confirmed history	No specific action required
1 x 1st / 2nd degree relative with breast cancer <60	
2 x 1st/2nd degree relatives with breast cancer, on different sides of family.	
1 x 2nd degree relative with breast cancer	

Ovarian Cancer Risks⁴
19.04.07 from Cancer Research UK⁴

<ul style="list-style-type: none"> • 1300 extra cases of ovarian cancer 1991-2005 • Current HRT users v Never Use HRT RR 1.20 <p>Numbers in Perspective</p> <ul style="list-style-type: none"> • 1 extra case per 2500 users, • 1 extra death per 3300 users
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Endometrial Cancer Risks⁵

	RR	Endometrial Cancer (cases per 1000 women / 5 yrs)
• ccEPT	0.75	2
• seq EPT	1.05	3
• Tibolone	2.02	6
• Oestrogen alone	1.80	5
• Never Use	1.00	3
There is no significant increase in risk if adequate progestogen used		

- If previous history of endometrial carcinoma, as with breast cancer, weigh pros and cons based on symptoms, risk of osteoporosis v differentiation, stage and prognosis of lesion
- Use continuous combined or 12-14 days of appropriate sequential progestogen.

Cardiovascular Disease Risks

WHI Study: Combined analysis CEE / CEE + MPA v Placebo⁶

50-59 yr age group
<ul style="list-style-type: none"> • no increase in risk of CHD / stroke • 30% reduced risk of all cause mortality (10:10000 less deaths) • Significant at P<0.05 level, JAMA changed significance level to P<0.01 • cf70-79yr age group – 16 extra deaths per 10000 women

4 Ovarian cancer and hormone replacement therapy in the Million Women Study. Lancet. 2007 May 19;369(9574):1703-10

5 Beral V, Bull D, Reeves G; Million Women Study Collaborators. Endometrial cancer and hormone-replacement therapy in the Million Women Study. Lancet. 2005 Apr 30-May 6;365(9470):1543-51.

6 Rossouw JE, Prentice RL, Manson JE, et al. Postmenopausal hormone therapy and risk of cardiovascular disease by age and years since menopause. JAMA 2007;297:1465-77

IMS Press Statement 2007

“...these recent results of the WHI and Nurses’ Health Study are in line with the “window of opportunity” theory, which is based on the assumption that estrogen is cardioprotective when the arterial endothelium is still intact.”^{7,8}

Bone Risks^{9,10,11}

Grade A evidence of fracture prevention in both hip and spine

- Bone Benefits maintained many years after stopping HRT
- Bone benefits maintained by ultra low doses of HRT

Venous Thromboembolism (VTE) Risks¹²

- The highest risk is in the first year of use but the absolute risk is small of 1.7 per 1000 in women over 50 not taking HRT
- Additional risk for women aged 50-59 years was 0.8 (WHI)
- Increase in risk of 2 to 4 times baseline risk with HRT and SERMS (typical increase from 15 to 30 per 10 000 per annum)

Mortality – Age Related

Meta analysis of RCTs in women using HRT from 1966 to Sept 2002
26 708 women mean age 54 years.¹³

- Significant reduction in mortality (39%) in women < 60y
- RR 0.61 (CI 0.39 – 0.95)

7 Grodstein F, Manson JE, Stampfer MJ. Hormone therapy and coronary heart disease: the role of time since menopause and age at hormone initiation. *J Womens Health (Larchmt)*. 2006 Jan-Feb;15(1):35-44.

8 Hsia J, Langer RD, Manson JE et al. Conjugated equine estrogens and coronary heart disease: the WHI. *Arch Intern Med*. 2006 Oct 23;166(19):2160

9 Ettinger B, Ensrud KE et al. Effects of ultralow-dose transdermal estradiol on bone mineral density: a randomized clinical trial. *Obstet Gynecol*. 2004 Sep;104(3):443-51.

10 Weinstien RS, Parfitt AM, Greenwald M et al. Effects of raloxifene, hormone replacement therapy, and placebo on bone turnover in postmenopausal women. *Osteoporos Int*. 2003 Oct;14(10):814-22. Epub 2003 Aug 28.

11 Cauley JA, Robbins J et al. Effects of estrogen plus progestin on risk fracture and bone mineral density: the WHI randomised trial. *JAMA* 2003;290(130):1729-38

12 Scarabin PY, Olger E, Plu-Bureau G. Differential association of oral and transdermal estrogen replacement therapy with venous thromboembolism risk. *Lancet* 2003;362:428-32

13 Salpeter SR, Walsh JM, Greyber E, Ormiston TM, Salpeter EE. Mortality associated with hormone replacement therapy in younger and older women: a meta-analysis. *J Gen Intern Med*. 2004 Jul;19(7):791-804. Review.

Appendix VI

Breast Care Management and the Ordering of Mammograms from GOPD ^{14,15,16,17,18,19,20,21,22,23,24,25,26,27}

All women attending GOPD should be routinely asked whether they perform self-breast examination (SBE) and be offered a check and teaching session if necessary. Those women considered at increased risk of breast cancer should be properly identified and monitored at a specialist breast unit:

- Family history of breast cancer
- Family history of ovarian or endometrial cancer
- Past history of significant benign breast disease

Breast density - Some HRT preparations can increase the breast density seen on mammograms. Current evidence from clinical trials suggests that about 1 in 4 women who use combined HRT (estrogen and progestogen) show this increase in density. Estrogen on its own does not appear to affect the density. Tibolone, another form of treatment for menopausal symptoms, does not appear to have any significant effect either. Evidence suggests that the density of the breast prior to starting HRT is the significant factor in cancer risk. (IMS position statement 2007)

Indications for Mammogram

Under 50 years old - Women under 50 are not offered routine screening. Mammograms seem not to be as effective in pre-menopausal women possibly because the density of the breast tissue makes it more difficult to detect problems and because the incidence of breast cancer is lower.

Between 50 and 65 - All women should be registered with the National Breast Screening programme. Patients should be called automatically for the first time between their 50th and 51st birthdays. If a woman has been missed she should be advised to attend her GP and ask

14 Writing Group for the Women's Health Initiative Investigators. Risks and benefits of estrogen plus progestin in healthy postmenopausal women: principal results From Women's Health Initiative randomized controlled trial. JAMA 2002; 288(3): 321-33.

15The Women's Health Initiative Steering Committee. Effects of Conjugated Equine Estrogen in Postmenopausal Women With Hysterectomy: The Women's. Health Initiative Randomized Controlled Trial. JAMA 2004; 291(14):1701-1712.

16 Blanks RG, Moss SM, McGahan CE, Quinn MJ, Babb PJ. Effect of NHS breast screening programme on mortality from breast cancer in England and Wales, 1990-8: comparison of observed and predicted mortality. BMJ 2000;321:665-9.

17 Greendale GA, Reboussin BA, Sie A, et al. Effects of estrogen and estrogen-progestin on mammographic parenchymal density. Postmenopausal Estrogen/Progestin Interventions (PEPI) Investigators. Ann Intern Med 1999;130:262-269.

18 Mandelson MT, Oestreicher N, Porter PL, Taplin SH, White E. Breast density as a predictor of mammographic detection: comparison of interval and screen detected cancers. J Natl Cancer Inst. 2000;92:1081-1887.

19 Litherland JC, Stallard S, Hole D, Cordiner C. The effect of hormone replacement therapy on the sensitivity of screening programmes. Clin Radiol 1999;54(5):285-8.

20 Thurfjell EL, Holmberg LH, Persson IR. Screening mammography. Radiology. 1997;203:339-341.

21 Raafat AM, Hofseth LJ, Li S, Bennett JM, Haslam SZ. A mouse model to study the effects of hormone replacement therapy on normal mammary gland during menopause. Endocrinology 1999;140:2570-2580.

22 NHS Breast Screening Programme. NHS BSP 1999 review. Sheffield:NHS BSP, 1999.

23 Collaborative group on hormonal factors in breast cancer. Lancet 1997;359:1047-59.

24 Shairer C, Lubin J, Troisi R, Sturgeon S, Brinton L, Hoover R. Menopausal estrogen and estrogen-progestin replacement therapy and breast cancer risk. JAMA 2000;283:485-91.

25 Ross RK, Paganini-Hill A, Wan PC, Pike MC. Effect of hormone replacement therapy on breast cancer risk: estrogen versus estrogen plus progestin. J Natl Cancer Inst. 2000;92:328-332.

26 Magnusson C, Baron JA, Correia N, Bergstrom R, Adami H-O, Persson I. Breast cancer risk following long term oestrogen and oestrogen-progestin replacement therapy. Int J Cancer. 1999;81:339-44.

27 British Association of Surgical Oncology guidelines. Eur J Surgical Oncol 1998: 24, 464-76.

for referral. If this is not possible she should be asked to contact the regional screening centre at Charing Cross Hospital. A note should be made of their response and what the result was.

Screening is especially important if a woman is on estrogen therapy and **over the age of 50**. Screening is not necessary before the age of 50 as it is the additional years of exposure to estrogen that is of concern.

Over the age of 65 - If the patient is on HRT and over the age of 65 the GP should be advised to continue sending the women for 3 yearly mammograms.

Other possible indications and what to do.

Symptomatic / Lump - Refer urgently to a breast surgeon for assessment within new national guidelines of two weeks. They will have immediate access to mammography and ultrasound \pm fine needle aspirate as appropriate.

Fax a written letter directly to Mr Gui or Mr Sacks, via the secretary, at the Royal Marsden Hospital. DO NOT dictate on to a normal clinic tape as the patient must be SEEN within two weeks. Tel: 020 7808 2783 Fax: 020 7808 2673

Past history of benign breast disease or lumps - Only a past history of "ductal" or "lobular atypia" increases the incidence of future malignancy, so this is very specific. These patients should be being followed up by their own breast surgeon. If not, make a request via the GP.

Opportunistic - The patient who has never had a mammogram and does not appear to be in the screening program; advise to join screening programme via GP.

Anxiety - The anxious patient >50 – reassure and advise then to speak to their GP to be registered with the national breast screening programme. The anxious patient <50 - reassure and advise / teach self breast examination.

Past history of breast cancer or gynaecological cancer which may be linked or estrogen dependent - These women should be being followed up by their oncologist or breast surgeon, who should be arranging appropriate imaging as necessary. If not write to the consultant who looked after the patient, request further information, and what further monitoring is appropriate.

Family history of breast cancer - 90% of Breast cancer is sporadic, not familial, so most people are not at an increased risk. We should only be seeing the "low risk" women. If there is a significant increased risk by the guidelines (see below), then refer to a clinical geneticist for appropriate counselling as to whether there is a real increased risk and whether testing for the BRCA genes is appropriate. If a real increased risk is identified these women should be followed up by a breast surgeon. Write a letter to the clinical geneticists at the Kennedy Galton Centre, at Northwick Park Hospital. There is also a centre at the Royal London Hospital.

Appendix VII Hormone Implants

Hormone implants are a slow release crystalline formulation, which gradually dissolves and is absorbed from the subcutaneous tissue. They are designed to last six months, but there is a residual effect from remaining pellets continuing to release hormone. This may last up to 12 months and can lead to a gradual increase in plasma hormone levels, particularly Estradiol.

Plasma Estradiol levels - this should be within the range 200-800pmol, max 1000pmol/l. Because of the risk of Tachyphylaxis, any woman with levels above 1000pmol/l should NOT be re-implanted at the Implant clinic. She should be

Frequency of implant - Implants should not usually be given at any shorter intervals than six monthly. No patient should be allowed to book an appointment for repeat implantation for less than six months unless agreed by a senior clinician. If problems arise an appointment can be made for them in the Menopause Clinic.

Estradiol implant dose - The standard dose of estradiol implant is 50mg, although 25mg is often adequate. This should only be increased in exceptional circumstances, by a senior clinician. Any patient currently on >50mg estradiol should be offered only 50mg estradiol at their next appointment with "top up" as necessary and the reasons explained. If there are further questions they should be referred to the Menopause Clinic. A 25mg estradiol implant should be considered for women over the age of 60.

Tachyphylaxis - Some women are sensitive to the rate of decline of estradiol in their system and present earlier than six months with menopausal type symptoms. This may also occur if too higher a dose is being given or if the frequency is less than 6 months. The women usually have supra physiological plasma estradiol level, >1000pmol, high despite symptoms. No further estrogen implants should be given until levels fall below 1000pmols and offered alternative "top up" therapy and referred to a senior menopause clinician at the Menopause clinic for review.

"Top up" therapy - use of low dose Estradiol gel (0.5-1.0mg daily) or estradiol patches (25 or 50 mcg/24 hrs - apply one patch twice a week) to relieve symptoms whilst awaiting the decline of the plasma Estradiol or awaiting the next implant. "Top up" treatment can be offered if the patient becomes symptomatic before 6 months. Any "top up" treatment offered should be clearly documented. "Top up" treatment used should be recorded at each consultation as this will affect the plasma estradiol level.

Testosterone implants - Indications for Testosterone are lack of energy and loss of libido. The standard dose of testosterone implant is 100mg, although 50mg or even 25mg may be used. Use is decided on a patient by patient basis. Patients can always be referred to the Menopause clinic for discussion. Patient response is variable and some women may require a lower dose if they experience hirsutism, aggression, excessive libido or male pattern baldness.

Checking plasma levels - Estradiol +/- testosterone & SHBG levels should be estimated annually in women who are stabilised on implants but six monthly initially and if there is any doubt regarding response. Blood levels should be taken at the end of 6 months

Discontinuation of Estradiol implants - It is essential to ensure that women who have been on implant therapy and who have an intact uterus continue their progestogenic opposition for **at least two years** after their last implant or until E2 is <100pmol. Continued release of estrogen from remaining implants could cause endometrial hyperplasia if unopposed. Periodic serum estradiol levels will guide how long progestogen should be continued.

Bone mineral densitometry - is usually not indicated in women on long term implants, as it will be higher than most other women of their age. However, it may be indicated if implants are being used in the management of eg: osteoporosis or premature menopause.

Follow-up - patients should be reviewed in the menopause clinic every five years from the date of commencing implants.

Training - all new clinicians to the clinic must have supervised practice until competency to insert implants has been gained.

Insertion Technique for Estrogen and Testosterone Implants

- Ensure another nurse present
- Ensure relevant sterile equipment and drugs available
- Ensure availability of anaphylaxis/resuscitation equipment
- The procedure should be performed under full aseptic no touch technique
- Implant should be inserted subcutaneously into an area where there is relatively little movement or blood supply such as the lower abdominal wall or buttock.
- The patient is placed in a comfortable position according to the site chosen either supine with lower half of abdomen exposed or L or R lateral if buttock chosen
- Clean skin with antiseptic solution/wipe
- Use a 5ml syringe containing 0.5ml of 2% Lignocaine and an orange needle to raise a skin bleb of local anaesthesia subcutaneously above insertion site
- Allow time for the anaesthesia to work – check this with patient by checking sensation with a clean needle on the surface of the skin, also check throughout procedure by asking patient
- Make a 0.5cm skin incision over the skin bleb using a scalpel
- Push the trocar and introducer under the skin into the subcutaneous fat along anaesthetised tract for a distance of 5cm
- Remove the trocar and use sterile forceps to insert the hormone pellet into the introducer and push the pellet to the end of the introducer with the trocar.
- **Always insert estrogen FIRST and testosterone SECOND to reduce risk of extrusion**
- Remove the trocar and introducer from incision, appose skin edges and use a fine dissolvable suture or steristrips to close the wound (this will depend on patient preference/or the presence of any allergies)
- Cover with an appropriate wound dressing
- Record details of procedure in woman's medical records and sign notes

Appendix VIII

Osteoporosis Risks and Dexa Scan²⁸ (Bone Mineral Density)

Osteoporosis means “porous bones” or thinning of the bones so that they become more fragile and break more easily. Osteoporosis is not painful at an early stage and is often undiagnosed until a fracture occurs, commonly at the wrist, spine or hip. Bone is built up during childhood, adolescence and young adult life usually reaching maximum density in the early thirties. In later life bone slowly gets thinner, particularly in women after the menopause when the ovaries no longer produce estrogen. Before the menopause this hormone is important for bone health and protects the bones against thinning.

Risk factors for osteoporosis

- Genetic - Positive family history especially first degree relative
- Constitutional - Low body mass index, Early menopause (<45yr of age)
- Environmental - Cigarette smoking, Alcohol abuse, Low calcium intake, Sedentary life style
- Drugs - Corticosteroids, > 5 mg prednisolone or equivalent daily
- Diseases - Rheumatoid arthritis, Neuromuscular disease, Chronic liver disease, Malabsorption syndromes, Hyperparathyroidism, Hyperthyroidism, Hypogonadism

Indications for densitometry

- Any estrogen deficient postmenopausal woman who would want to be treated or would want to continue treatment if found to be osteopenic or osteoporotic.
- Patients suspected to be osteoporotic or osteopenic on X-ray, or clinically through height loss. Patients > 50 who have experienced any low impact fracture eg Colles.
- Patients who have a medical condition predisposing to osteoporosis if effective treatment is available, eg metabolic bone disease, thyroid disease, liver disease, anorexia nervosa,
- Malabsorption syndromes and other rarer causes of osteoporosis.
- Patients using systemic corticosteroids of a projected duration of 3 months or greater.
- Estrogen deficient women who experience primary amenorrhoea or secondary amenorrhoea (including hysterectomy) below the age of 45 years.
- Patients with a positive family history of osteoporosis – including significant height loss - in at least one first degree relative and particularly if maternal hip fracture.

Interpretation of Bone Mineral Density results

Category	Fracture Risk	Action
Normal	BMD >-1SD below	Below average Nil. Young adult mean i.e. T score > -1
Osteopenia	T score <-1 but >-2.5	Above average HRT or alternative. Watch, correct risk
Osteoporosis	T score <-2.5	High Exclude secondary causes. Consider therapeutic intervention
Severe osteoporosis	T score <-2.5 and prevalent	Established clinical Specific treatment with agents fragility fractures osteoporosis known to reduce fractures

Interventions for the prevention and treatment of osteoporosis in the spine and hip

- Bisphosphonates: Etidronate, Alendronate, Risedronate, Ibandronate
- Calcium and Vitamin, Calcium, Calcitriol, Calcitonin
- Estrogen
- Selective Estrogen Receptor Modulators (SERMS)
- Parathyroid hormone peptides

²⁸ NICE 2005. Osteoporosis - secondary prevention: Quick reference guide. <http://guidance.nice.org.uk/page.aspx?o=412034>. Jan 2005