CURRICULUM VITAE

MRS. VINAY SHARMA

MBBS, DCH, FRCOG, PhD, Hon PhD

Consultant in:

- Benign gynaecology
- Gynaecological Endocrinology
- Reproductive Medicine & Surgery
- Assisted Reproduction Technologies (ART)
- Fertility Preservation

FULL-TIME NHS APPOINTMENT (August 1991- February 2017)
Consultant Obstetrician & Gynaecologist & HFEA Person Responsible
The Leeds Centre for Reproductive Medicine *(now Care Fertility, Leeds)*
Leeds Teaching Hospitals NHS Trust
Seacroft Hospital, York Road, Leeds LS14 5UP

RETIRED FROM CLINICAL PRACTICE: On 31ST OF Dec 2024
IN FULL-TIME MEDICO-LEGAL PRACTICE: From 1st of Jan 2025

PROFESSIONAL PROFILES

1. Mrs Vinay Sharma : Obstetrics and gynaecology (bupa.co.uk)
2. C:\DOC\MSS\Vinay_CV (newa.expert)
3. https://www.researchgate.net/profile/Vinay-Sharma-18

Formerly:
Consultant Obstetrician & Gynaecologist
& HFEA Person Responsible
The Leeds Centre for Reproductive Medicine *(now Care Fertility, Leeds)*
Leeds Teaching Hospitals NHS Trust
Seacroft Hospital, York Road
Leeds LS14 5UP
Retired from NHS March 2017
&
Retired from Private Clinical Practice on 01.01.2025

CARDIFF UNIVERSITY BOND SOLON Civil Expert Witness Certificate ACHIEVED 2022

AI Expert Witness Awards 2024
Winner!
Mrs Vinay Sharma Ltd
Best Gynaecological Pathology Expert Witness 2024 (UK): Vinay Sharma

BIO-DATA:

NAME: SHARMA Vinay

DATE OF BIRTH: 9.3.53

NATIONALITY: British

ADDRESS: Hi-View, 131 Alwoodley Lane, Leeds LS17 7PG

TELEPHONE Nos: Mobile Nos: 0777 9137 169 & 0752 5182762

Please leave an SMS message or send an email if we do not answer.

EMAIL ADDRESSES: vinay@mrsvinaysharma.com; Preferred Microsoft 365 address mrsvinaysharma@hotmail.com

REGISTRATION:

- **GMC Registration Full:** No. 3035566
- **MY DESIGNATED BODY FOR REVALIDATION:**
  Independent Doctors Federation, Lettsom House, 11 Chandos Street, London W1G 9EB
- **National Insurance No.** WL 432012C
- **Fellow of the Royal College of Obstetricians and Gynaecologists:** Reg no 11119

EDUCATION AND QUALIFICATIONS

1. UNDERGRADUATE HONOURS & DISTINCTIONS

1.1. **Pre-University examination, 1970**

1.1.1. Distinction in Physics & Chemistry

1.2. **Pre-Medical examination, 1971**

1.2.1. First in the University among girls

1.2.2. Fifth position in the overall honours list

1.2.3. Distinction in Physics & Chemistry

1.3. **First MBBS examination, 1972**

1.3.1. Silver Medal in Anatomy

1.3.2. 2nd Prize in Physiology

1.4. **Second MBBS examination, 1972**

1.4.1. Bronze Medal in Social and Preventive Medicine

1.5. **Final MBBS examination, 1974**

1.5.1. College Council Gold Medal for being the best graduate of session 1970-76

1.5.2. Certificate of Merit awarded by the University

1.5.3. Gold Medal in General Surgery

1.5.4. Silver Medal in General Medicine

1.5.5. Bronze Medal in Ophthalmology

2. POSTGRADUATE DEGREES:

2.1. **FRCOG**: Awarded in September 1997

2.2. **MRCOG**: July 1984

2.3. **DCH**: September 1979

2.4. **Ph.D. (London):**November 1995

Title: Endocrine factors affecting the outcome of assisted reproduction.

3. MEDICO-LEGAL QUALIFICATIONS:

The Cardiff University Bond Solon (CUBS) Expert Witness Civil Certificate (2022)

In the Cardiff University Bond Solon (CUBS) [Civil, Criminal, Family] Expert Witness Certificate I have undergone the following Bond Solon expert witness training courses:

- ***Civil Law and Procedure (2022)***
- **Excellence in Report Writing (2022)**
- **Courtroom Skills (2022)**
- **Cross-Examination Day (2022)**

4. OTHER HONOURS AND DISTINCTIONS:

4.1. **Yorkshire Woman of the Year** (unsolicited nomination and election) in the Overall and Career category: 1995

4.2. **Honorary Ph.D.** (Leeds Metropolitan University) Awarded May 1997

4.3. **Nomination** (unsolicited nomination) Asian Woman of the year (2000)

4.4. **Independent member of the Board of Governors (Leeds Metropolitan University)**: August 1997 to 2007 (10 years of service)

4.5. **Awarded the Best Gynaecological Pathology Expert Witness Award 2024 (UK) Vinay Sharma by AI Global Media Ltd**

CURRENT PRACTICE:

I was in Full time private practice as a Consultant in Gynaecology, Reproductive Medicine & Surgery until 31st of March 2024. From 1st of April 2024, I curtailed my clinical service with virtual consultations only and intend to be in Full time Medico-Legal practice from now on

LAST FULL-TIME NHS APPOINTMENT (1991-2017):

Consultant Obstetrician & Gynaecologist & HFEA Person Responsible
The Leeds Centre for Reproductive Medicine (LCRM) **(Now Leeds Fertility)**
Seacroft Hospital, Leeds Teaching Hospitals NHS trust, York Road, Leeds LS14 6UH

MY SPECIALISMS:

This is not an exhaustive list, also refer to Medico-Legal Section below.

1. **CONSULTANT in BENIGN GYNAECOLOGICAL DISORDERS** (e.g., Fibroids, Endometriosis, Pelvic Inflammatory Disease, Menstrual disorders, Early Pregnancy complications and Retained Products Of Conception)
2. **ASSISTED REPRODUCTION TECHNOLOGIES** (IVF, ICSI and other related treatments)
3. **REPRODUCTIVE ENDOCRINOLOGY (e.g., Polycystic ovaries,** menopause**)**

4. **REPRODUCTIVE SURGERY** (Laparoscopic and Hysteroscopic procedures related to Septal and polyp resections, Endometriosis ablation, Ovarian cystectomies, Salpingectomies, Adhesiolysis, Myomectomies and Hysterectomy)

Transitional changes in my Career profile & Scope of practice:

1. On 1st August 1991, I was appointed Consultant Obstetrician and Gynaecologist in St James's University Hospital and Honorary Senior Lecturer in the University of Leeds. I functioned as such until 2005.

2. From 1992-2016, I functioned as the HFEA Person Responsible for Assisted Conception Unit, St James's University Hospital (1992-2010); Leeds Centre for Reproductive Medicine now known as Leeds Fertility or Care Fertility Leeds (2010-2016)

3. **As a Trainee:** Overall, as a trainee gynaecologist between 1982-1991, and as a consultant since 1991, I have close to 40years of medical and surgical experience across the width of my speciality. Before my appointment as a consultant, I had received the *"old school"* comprehensive medical and surgical training in all sub-specialist areas of Obstetrics and Gynaecology. This was when the concept of sub-speciality had not yet emerged. So initially, I practised all sub-specialities.

In 90's and 2000's, our professional body, The Royal College of Obstetricians and Gynaecologists reorganised into sub-specialities. Being in a tertiary hospital as an academic NHS consultant, I adapted and changed with practice evolution ahead of the secondary care district general hospital consultants. The approximate time line of change is below:

4. **As a Consultant in 1991:** I stopped undertaking cancer surgery; our department had a consultant with subspecialist training in oncology that was only available in United States and Scandinavia at the time.

I had founding experience in the subspeciality of Reproductive Medicine & Assisted Conception and hence I became recognised as the lead regional subspecialist and trainer.

I maintained my academic interest, medical and surgical practice in all aspects of Benign Gynaecological Surgery, Obstetrics and Ultrasound in my discipline.

5. **In approximately 2000-1:** In collaboration with a paediatric oncologist, I set up the nation's first Joint clinic for the assessment, monitoring and treatment of adolescents and children who were survivors of cancer and who had received gonadotoxic treatments that had potential to affect their puberty, menstrual nd reproductive potential.

6. **In approximately 2005-6:**

6.1. <u>In Gynecology:</u>

I started developing laparoscopic and hysteroscopic surgical skills whilst maintaining my practice in all disciplines and in open surgery.

Hitherto, I had undertaken gynae-urology surgery and trained many juniors who went on to become Gyane-urologists. However, as I concentrated in Reproductive Medicine and Surgery, gradually this sub-speciality's work in my domain reduced. The Urology sub-specialist clinics were set up to which the patients were directed at referral.

6.2. <u>In Obstetrics:</u>

I stopped labour ward practice in Obstetrics, as I did not have 24hr on site attendance in my timetable. I was already doing an equivalent of 17-18 sessions as per consultant time-table reorganisation system, that trust was legally mandated to reduce.

However, for some years, I continued with antenatal care with a special interest in IVF pregnancies that were often complicated by other intercurrent systemic or abdominal disorders, past medical and surgical treatments, endocrine issues and multiple pregnancy.

7. From 2008-9 until retirement in 2017:

I stopped active obstetrics including antenatal care. However, I remained the *"second on call consultant"* for the labour ward in a gynaecological surgeon's role, supporting the obstetrician in per- and post-operative surgical complications *(i.e., during and after caesarean sections)*.

I medically and surgically managed all disorders that present in benign gynaecology clinics, and as an acute or semi-acute gynaecological emergencies.

I continued with management of pregnancy in the 1st trimester, post-partum complications but excluded management of 2nd & 3rd trimester.

I managed all pregnancies conceived in my care after ART during the 1st trimester in the Assisted Conception Unit at St James's *(for approximately 20 years, Aug 1991-Dec 2010),* in The Leeds Centre of Reproductive Medicine from 2011-2017 and within private practice.

8. Summary of experience in Reproductive Endocrinology, Early Pregnancy, Reproductive Medicine & Assisted Reproduction Technologies (ART):

8.1. As a research registrar and speciality trainee (1984-1991), I worked in the field of Reproductive Medicine & Endocrinology with Professor W Collins *(Biochemist & Endocrinologist)* at Kings College Hospital, London; with mutual agreement interdigitated with Professor H Jacobs *(Physician & Endocrinologist)* by attending his weekly educational meetings. I completed my Ph.D. in 1995 from University of London, with Professor H Jacobs and Prof M Hull *(Gynaecological Endocrinologist)* as examiners.

8.2. I continued my work as a Consultant in Leeds from August 1991.

8.3. Before this, I completed 4 years of general training in Obstetrics and Gynaecology *(the latter 2 years as a registrar at The London Hospital, Whitechapel).*

8.4. Reproductive Endocrinology:

8.4.1. My mainstream work throughout my career, within the NHS and the private sector, before and since my retirement, as a trainee and a consultant, involved endocrinology based gynaecological problems and resolutions.

8.4.2. This included treating girls and women with a wide array of physical, endocrinological and central nervous system manifestations without pelvic pathology in every clinic, day to day.

8.4.3. The age range of my patients in the same clinic varied from adolescence to climacteric and post-menopausal years.

8.4.4. Their objectives for attendance was health often combined with fertility but not solely fertility.

8.4.5. For comprehensive care, I organised myself in a multidisciplinary set-up and in close liaison with other specialists *(e.g., endocrinologists, diabetologists, paediatric endocrinologists and puberty specialists, oncologists, psychiatrists & counsellors).*

9. Summary of Relevant Experience in Early Pregnancy & Assisted Reproduction Technologies (ART):

9.1. I have worked in the field of Reproductive Medicine since 1984 *(King's College Hospital, London 1984-1991)*, and as a Consultant in Leeds since 1991. During my tenure as Consultant in Leeds, I was the HFEA Person Responsible. During the last 30 years, I have conducted and supervised more than 20,000 treatments in Assisted Reproduction Technology (ART; includes IVF, ICSI, Egg, Sperm and Embryo donation, IUI, Ovulation Induction & Reproductive Gynaecological surgery). This will include the management of >5000 pregnancies during the 1st Trimester. During my ART career, I provided a comprehensive service for patients suffering from all forms of sub-fertility and attended to the reproductive health needs of cancer survivors. *(Refer to Section 1.1.7. below)*

9.2. Before starting in this field, I had already completed 4 years of general training in obstetrics and Gynaecology *(the latter 2 years as a registrar at The London Hospital, Whitechapel)*. Before starting in this field, I had already completed 4 years of general training in Obstetrics and Gynaecology *(the latter 2 years as a registrar at The London Hospital, Whitechapel)*.

9.3. **Use of Ultrasound:**

9.3.1. From 1984-91, I was the member of the pioneering team that introduced abdominal scanning in ART for gynaecological baseline assessment, monitoring of response to IVF treatment, ultrasound directed egg recovery, luteal phase, and early pregnancy monitoring in IVF cycles.

9.3.2. In late 1980's, vaginal route for ultrasound scanning was developed by Phillips, USA and I was amongst the leading groups who introduced this technique for scanning in our discipline. I was engaged in teaching and training of many doctors who became consultants in this field. This training was later extended also to the senior appropriately trained nurses.

9.3.3. From 1984 and until I retired as a Consultant from the NHS (1991-2017), i.e., during the last 30+ years as a consultant, I have conducted and supervised more than 20,000 treatment cycles in Assisted Reproduction Technology (ART; includes IVF, ICSI, Egg, Sperm and Embryo donation, IUI, Ovulation Induction & Reproductive Gynaecological surgery).

9.3.4. My role in this speciality included performing 7-10 ultrasound scans during each IVF cycle, and in the first trimester until 12 weeks' gestation.

9.3.5. I published the first and world's largest series on the use of ultrasound in IVF cycles and the factors that affected outcome.

*Riddle AF, **Sharma V**, Mason BA, Ford NF, Pampiglione J, Parsons JP, Campbell S (1987) Two year's experience of ultrasound directed oocyte retrieval. Fertil Steril 48 454.*

***Sharma V**, Riddle A, Mason BA, Pampiglione JS, Campbell S (1988) An analysis of factors influencing the establishment of clinical pregnancy in an IVF programme using ultrasound directed trans-abdomino-vesical route for oocyte recovery. Fert and Steril 49 468.*

9.3.6. **Early Pregnancy Management:**

9.3.7. In 1991, I established, developed, and acted as the lead clinician and as the HFEA person Responsible in the Assisted Conception Unit at St James's Hospital, we have had the statutory obligation to inform the HFEA of all treatment outcomes at pregnancy test, pregnancy outcomes at 12 weeks' gestation and at birth.

9.3.8. From 2010, the Assisted Conception Unit at St James's Hospital merged with the unit in Leeds General Infirmary as The Leeds Centre for Reproductive Medicine (LCRM) that later became known as Leeds Fertility and is now owned by Care Fertility.

9.3.9. From 2010-2017, I was a senior Consultant and the HFEA Person Responsible in this service, performing the same clinical role daily as described in Section 1.1.7. above.

9.3.10. I managed all pregnancies conceived in my care after ART during the 1st trimester in the Assisted Conception Unit at St James's *(for approximately 20 years, Aug 1991-Dec 2010),* in The Leeds Centre of Reproductive Medicine from 2011-2017 and within private practice.

9.3.11. Specifically, as a Consultant Gynaecologist from 1991-2017, I managed all complications of first trimester in pregnancy.

9.3.12. As a Consultant Obstetrician, between 1991-2005/6, I also managed pregnancies in the antenatal care, intra and post-partum period of thousands of women, where I was often called upon to do scans, in the early years also amniocentesis and chorionic villus sampling (CVS).

9.3.13. In 1991, with prior training at Kings College, I introduced ultrasound directed techniques for both amniocentesis and CVS in my hospital, Leeds for an improvement in their safety profile.

9.4. **Retirement from NHS:** I retired from the NHS duties as Consultant in Gynaecology, Reproductive Medicine, Assisted Conception and Benign Gynaecological Surgery in Leeds Teaching Hospitals NHS Trust and Honorary Senior Lecturer in the University of Leeds on 1st March 2017. Since retirement from the NHS, I have remained in active practice of Benign Gynaecology, Reproductive Medicine, and Surgery, including outpatient consultancy work in Assisted Reproduction Technologies (ART) and management of the 1st trimester of pregnancy.

10. **Post retirement collaboration (Oct 2017 – March 2018):** For a period of 6 months, I collaborated with the London Women's Clinic, BMI Woodlands Hospital, Darlington and the London Women's Clinic, 112-113 Harley Street, London with a view to risk assessments and HFEA regulatory issues and exploring the feasibility for more substantive collaborative relationship.

11. **Retirement from Private Clinical Practice:** On 31st of March 2024, I stopped operating and from 31st of Dec 2024, I have stopped accepting private patient referrals for consultations.

CLINICAL EXPERIENCE:

Below I have summarised the key roles I have played in my current post over the last >20 years. Even though I have been active in my academic and research roles throughout my career, I consider myself to be first and foremost **'a service provider'** as an NHS consultant.

Critical events that shaped me: Since my training and appointment as a consultant, there have been many changes in health service to which I have enthusiastically adapted.

1. Technological and medical advancement: Progress has placed increasing demand and consistently outstripped the NHS budget. There is a progressively increasing emphasis on efficiency, safety and quality of services.

2. National adverse events: There have been several national events such as the Bristol and Alder Hey Enquiries that have had a major impact on practice and regulation. There was also a major local incident in another unit, leading to international adverse publicity, liability and national introduction of statutory witnessing procedures.

3. Informed Consent: There is a general public demand for accountability and transparency. GMC explicitly advises the doctors to do all that is necessary to ensure Informed Consent.

With a 'hands on approach' at all levels, I actively developed a safe and compliant service at SJUH to start with and have taken the same ethos to The Leeds Centre for Reproductive Medicine at Seacroft Hospital. I have been committed to constant improvement and have adapted with

change in regulation, service requirements and society demographics. Even when I see my favoured pathway, I have always sought consensus and am a team player. I also understand the difficulties experienced by professionals in simultaneously meeting all of the demands of the public, the regulating bodies and the trust.

In this environment and with the introduction of GMC validation, it is more important than ever before that both the public's and the professional's safety is protected. I feel that my breadth of experience and ethos enables me to be a safe, fair, problem solving and supportive appraiser.

Summary of Experience in Benign Gynaecology, Surgery and Endometriosis :

1. **Training and experience:** As a trainee gynaecologist between 1982-1991, from 1984 at Kings College Hospital, London and as a Consultant Gynaecologist and Obstetrician in Leeds Teaching Hospitals since 1991, I have 40years of experience in managing all benign gynaecological and obstetric disorders.

2. **Obstetrics:** Even though since 2005-6, I have not been engaged in active antenatal obstetric and labour room management, I remained the 2nd on call covering consultant for the labour ward, in a supporting surgeon's role for the obstetricians for advanced surgery such as caesarean hysterectomy, when needed.

3. **Benign Gynaecology:** I provided medical and surgical treatments for all benign gynaecological disorders carefully balancing the benefits and risks of every treatment with appropriate and due emphasis on Informed Consent as recommended by the GMC.

   In my practice, I ensured an inclusion of >1 open and transparent discussions with the patient, where I placed in my patient's domain *(both verbally in consultation and in writing)* all of the published evidence for potential benefits and their duration, short term morbidity and long-term risks especially with serious complications. An opportunity to reflect and ask questions always takes centre stage.

   Where necessary, pre-operatively I referred the patient to a colorectal surgeon to ensure that they were aware of potential implications of bowel injury in the short and long term.

3.1. **Emergency Gynaecology:** Until retirement from NHS in 2017, I provided On-call Consultant Gynaecologist services for Gynaecology Assessment and Treatment Unit (GATU) and A&E emergencies in a 1:8 consultant rota at St James's University Hospital, Leeds.

   The GATU sees approximately 1000 acute cases annually. Bleeding in pregnancy, viable or non-viable pregnancy, miscarriage *(complete or incomplete with RPOC),* ectopic pregnancies and pelvic inflammatory disease are the most common gynaecological emergencies or acute visits.

Summary of Experience in Reproductive Medicine:

1. I have worked in the field of Reproductive Medicine since 1984 *(King's College Hospital, London 1984-1991)*, and as a Consultant in Leeds since 1991. During my tenure as Consultant in Leeds, I was the HFEA Person Responsible. During the last 30 years, I have conducted and supervised more than 20,000 treatments in Assisted Reproduction Technology (ART; includes IVF, ICSI, Egg, Sperm and Embryo donation, IUI, Ovulation Induction & Reproductive Gynaecological surgery). This will include the management of >5000 pregnancies during the 1st Trimester. During my ART career, I provided a comprehensive service for patients suffering from all forms of sub-fertility and attended to the reproductive health needs of cancer survivors. *(Refer to Section 1.1.7. below)*

2. Before starting in this field, I had already completed 4 years of general training in obstetrics and Gynaecology *(the latter 2 years as a registrar at The London Hospital, Whitechapel)*. Before starting in this field, I had already completed 4 years of general training in Obstetrics and Gynaecology *(the latter 2 years as a registrar at The London Hospital, Whitechapel)*.

I published the first and world's largest series on the use of ultrasound in IVF cycles and the factors that affected outcome.

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Summary of Experience in Fertility Preservation:

1. In 1995, In collaboration with Professor R Gosden (scientist) and my colleagues from LGI we received a 3year LIF grant for developing "Cryopreservation of ovar8ian tissue as a strategy for conserving fertility."

2. In 1996, I published a report on the performed the first ever surgical procedure for storage of ovarian tissue on experimental basis from a girl child who was suffering from cancer. in 1997 or so.

   Newton H, Aubard Y, Rutherford A, Sharma V and Gosden R (1996) Low temperature Storage and Grafting of Human Ovarian Tissue. Human Reprod. 11 (7) 1487.

3. From 2000 - 2017: In collaboration with Paediatric Oncology, I established a joint '*Late Effects Clinic for the Survivors of Cancer'*. This was UK's first.

3.1. In the beginning it concentrated on assessing the impact of ***'Induction of Puberty'*** on genital tract development, impact of cancer treatments on menstrual & reproductive health. We performed ovarian reserve assessments and provided prognostic information to girl/ adolescent/ young women who were survivors of cancer. This included providing HRT to some.

3.2. Gradually the service progressed from assessment to proactive storage including boys.

3.3. From assessment of aftereffects, in addition to storage of ovarian tissue, we started to store Mature Eggs after conducting an IVF cycle.

3.4. My work related to Storage of Ovarian Tissue was halted after Human Tissue Act and EUTCD as the prescribed facilities required to store human tissue for clinical use required a higher specification, that were available only in one centre in the UK.

Summary of Experience in the use of Ultrasound in Early Pregnancy, Reproductive Medicine & Assisted Reproduction Technologies (ART):

1. Use of Ultrasound:

1.1. From 1984-91, I was the member of the pioneering team that introduced abdominal scanning in ART for gynaecological baseline assessment, monitoring of response to IVF treatment, ultrasound directed egg recovery, luteal phase, and early pregnancy monitoring in IVF cycles.

1.2. In late 1980's, vaginal route for ultrasound scanning was developed by Phillips, USA and I was amongst the leading groups who introduced this technique for scanning in our discipline. I was engaged in teaching and training of many doctors who became consultants in this field. This training was later extended also to the senior appropriately trained nurses.

1.3. Since 1984 and until I retired as a Consultant from the NHS (1991-2017), i.e., during the last 30+ years as a consultant, I have conducted and supervised more than 20,000 treatment cycles in Assisted Reproduction Technology (**ART; includes IVF, ICSI, Egg, Sperm and Embryo donation, IUI, Ovulation Induction & Reproductive Gynaecological surgery**).

1.4. My role in this speciality included performing 7-10 ultrasound scans during each IVF cycle, and in the first trimester until 12 weeks' gestation.

2. Early Pregnancy Management:

2.1. In 1991, I established, developed, and acted as the lead clinician and as the HFEA person Responsible in the Assisted Conception Unit at St James's Hospital, we have had the statutory obligation to inform the HFEA of all treatment outcomes at pregnancy test, pregnancy outcomes at 12 weeks' gestation and at birth.

2.2. From 2010, the Assisted Conception Unit at St James's Hospital merged with the unit in Leeds General Infirmary as The Leeds Centre for Reproductive Medicine (LCRM) that later became known as Leeds Fertility and is now owned by Care Fertility.

2.3. From 2010-2017, I was a senior Consultant and the HFEA Person Responsible in this service, performing the same clinical role daily as described in Section 1.1.7. above.

2.4. I managed all pregnancies conceived in my care after ART during the 1st trimester in the Assisted Conception Unit at St James's *(for approximately 20 years, Aug 1991-Dec 2010),* in The Leeds Centre of Reproductive Medicine from 2011-2017 and within private practice.

2.5. Specifically, as a Consultant Gynaecologist from 1991-2017, I managed all complications of first trimester in pregnancy.

2.6. As a Consultant Obstetrician, between 1991-2005/6, I also managed pregnancies in the antenatal care, intra and post-partum period of thousands of women, where I was often called upon to do scans, in the early years also amniocentesis and chorionic villus sampling (CVS).

2.7. In 1991, with prior training at Kings College, I introduced ultrasound directed techniques for both amniocentesis and CVS in my hospital, Leeds for an improvement in their safety profile.

KEY ROLES IN SERVICE: During the course of my career, I have fulfilled many roles that could be broadly described in the following categories:

1. CLINICAL

1.1. Establishment of services

1.2. Service Delivery, Administration, Regulation & Compliance

1.3. Teaching & Training

2. MEDICO-LEGAL

3. RESEARCH & PUBLICATIONS

1. CLINICAL

Prior to the establishment of formal training programmes in RCOG, I was fortunate to have received **dual sub-speciality** training in both **Reproductive and Feto-Maternal Medicine** in the premier institution of that time, the King's College hospital.

In 1991, I was amongst the **first wave of specialist formally trained consultant appointments** in Reproductive medicine.

Since 2005, I have worked as a Consultant Gynaecologist concentrating on benign gynaecology and reproductive medicine at LTHT.

2. ESTABLISHMENT OF SERVICES

The key features of my career have been the following:

2.1. I **pioneered ambulatory ultrasound-based ART** and published on the world's largest series of USS based collection in 1987.

2.2. At the invitation of the **Ministry of Health, Singapore**, I established The Assisted Conception Units at the Singapore General Hospital and Thomson Medical centre in 1987-88.

2.3. I **established and developed The Assisted Conception Unit** (ACU) at SJUH **in 1991** and ran this entire service **single-handed from August 1991 - Dec 2009.**

3. SERVICE DELIVERY, ADMINISTRATION, REGULATION & COMPLIANCE

3.1. **As HFEA Person Responsible, I have:**

3.1.1. **written and inspired almost all of the protocols /operating procedures** for **standardisation** of the service well ahead of practice in other parts of medicine. I have continued to take the lead in doing so at The Leeds Centre for Reproductive Medicine.

3.1.2. **developed a risk aware culture and conducted risk managements** in the ACU **several years ahead** of the trust lead developments.

3.1.3. established **ISO 9001 accreditation** for the clinical service, which is amongst the first of this kind in the trust

3.1.4. lead the **annual review, modification and adaptation** of practice to the changing requirements namely **HFEA, RCOG, NICE and European Union Tissue Directive (EUTD)**

3.1.5. with local and neighbouring **PCTs and Strategic Health authorities**, I have been involved from inception in the development and subsequent review of the local policies for the assessment and provision of sub-fertility services in the region

3.1.6. in mid-1990's, I established direct links with commissioning officers and local consultants in the regions of **South Humber, North Lincolnshire and East Lancashire** winning contracts from other competitive providers in the North of England. These relationships continue to date and have brought in excess of a £1M annually of extra-contractual income into the trust

3.1.7. developed the local **satellite services with the Wakefield centre in Pinderfields** hospital, standardising and developing their secondary service in parallel with us by providing the relevant SOPs, guidance and training to their consultant, nurses and ultra-sonographer

3.1.8. assessed, audited, inspected and provided support to other **three satellite services (Bradford, Calderdale, and Isle of Man)** that feed substantial work into the trust. This too was with the provision of or own SOP's patient information, guidance and advice to ensure patient safety and regulatory compliance

3.1.9. have written and reviewed most if not all of the **Risks assessments and Management** documents in ACU, at SJUH since early 2000; since merger in 2010 in the LCRM at Seacroft Hospital

3.1.10. developed the **custom made LTHT data base with the Informatics personnel (my brainchild and intellectual property with the trust in principle)** over 7-8years to provide a Quality Assurance system within the service that provides the trust:

3.1.10.1. reassurance that activity is accounted, and trust receives its due remuneration

3.1.10.2. that the unit KPI's can be regularly monitored

3.1.10.3. that the statutory obligations for electronic data submission to the HFEA can be met

3.1.10.4. that the running cost of the database can be minimised by incorporating data input into clinical team's duties

3.1.10.5. that the data is as up to date and accurate as possible by enabling real-time and direct input at source

3.1.10.6. that the cost of data input errors can be minimised by ensuring that the team leaders have reports generated to appraise and correct their team members

3.1.10.7. working relentlessly until regular data reports can be generated from the database with accuracy and errors through incomplete submission can be eliminated

3.1.11. I developed the **Patient Satisfaction Questionnaire** in early 2000 for continuous and objective patient feedback and for a realistic appraisal of the service by the majority of clients

3.1.12. developed a structured protocol for the **training of the junior doctors** in the service

3.1.13. developed a **standardised procedure for regular and mandatory audits** for the service with nominated personnel and timelines/schedule for completion so that the unit has demonstrable compliance throughout the year for Unannounced HFEA inspections

3.2. As the **Head of Service at SJUH and HFEA-PR at LCRM**:

I have played a key role in the **design, licensing, establishment and management** of our services. In this:

3.2.1. despite late nomination for leadership in this activity, I ensured that the trust's timelines for **submission application for a new HFEA licence and the relevant documents** were met. This enabled the service to be opened on time with no inconvenience to the patients and with no financial loss to the trust.

3.2.2. in the first 20 years, I did not take my full complement of **annual leave before 2000**. Additionally, despite significant injuries, continuity of service for the patients and activity for the trust was never disrupted.

3.2.3. after merger, in the first 4 years at LCRM, I acted as a consistent and dependable figure in the service inputting **250-300hrs each year** over and above those that were recognised by the trust in job plans.

3.2.4. **Troubleshooting activity:**

In the first 3 years after merger, I worked hard **to rectify a significant decline in the unit success rates**...

This included:

3.2.4.1. **Laboratory services:**

3.2.4.1.1. arranging training in **management of 'clean laboratory'** as per the requisite standards by arranging an educational tour of a Grade A laboratory in the Seacroft blood Bank laboratory

3.2.4.1.2. convincing the embryologists that the laboratory **lighting** needed to be significantly reduced as per peer practice; bulbs and tubes were changed, and windows blackened

3.2.4.1.3. not giving up on the investigation of the source of **fluctuating and 'too low' temperatures** in the laboratory as well as theatre area; the thermostat's recorded range in temperature and frequency of air flow changes between laboratory and theatre were adjusted to minimise damage to the gametes and embryos during transit

3.2.4.1.4. identifying that the **choice of culture medium** was out of step with peer practice and in the course finding that the laboratory was not even using their selected medium as manufacturer's recommendations; arrangements were made to send the two seniors to the manufacturing plant in Denmark for training

3.2.4.1.5. identifying that the 3 yearly **rolling contracts of the chosen culture medium** signed by the trust, reporting, discussing and negotiated change to a more suitable medium

3.2.4.1.6. facilitating / supporting **peer appraisal of the laboratory practice** by an senior external embryologist and affecting change as per recommendations

3.2.4.1.7. initiating the first two **FET cycle audits**; that changed practice for the service and very substantially improved the unit performance figures

3.2.4.1.8. providing impetus for **reintroduction of vitrification** of mature eggs and embryos using the elsewhere tested and tried **'open system'** as opposed to the previous independently selected and subsequently failed 'closed system'

3.2.4.2. **Clinical services:**

3.2.4.2.1. **Retraining the 4th consultant**

3.2.4.2.2. training 3 SSPRs and 5 registrars since 2010 and auditing the practice of all operators in the service

3.2.4.2.3. **auditing** the practice of the **satellite** patients against the primary centre

3.2.4.2.4. introducing **patient specific** and suitably tailored treatment regimens

3.2.4.2.5. introducing **luteal phase monitoring** of at risk patients for OHSS, methods for early identification and treatment

3.2.4.2.6. introducing **step up and down** regimens

3.2.4.2.7. revisiting the **hormonal support in luteal phase** of fresh and FET cycles

3.2.4.2.8. encouraging **training in critical appraisal** of failed cycle parameters at review, learning and rectifying errors for the future

3.2.4.2.9. **standardising documentation** of discussion and recommendation for treatments especially for FET cycles, no of embryos to be thawed and transferred

3.2.4.2.10. **implementing** unit strategy in meeting the **HFEA targets for minimising the risk of multiple pregnancy**

3.2.4.2.11. have developed a **structured process for preparation** in lieu of Unannounced HFEA inspections

3.2.4.2.12. for appropriate devolution of **accountability and responsibility** to the team leaders, I have developed a structured process for documenting recommendations and action points from the **HFEA Inspection Reports**. Such reports have been used to ensure that all action points are delegated with timelines, met and fed into the trust's Divisional Governance groups.

3.2.4.3. over the years, many of my procedures have been adopted, adapted and promoted to other centres by the HFEA for a national guideline and I have received commendations from HFEA inspectorate

3.2.4.4. I have received **commendations** from HFEA

3.2.4.5. I have been an invited member of the **HFEA Licensed Centre's Panel**

3.2.4.6. I have above all been a **compliant and safe** service provider, with no major surgical complications and no major incidents in my watch to date

3.2.4.7. I have managed the **stored gametes and embryos** from cancer patients (>200 cases), that were inherited from the LGI unit; which had expired legal duration of storage making their storage illegal. Each of the cases were individually traced via National Tracing Agency and reviewed, corresponded to, or followed up until full compliance was achieved in early 2015

3.2.4.8. I have instituted **laboratory, clinic and informatics protocols** for the on-going work of review correspondence and tracing of patients in order to avoid a recurrence of non-compliance with the law

3.2.4.9. I have taken steps when required to protect the **trust's reputation.** The last in-depth inspection a number of **major non-compliances and defence of the** were identified by HFEA:

3.2.4.10. Only one was clinical; we successfully convinced HFEA to downgrade their assessment, as no specific professional or HFEA guidance had been / is available. In fact, in the end, all they wanted was a *'local risk assessment'* which was completed with the Lead Virologist in the trust, the SOP and the screening policy was suitably amended

3.2.4.11. There were a number of major non-compliances in the laboratory that had not been known to the PR, other consultants or approved by anyone in responsibility. These were rectified and monitoring process instituted

3.2.4.12. The inspection reports are made public and despite our good success rates, there was a risk of disrepute in the press. I acted with evidence to change the tenor of report in order to minimise the adverse impact of non-compliances on the trust's business activity.

3.3. In the development of national and regional service, I have:

3.3.1. been a member- **HFEA Licensed Centre's Panel**

3.3.2. been an Invited Member of **ESHRE working group** for development of Reproductive Health services for cancer patients

3.3.3. been a Member of **DOH working party** in the development of - Patient Pathway 18 Wk Target-Infertility,

3.3.4. been an **RCOG Assessor for Failing Services & Doctors**.

3.3.5. have been a member of the **Strategic Commissioning Group** in the development of Guidelines for Yorkshire and Humber Group guidelines for:

3.3.6. The -Assessment & Management of subfertility

3.3.7. Policies for the Storage of Fertility in Cancer patients

3.4. As a teacher, I have had:

3.4.1. a substantive role in the training of **21 subspecialists** in Benign Gynaecology and Reproductive Medicine (**1 is currently a professor, 1 a Reader in O&G & 18 are NHS Gynae/Repro Med consultants** in the UK).

3.4.2. have been the Sub-speciality Training Programme Director in Reproductive medicine at LTHT

3.4.3. have been asked to **train HFEA inspectors** in how to meet regulatory requirements from a service provider's view.

3.5. As a trainer, I have had:

3.5.1. Even before appointment as a consultant, I trained many juniors and seniors in ART.

3.5.2. Since my appointment as a consultant in 1991, I have trained more than 25 middle grade doctors in the sub-speciality of Reproductive Medicine & Surgery, many are Consultant Sub-specialists and one is a Professor in Reproductive Medicine.

3.5.3. I have supervised many research projects & postgraduates, 8 MDs and 2 MSc's

3.5.4. Jointly with Paediatric Endocrinologists in ~2000, I established the nation's first ***'Late Effects Clinic for the Survivors of Childhood Cancer.'*** This soon progressed to include Pre and post treatment counselling, assessment and fertility preservation of patients from

'Adult Oncology.' I saw many patients requiring ***'Induction of Puberty'*** and/or ***'Premature Gonadal Insufficiency'*** and ***'Hormone Replacement Therapy'*** (HRT).

3.5.5. I worked for RCOG as an assessor for gynaecological and assisted conception services.

4. MY ROLE AS EXPERT WITNESS IN MEDICO-LEGAL CASES

4.1. My Qualifications and Experience:

4.1.1. Since my appointment as a Consultant in Obstetrics and Gynaecology on the 1st of August 1991, I have been regularly asked for advice on medico-legal issues both within the trust for defence and by solicitors acting for Claimants.

4.1.2. In 2022, in line with requirements, I have completed the **Cardiff University Bond Solon's (CUBS) online training course in Civil Law** cases with certification.

4.1.3. Between 1st of Jan 2022 and 1st of Jan 2025, in the 3 years, I have acted as a Medical Expert in 44 cases and have provided approximately 74 reports.

4.2. My areas of expertise:

4.2.1. I specialise in all subjects related to Benign Gynaecology, Reproductive Medicine and Surgery. The common subjects that I have reported upon recently include. *Please note that this list is not exhaustive, has been composed to serve as a guide of the subjects that I have reported upon in the recent years.*

4.2.1.1. **General Gynaecological Disorders:**

4.2.1.1.1. Endometriosis

4.2.1.1.2. Miscarriages

4.2.1.1.3. Retained Products of Conception

4.2.1.1.4. Ectopic Pregnancy

4.2.1.1.5. Secondary haemorrhage

4.2.1.1.6. Uterine Malformations

4.2.1.2. **Uterine Surgery including:**

4.2.1.2.1. Uterine polyp resection

4.2.1.2.2. Uterine septal resection

4.2.1.2.3. Myomectomies

4.2.1.2.4. Hysterectomies *(elective and emergency)*

4.2.1.3. **Infertility related to:**

4.2.1.3.1. Pelvic Sepsis

4.2.1.3.2. Peritonitis due to various causes such as bowel injury, bowel perforation and ruptured appendix

4.2.1.3.3. Tubal disease

4.2.1.3.4. Sexually Transmitted Infections

4.2.1.4. **Endocrine issues pertaining to Reproductive, Menstrual, Gynaecological and Mental health:**

4.2.1.4.1. Menopause, Premature menopause and Premature Ovarian Insufficiency *(inherited or induced)* by *(disease, delay in diagnosis and treatment, surgery or medications)*.

4.2.1.4.2. Reproductive Endocrine and Hype-androgenic disorders such as Polycystic Ovary syndrome

4.2.1.4.3. Benign Ovarian Cysts & complications such as Torsion or Rupture or excessive enlargement leading to avoidable oophorectomy.

4.2.1.5. **Accidental Injuries with implications to gynaecological health:**

4.2.1.5.1. Pregnancies *(first trimester only)*

4.2.1.5.2. Pelvic fractures and implications to long-term Reproductive, Menstrual, Gynaecological, Sexual and Mental health

4.2.1.6. **Fertility Preservation** (including Mature Egg and Ovary Preservation):

This is in relation to both males and females where this option was not considered before potentially sterilising treatments.

4.2.1.7. **Misdiagnosis leading to an SUI**

This has been in cases with both a potentially reversible and irreversible impact.

4.2.1.8. **Failure in taking an Informed Consent**

This has been in cases where clients have in hindsight not received comprehensive information and/or not understood all implications before undergoing irreversible procedures**.**

4.3. My Reports as an Expert Witness:

4.3.1. Since retirement from the NHS in 2017, and especially in the last 5 years, I have concentrated on medico-legal work as an expert witness and have reported on 12-20 cases per year.

4.3.2. I have been called upon to report as an Expert by both Claimants and Defendants (80:20).

4.3.3. **For the Claimants, I have report on:**

4.3.3.1. Causation or Breach of Duty**,** Long term Implications of an episode, Condition and Prognosis.

4.3.3.2. I have reported on many "Serious Untoward Incidents."

4.3.3.3. I have also reported on "Never Events."

4.3.3.4. I have reported where prognosis and quantum assessment is being performed after the defendant has already admitted liability.

4.3.4. **For the defendants, I have reported on** several "Serious Untoward Incidents" and a "Never Event."

4.3.5. **I have used the CUBS Template** for my Medical Reports since being certified by Bond Solon, Cardiff University.

Below are examples of my reports in an anonymised copy of an old, an old, settled case and a recent SUI, as yet unsettled.

CUBS REPORT TEMPLATE.docx

Medical Report Anonymised.pdf

XXXX MEDICAL REPORT Anonymised

4.4. My Practice:

4.4.1. Virtual Consultations:

I find that in my specialism, most face to face consultations and even a physical examination, offers little in terms of added information to the content of the medical report. On the other hand, obtaining medical history directly from the client is very helpful.

Hence I perform Virtual Consultations via WA Video call (commonest as most clients have ready access), Microsoft Teams or Zoom.

4.4.2. **Meetings with the Solicitors and the Counsel:**

Routinely, I am requested to undertake this in assessment and discussion of the evidence.

4.4.3. **Court appearances:**

4.4.3.1. I have never had to appear in the Court as clients have had prior settlement.

4.4.3.2. I have received training for cross examination during the Bond Solon Course.

4.5. My limitations:

4.5.1. **Obstetrics:**

In line with national service developments around 2005, I stopped active obstetric practice to concentrate on my sub-speciality of Reproductive Medicine and Surgery that included first trimester pregnancy management, but I CONTINUED to provide advanced surgical cover for my obstetric consultant colleagues in keep with the departmental requirements.

Hence, I do not report on complications arising in pregnancy during the:

4.5.1.1. Second and third trimester

4.5.1.2. Intrapartum period

4.5.2. **Adolescent Gynaecology:**

Although within the NHS, I would see all post and pre pubertal females, especially in my highly specialised clinic that catered to Reproductive Health of Survivors of Childhood Cancer, I did not do so in the private sector because of specific resuscitation training requirements for children that are reserved for paediatricians.

Hence I report on long term implications into adulthood in conjunction with paediatricians with medical history (taken virtually) and medical records.

4.5.3. **Criminal Law:**

I did not work in this field during my NHS career and have not trained in Criminal Law. Hence I do not undertake this work.

4.5.4. **Geographical:**

I work with cases with in the geographical limitations of the United Kingdom.

5. MY RESEARCH & PUBLICATIONS HISTORY

Even as a full-time NHS consultant, I remained **academically active** and have:

5.1. had my research and PHD cited as the **only Prior ART in EU Patent Application for long acting FSH in 2007**

5.2. published **81 peer reviewed papers**

5.3. raised **research grants worth £664,108 approximately**

5.4. supervised **8 post graduate students for an MD** & **2 MSc students** with Leeds University

5.5. I have been a **reviewer for the journals**: The Lancet, Human Reproduction, Human Fertility, European J of O &G

5.6. I have been an active **contributor to service developments** with **funds**:

5.7. I contributed 50% to costs of establishing a **Chair in Reprod Biology**, Leeds Univ

5.8. As a supra-regional service provider **contribute >£5Million annually to the Trust's budget**.

5.9. As a **researcher: I have had the following Grants since 2005:**

5.9.1. LRF 1995, 3 years - Cryopreservation of ovarian tissue as a strategy for conserving fertility - with R Gosden and A Rutherford: £91,752

5.9.2. Wellbeing/RCOG 1996, 2 years - Growth and Maturation of human oocytes in vitro - with R Gosden and D Miller: £ 37,164

5.9.3. Serono Laboratories 1995: Grant for the establishment of biochemistry labs in the ACU at St James's : £35,000

5.9.4. Candlelighters research grant 2002, 3 years - Oocyte and ovarian tissue cryopreservation as a means to preserve the fertility of young cancer patients - with Dr H Picton, Dr A Glaser and Mr A Rutherford: £183,751

5.9.5. Ferring Pharmaceuticals 2004: Grant for laboratory developments at ACU, St James's : £30,000

5.9.6. Candlelighters research grant 2005, 3 years - Development and implementation of methods for restoring the fertility of young female cancer patients: £256,441

5.9.7. Organon Pharmaceuticals 2005: Grant to the trust fund for research and educational purposes: £10,000

5.9.8. Founder member of a Working Party for the Establishment of national framework for conservation of fertility for young oncology patients – first national meeting March 06 - funded by The Candlelighters.

5.9.9. 2008: Unrestricted research grant of £10,000 from Nordic Pharma.

5.9.10. 2010: Unrestricted research grant of £10,000 from Nordic Pharma.

5.10. **Past Collaborative Projects:**

5.10.1. Prediction of ovarian function, fertility and menopause after chemotherapy and radiotherapy in childhood and adolescence (in collaboration with paediatric oncologists)

5.10.2. Role of Somatostatin in the human ovary (in collaboration with local endocrinologists).

5.10.3. Regulation of granulosa cell superoxide dismutase activity (in collaboration with local endocrinologists).

5.10.4. A Phase IV, randomised, multicentre study to compare the safety and efficacy of Gonal-F with Metrodin HP to induce superovulation in women undergoing Assisted Conception Techniques.

5.10.5. To study the effect of IVIg administration in patients with a history of recurrent unexplained pregnancy loss (with a local immunologist).

5.10.6. Investigation into the efficacy and safety of the LHRH-antagonist Cetrorelix in women undergoing fertilisation treatment.

5.10.7. The generation of Human Stem Cells: Current Collaborative work with University of Leeds (Dr Helen Picton), York (Professor Henry Leese) and Edinburgh (Professor Austin Smith and Dr Jenny Nicholls).

5.11. **Recent Collaborative COREC projects:**

5.11.1. Gene polymorphisms implicated in fallopian tube disease and patho-physiological effects of chlamydia infection on the development of the egg in females suffering from infertility : a series of studies completed with Dr Nic Orsi: Subject of a completed MD thesis (Ms Sumita Bhuiya: pass April 2012)

5.11.2. Study of cytokines in the follicular fluids of follicles and their correlation with egg and embryo development: a series of studies in progress in collaboration with Dr Nic Orsi. Subject of an MD thesis (Dr Ellissa Baskind)

5.11.3. Further studies of oxygen stress using NMR in follicular fluids of natural and stimulated cycles (in collaboration with Dr Julie Fisher; PhD student Ms Cassie Macrae)

5.12. **Collaborative COREC projects that were active or had recently completed before retirement:**

5.12.1. Comparison of cytokines in Follicular fluid after various ovarian stimulation regimens in humans and lower mammals (Collaboration with Dr Nic Orsi; MSc student Ms Sarah Field).

5.12.2. Gene polymorphisms in women at risk of ovarian hyperstimulation syndrome (collaboration with Dr Nic Orsi).

5.12.3. A randomised comparative study of various forms of luteal phase support in women after ovarian stimulation for IVF (Dr Nic Orsi & Dr E Baskind).

5.12.4. Multi-centre trial (Principal Investigator; LCRM): Evaluation of non-invasive semen and urine sampling in the assessment of testicular and prostate function and pathology. (Chief Investigator: Prof D Miller, Leeds University).

5.12.5. Multi-centre NIHR funded trial (Principal Investigator; LCRM): Selection of sperm for Assisted Reproductive Treatment by prior hyaluronic acid binding: improving the outcomes of fertility procedures by increasing pregnancy and reducing miscarriage rates. (Chief Investigator: Prof D Miller, Leeds University). This project has been completed and published in the NIHR journal as well as is in the process of being published in The Lancet.

5.12.6. North of England Reproductive medicine Group; Collaboration of ART culture characteristics (specifically culture medium, incubator type, oxygen level and culture duration) within an IVF-treated cohort. (Chief Investigator: Prof Daniel Brison, Manchester University)

MY PUBLICATIONS *(Peer-Review Journals & Book Chapters)*

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What is missing?

In the interest of brevity, several hundred posters and co-authored, published and presented oral abstracts have not been listed in this CV.