Report by Dr Krishnan Anantharamakrishnan MBBS, MS, FRCS, MSc, FEBU

Consultant Urological Surgeon, Sherwood Forest Hospitals NHS Foundation Trust, Masnfield Road, Sutton-in-Ashfield, Nottinghamshire, NG17 4JL

INDEPENDENT EXPERT REPORT
Prepared for the Court

Date of Report: 08-2024

Instructed By: [redacted]

Case Reference: [redacted] (EMG)

Patient: [redacted]

Date of Birth: [redacted]

REPORT CONTENTS

1 Introduction & My Instructions

1.1 I have been instructed by [redacted] to provide an independent condition and prognosis report in relation to a clinical negligence claim brought against [redacted]

1.2 In page 2 of 3, I have been asked to comment on causation - LOI - KA docx

1.3 I have been specifically asked to address the following points:

1.4 1. Do you consider there was a 6 month delay in diagnosing the VVF? Should this have been diagnosed earlier? If so, by when?

1.5 2. On the balance of probabilities, had the LLETZ procedure been performed adequately, would the Claimant have avoided a punctured bladder, uncontrollable incontinence and VVF?

1.6 3. On the balance of probabilities, would early conservative treatment have avoided the need for surgical repair? If so, please detail what conservative treatment and how this would have changed the Claimant's outcome.

1.7 4. Please identify any other failings or potential allegations not yet raised

2 My Details

2.1 A highly trained and experienced Urological Surgeon from the United Kingdom. I believe that I can assist in your aim to provide high quality urological and surgical services to the people. I am keen on improving patient safety and healthcare standards globally.

2.2 My special interests are in female urology, neurourology, urodynamics and reconstruction, lower urinary tract dysfunction, urinary stone disease, andrology and paediatric urology. I have used my skills as a team worker to develop my own expertise as well as of those around me to introduce new procedures and conduct research in these areas.

2.3 I work as a consultant urological surgeon at the Sherwood Forest Hospitals NHS trusts. I have a special interest in andrology, benign prostate management and urinary incontinence. I've performed on-calls in a busy tertiary trauma centre of Queen's Medical Campus, Nottingham. I am a general urologist with an emphasis on diagnosis and treating urology cancers, prostate biopsies, bladder tumour resection, bladder and kidney stone management, TURPs, vasectomy, vasectomy reversals, urinary tract injuries arising from trauma and surgery. I have a very busy practice in general urology consisting of scrotal complaints, prostatitis, lower urinary tract symptoms in men and women, peyronies penile bend, erectile dysfunction, ejaculatory disorders, ureteroscopies, stenting, and urethral catheterisations.

2.4 I emphasise with the team about importance of thorough clinical assessment, record keeping and follow-up as well as informed consent and good communications with the patients.

2.5 I have a longstanding interest in the medico-legal issues in urology. I have undergone training in medico-legal report writing. I keep up to date with medico-legal developments. I am aware of the requirements of Part 35 and Practice Direction 35, the Protocol for the Instruction of Experts

3 Documents Reviewed

3.1 Duty of Candour Letter

3.2 Draft Serious Investigation Report

3.3 3 day Incident Day Report

3.4 Clinician meeting with [redacted]

3.5 Clinician Comments from [redacted] dated 21.02.23

3.6 Duty of Candour Letter dated 04.07.22

3.7 Liability expert report of Dr Anantharamakrishnan Consultant Urological Surgeon dated 27.06.23

3.8 Liability expert report of [redacted] dated 06.11.23

3.9 Claimants Schedule of Loss dated 13.06.24

3.10 Claimants condition and prognosis expert report of [redacted] November 2023

3.11 Serious Investigation Report dated 31.10.22

3.12 Screening Incident Assessment Form dated 11.07.22

3.13 3 day Incident Day Report to CCG dated 26.11.21

3.14 Letter of Claim dated 24.11.23

3.15 Letter of Response dated 05.02.24

3.16 Letter of Apology dated 06.02.24

3.17 Clinician comments of [redacted] dated 27.01.23

3.18 Clinician comments of [redacted] 21.02.23

3.19 Advisory Report (Standard)

3.20 JUNE24 - LOI

3.21 Letter of Instruction - KA

3.22 claimants medical records

3.23 MedBrief Access

4 Chronology and the Claimant's Relevant Medical History

4.1 1.1 Those involved are

4.2 [redacted]

4.3 DOB 18/05/1952

4.4 Claimant

4.5 [redacted]

4.6 Gynaecology Registrar

4.7 [redacted]

4.8 [redacted]

4.9 Gynaecology Registrar

4.10 [redacted]

4.11 [redacted]

4.12 Gynaecology SpR

4.13 [redacted]

4.14 [redacted]

4.15 Gynaecology Consultant

4.16 [redacted]

4.17 [redacted]

4.18 Consultant Urologist

4.19 [redacted]

4.20 1.2 Outline of events

4.21 1.2.1. 2005 anterior resection for bowel cancer followed by chemotherapy [redacted, further polyps excised in 2013 which were returned as benign] and other clinical background include the referral being made following a cervical smear, which demonstrated the presence of the high-risk human papilloma virus (HRHPV) with moderate dyskaryosis on cytological assessment. At the time of original referral, she was aged 68 years old. She was nulliparous. Her previous smear history included colposcopic assessment on 22nd September 2016 because of recurrent HRHPV detection with normal cytology. At the time, the colposcopic impression was CIN1 and this was confirmed on biopsy. A plan was to repeat screening in 12 months, which was undertaken on 28th November 2017. At that colposcopic assessment the cervix appeared normal, and a plan was made to return to the usual screening programme with a repeat smear in 3 years' time. Subsequently patient presented for a colposcopy appointment on 3rd December 2020. The detailed chronology is as follows:

4.22 1.2.2. 22/09/2016 Referred to Colposcopy clinic with HPVx3 (Normal cytology), Colposcopic Impression CIN 1, Biopsy – CIN 1 Plan repeat screening in 12 months

4.23 1.2.3. 28/11/2017 Referred to Colposcopy with HPV + Mild dyskaryosis Colposcopic impression Normal. Plan for repeat screening in 3 years

4.24 1.2.4. 03/12/2020 Referred to Colposcopy with HPV + Moderate dyskaryosis, on 24/12/2020, Colposcopist [redacted] reports small introitus, difficult access. Colposcopic impression CIN 1-2. LLETZ performed revealed – CIN 1 but no high- grade CIN and for Test of cure (TOC) screening in 6 months.

4.25 1.2.5. 27/08/2021 Referral to Colposcopy TOC screening HPV positive, normal cytology Colposcopist reports very narrow introitus, atrophic cervix, biopsies taken. TZ type 2. Colposcopic impression HPV. Biopsy reported 10/9/21 atrophic changes only and smear reported atrophic changes only on 14/9/21, however the biopsy was considered inadequate, therefore requested for diagnostic Loop.

4.26 1.2.6. 26/11/2021 Attended Colposcopy and discussed options of further screening and review in 12 months, or for diagnostic LLETZ. Opted for LLETZ. Colposcopist reports TZ type 3, difficult examination due to vagina atrophied. LLETZ obtained in multiple pieces. Local anaesthetic used. No complications recorded. Management options explained to patient as per 'Gynaecology Clinical Guideline for Colposcopy [ID 13859]. Verbal consent recorded for LLETZ

4.27 1.2.7. After the procedure on 26/11/21 [redacted] immediately noticed that she was incontinent of urine and had lost control. On 27/11/21 her GP noted the previous day's procedure and subsequent incontinence of urine; the GP contacted the Gynaecology on-call team who declined admission but was advised to send her to A&E at the hospital. [redacted] also contacted NHS 111 who at 17.32hrs also advised her to attend A&E. She attended at 20.15hrs with 'problem related to vagina' but 'claimant left before clinical assessment'. Did not wait to see clinician, left ED at 21.36

4.28 1.2.8. 30/11/2021 Attended ED at 10.55 with pain in genital area. EWS 0. Seen by ED clinician at 11.35. LLETZ procedure 4 days ago, since then continuous leakage of urine, been using pads & urine soaking through clothing. Had similar procedure done few years ago with no complications. No abdo pain, no back pain, some tingling to perineal area. Urinary incontinence is new, no feeling of urgency. No previous bladder issues. LOB yesterday, normal stool. Small amount of blood from vagina not unusual after procedure, no smelly/abnormal colour discharge. No fever. Impression ? UTI ? complication from LLETZ. Examination of external genitalia. No active bleeding, no purulent discharge, urine leakage. Senior review: Bladder scan 0mls DW Gynae reg on call: 'Unlikely complication from LLETZ procedure, usually bleeding/infection, had not seen patients present with incontinence following procedure.' Discussed with ED consultant- to discuss with urology discussed with urology reg on call. - '? trauma/stretch to bladder/Urinary tract during colposcopy procedure. Ideally should have improved over the week since the procedure, to treat as UTI, if not resolved in 2 weeks GP to refer to urology as an urgent referral.' Unable to obtain urine sample due to constant leakage. Plan explained to patient, discharge home with Trimethoprim.

4.29 1.2.9. 03/12/2021 Attended GP surgery MSU sent • UTI (Proteus) diagnosed

4.30 1.2.10.06/12/2021 Biopsy Result reported "smear negative and unsatisfactory colposcopy" MICROSCOPY: 'Fragments of fibromuscular and adipose tissue, with a single detached strip of squamous epithelium showing severe diathermy effect and therefore difficult to assess. No other epithelium is identified and there is no evidence of TZ sampling.' Missed opportunity here, since no cervical tissue seen on microscopy.

4.31 1.2.11 14/12/2021 Attended GP surgery MSU sent• No growth of organisms

4.32 1.2.12. 23/12/2021 Result discussed at Colposcopy MDT Outcome suggests Offer to cease from screening or repeat screening in 12 months with course of oestrogen MDT discussion involving Gynaecologist (Colposcopist), histopathologist and Nurse Colposcopist.

4.33 1.2.13. On 12/01/2022 [redacted] symptoms persisted and on 12/1/22 her GP referred her urgently to Urogynaecology; the letter indicated that she had 'lost complete control of her bladder, she leaks regularly, has urinary frequency, is up 3-4 times / night and has to wear pads constantly. Her perineum is now becoming very excoriated'. The initial urgent referral was downgraded to routine by the Hospital but on 20/1/22 the GP wrote again asking for the appointment to be expedited. Expedite letter received 20/01/2022 but decision taken not to upgrade clinical priority based on clinical information provided. Here I identify that the urgency of clinical problem or possibility of post-LLETZ complication not being recognised. This is considered a care delivery problem.

4.34 1.2.14. On 24/1/22, [redacted] [Post CCT Fellow] recorded in relation to the 26/11/2021 colposcopy: "I saw [redacted] recently, in my colposcopy clinic. she is a 69 year old lady who was referred with recurrent HPV which has been present for some years now, As she is post menopausal and nulliparous, it was very difficult to view on colposcopy and the biopsies were inadequate, I therefore performed a diagnostic LLETZ, but this was very difficult as the vagina was very narrow, and I only got a small sample which unfortunately was non-diagnostic'

4.35 1.2.15. On 2/2/22 following referral for 'ongoing urinary incontinence and soreness of to urethra and vulva' In [redacted] (Urogynaecologist) clinic she was seen by [redacted] (SpR) who noted 'no control of bladder since colposcopy – both stress and urge incontinence' also nocturia and nocturnal enuresis. She 'has to wear incontinence pads throughout the day'. Prior to the LLETZ she was 'completely fine with a normal bladder'. On examination ' narrow introitus, pale vaginal walls, erythema around the vulva and no stress incontinence'. No pelvic examination was performed. Management was discussed with Mr Giannis who did not see her himself. DW Consultant to stop Solifenacin and commence Mirabegron. Referred for urodynamic studies for a better assessment. Request for GP to prescribe oestrogen cream for the vulva and pessaries. Management discussed with Consultant and follow up arranged. Here it was recognised that a missed opportunity to link clinical history and examination findings to consider VVF as a differential diagnosis.

4.36 1.2.16. Urodynamic studies was abandoned on 17/5/22. Prior to these she was advised to keep a bladder diary, and this indicated that she was reporting urinary leakage about 13 times each day. [redacted] indicated that the Urogynaecologist stated, 'I know exactly what is wrong with you' and recorded 'as history / symptoms suggestive of Vesico vaginal fistula.' OE Vagina narrow unable to tolerate catheter. History and symptoms suggestive of vesico-vaginal fistula. A decision to abandon urodynamic physiology studies was made. Explained possible diagnosis, and She was then referred to [redacted] n 20/5/22. Plan for MRI pelvis and referral. Here there was a recognition of significance of symptoms and history was noted.

4.37 1.2.17. A request for MRI on 25/05/2022 completed, for 'continuous urinary incontinence since LLETZ in December 2021. History and symptoms suggestive of vesicovaginal fistula'. MRI was reported on 13/06/2022 "Posterior bladder wall 11mm defect with resultant vesicovaginal fistula as described. No cause identified at MRI to suggest a suspicious underlying aetiology".

4.38 1.2.18. 23/06/2022 MRI result communicated to patient and DATIX completed by the hospital trusts

4.39 1.2.19. The duty of candour letter was sent to the claimant on 4/7/2022 from [redacted] where an apology was offered and explanation of process was undertaken. The extract is as follows:

4.40 Further to our discussion on the 4th July 2022 where I informed you that you had been involved in a matter which we are formally recording as an incident, I wish to express our sincere apologies that this incident occurred whilst in our care I would also like to provide you with the following further information. The details of the incident reported are as follows. You sustained an injury during the LLETZ procedure completed on 26th November 2021, you have developed a connection between the bladder and vagina called a fistula. This has left you with incontinence. This is a very rare and serious complication following a LLETZ procedure. Your case was discussed at the hospital's Serious Incident Group meeting on 27th June 2022 - the Serious Incident Group meet every working day to discuss all incidents that have been reported that cause concern, and it is chaired by the Chief Nurse, Medical Director or one of their deputies. Our initial view is that this incident meets the criteria for reporting outside of the Trust as a 'serious incident'. All incidents reported at this Trust are investigated however a serious incident receives a deeper level of analysis. We report serious incidents externally in line with NHS guidelines and I have enclosed an information leaflet that may help to explain this process to you in a little more detail. As a Trust we aim to provide a quality service to our patients, service users and their families, therefore alongside our wish to be honest, open and transparent with you, and inline with our Duty of Candour policy, we will investigate this incident as promptly as possible to ensure that a detailed investigation is completed. We want to ensure that we do everything we can to support you and your family during this process, and I would like to take the opportunity to introduce [redacted] to you, as our family liaison officer. [redacted] will act as your lead contact and will be in touch with you in the near future, to provide you with support and an opportunity to answer any questions you may have and keep you informed about the investigation. Once the investigation has been finalised, [redacted] can arrange for us to meet in order that we can discuss our findings from the investigation with you. Please be assured that it is not our intention to intrude upon you or your family at this time; however we would like to keep you informed if this is something you would like. Therefore please let me know if you do not wish to

be contacted by our family liaison officer. If you have any queries about this letter or, if you would like to speak to me about this incident, please do not hesitate to contact me.

4.41 Kind regards

4.42 Yours sincerely

4.43 [redacted]

4.44 Consultant Gynaecological Oncologist

4.45 1.2.20. An EUA and cystoscopy on 4/8/22 at [redacted], showed 2 connected fistulae within the bladder – one just at the bladder neck in the midline, and the second at 1 o'clock just behind the first but not communicating with the vagina, might open into the cervix. They are away from the ureteric orifices. The vagina was scarred, immobile and fixed. Difficult to assess the bladder capacity. A proposed operation date for repair of the VVF was given for 8/9/22 with a clinic review first.

4.46 1.2.21. Discussion in NNUH MDT of the EUA findings on 10/8/2022. Difficult to repair abdominally. Consider urinary diversion. Might be consider second opinion from elsewhere. [redacted] to discuss with UCLH.

4.47 1.2.22. [redacted], was contacted on 11/8/22 by telephone and offered to undertake a vaginal repair of the fistula at UCH. [redacted] was seen the following day, and the plan was explained. However there seems to have been a gap in communication as an MDT to discuss management was not performed until 10/10/22 with a further EUA and Cystoscopy recommended to assess a possible vaginal repair. This was performed on 10/1/23 and a subsequent MDT on 25/1/23 indicated that a vaginal repair would be possible but would probably close the cervix. A transvaginal scan was recommended to ensure the endometrium was thin, but [redacted] advised that closure of the cervix might delay the diagnosis of endometrial cancer if it was to occur. Hysterectomy could be performed at the time of the fistula repair if necessary.

4.48 1.2.23. On 31/1/2023, the urology registrar from UCLH kept [redacted] in the loop explaining to her that the fistula is treatable via vaginally but might mean the cervix would be covered. That means pathology in cervix might be missed. Also would liked to know more about the outcome of the LLETZ procedure. This explanation is following the Uro Gynaec MDT on 25/1/2023.

4.49 1.2.24. On 24/3/2023 [redacted] contacted the claimant explaining that the urology team wanted an ultrasound scan and that could be arranged in [redacted] for convenience. He also said that he would review her face to face and also not guaranteed that his effort to expedite the operation at UCLH from September 2023 would succeed.

4.50 1.2.25. On 17/4/23, [redacted] reviewed the client with regards to pelvic ultrasound scan and the viability of the vulva tissues. On 17/4/23 a Transvaginal scan showed a regular thin endometrium measuring 2.2mm. Discussed that the removal of the uterus and cervix is not a must for getting the fistula repaired and healed. Reassurances were given that there might be some precancerous cells remaining but that is very unlikely. The aim is to get the fistula repaired. Also, gave update about the incident report. Provisional date for surgery 9/5/23.

4.51 1.2.26.A Surgical repair of the vesicovaginal fistula was performed vaginally on 9/5/23, using a Martius flap from the labial fat pad, tunnelled into the vagina, and covering the repair. She was discharged on 11/5/23.

4.52 1.2.27. She returned for trial without catheter on 6/6/23 but this was deferred as fluoroscopy showed a small leak; however, on review of the images the catheter was successfully removed on 13/6/23.

4.53 1.2.28 The result of the Serious Untoward Incident investigation into the injury and the delayed diagnosis of the fistula was communicated to [redacted] on 14/6/23, along with an apology for the injury and an indication that 'our systems and processes require strengthening'.

5 Clinical Examination

5.1 I had a video conference in my consulting rooms at Nottingham Ramsay Hospital, Mansfield road, Nottingahm NG5 3FZ, on 1st July 2024.

5.2 [redacted] provided photographic proof of identity.

5.3 [redacted] was unaccompanied.

5.4 [redacted] was fed up with having to repeat all the history all over again.

5.5 However, I reassured her that I have had reviewed all the available records and focussed on the relevant questions that would enable me to complete the report satisfactorily and robustly.

5.6 No clinical examination was performed since this is a video consultation

5.7 The following comments are based on the claimant's response to my questions

5.8 [redacted] is 72 years old.

5.9 Prior to the index event [LTETZ] CM had no urinary symptoms.

5.10 CM had largely recovered from the vescio vaginal fistula repair on 9/5/23, that which is as as a result of the LLETZ procedure.

5.11 She voids 10 -11 times in a 24 hour period

5.12 Drinks about 5-6 cups of tea

5.13 She says that she could hold urine longer than before and declined any urine infections.

5.14 [redacted] is now continent, she does have mild symptoms of urgency but no urge incontinence and very occasionally has minor stress incontinence.

5.15 She describes no bowel disturbances.

5.16 She sometimes gets out once or twice out of bed to pass urine at night

5.17 She generally gets good restful sleep

5.18 She is not any uro-drugs

5.19 She mentioned that she has a healed incision on the labium (but cannot remember which one) from the donor site of the Martius graft – this does not affect her at all.

5.20 In my opinion the fistula repair has been successful and she is totally dry

5.21 In my opinion, [redacted] has gotten her quality of life back albeit with minor inconvenience of urinary disturbances

6 Condition and Prognosis

6.1 My diagnosis of the Claimant's current condition

6.1.1 1.1 I am unable to comment in detail regarding the psychological effects of the injury, the psychological effects of prolonged period of incontinence and that of the second corrective procedure and would advise that a psychological report be obtained.

6.1.2 1.2. [redacted] is now continent, she does not have any major bothersome urinary symptoms of note.

6.1.3 1.3. The fistula repair is successful

6.1.4 1.4 She does not need any catheter or pads nor does she need any spare clothes to carry around.

6.1.5 1.5 She described no fear of going out, albeit if out for shopping could become a "Toilet Mapper" i.e. knows where the toilets are when out in a shopping centre, to prevent any undue urgency related leakage of urine

6.1.6 1.6 She said to me that the gynaecology had discharged her from follow-up.

6.1.7 1.7. No mobility issues were described

6.1.8 1.8. She is able to manage all domestic tasks including cleaning, cooking, decorating, shopping except any heavy lifting

6.1.9 1.9. She is not going out that much like before and the afternoon socialising with friends for coffee had not resumed yet.

6.1.10 1.10. She does feel that she is not as sociable as before the fistula repair.

6.2 The effect of the Claimant's condition on their ability to work and/or perform activities of daily living

6.2.1 CM does not work at the moment

6.2.2 The claimant's condition has improved remarkably since the fistula repair.

6.2.3 She is not going out that much like she did before the complication.

6.2.4 There is no mobility issues identifeid

6.2.5 She lives in a bungalow with a toilet downstairs

6.2.6 Able to perform all domestic activities with out any assistance such as cleaning, cooking, showering, laundery and shopping.

6.2.7 No restriction of day to day activities noted.

6.2.8 No leak of urine when out and about however, uses safety panty liner, just in case.

6.2.9 She describes no fear of venturing out pertaining to the urinary symptoms.

6.2.10 Was sexually active but not anymore due to being put off by the recent events

6.2.11 There is no distress I could identify with reference to the above statement

6.2.12 She described no chronic pains

6.2.13 Her sister visits her regularly

6.2.14 She voids about 10 -11 times in a 24 hour that which is totally acceptable.

6.2.15 She did struggle with her mental health a bit and felt down and tearful and wanted all to be done and over with.

6.2.16 I could not identify any restriction in the claimant's condition on their ability to work and/or perform activities of daily living

6.3 The link between the Claimant's current condition and the alleged negligence

6.3.1 The claimant's current urological symptoms are, the now and again occasional urinary urgency as well as very rare genuine stress incontinence.

6.3.2 The occasional urinary urgency could be explained by the injury sustained to the bladder particularly as noted on the EUA findings of dermal loss of the trigone following the index procedure of LLETZ

6.3.3 There is a link between this symptom and the index procedure of LLETZ

6.3.4 The very occasional stress urinary leakage could be attributed to the bladder injury and the associated urgency

6.3.5 There is a link between the above symptom and the index procedure of LLETZ.

6.3.6 CM does not have any urgency urinary incontinence

6.3.7 CM does not have any cystitis or urine infections

6.3.8 CM is not on any antibiotics or uro-drugs or any other ancillary treatment such as pelvic floor exercises.

6.3.9 CM does not wear any incontinence pads

6.3.10 CM manages her urinary urgency with knowing where the toilets are and preventing any precipitating factors such as long journeys.

6.3.11 CM's symptoms have a mild impact on the quality of life.

6.3.12 The above urinary symptoms do not impact on activities of normal day to day living

6.4 The treatment available for the Claimant's condition

6.4.1 Without further investigations and treatment CM's mild urinary urgency and the genuine stress urinary incontinence [SUI] are likely to continue at the current level of severity [Mild].

6.4.2 There is a remote possibility of spontaneous improvement in overactive bladder symptoms [less than 10% - estimate]

6.4.3 There is a remote possibility of spontaneous improvement in SUI symptoms [less than 10% - estimate]

6.4.4 CM should have initial urological evaluation and 2 years follow-up

6.4.5 Initially that would consist of patient initiated bladder diary, urinary index score [UI], and Overactive Bladder Score [OAB] charts

6.4.6 I would recommend a combination of

6.4.7 1. Fluid intake advice

6.4.8 a. avoid caffeine

6.4.9 b. restrict fluid intake to below 2L/d

6.4.102. Bladder retraining

6.4.113. Drug treatment with anticholinergic medication [e.g., solifenacin] or mirabegron [£30 per calendar month, treatment available on NHS]. I would envisage treatment would need to be sustained for 2 to 4 years.

6.4.12CM has mild SUI. This is most likely resolved with supervised pelvic floor physiotherapy. [3/12 course of physiotherapy £400 - 500]

6.4.13With physiotherapy, advise +/- medication, I would expect full resolution of CM's urinary symptoms.

6.4.14CM is unlikely to require any surgical intervention in future for the above mentioned urological symptoms

6.4.15CM is unlikely to require any time off work as a result of the recommended treatment for the above mentioned urological symptoms

6.4.16 CM is unlikely to need any periods of recovery as a result of the recommended treatment for the above mentioned urological symptoms

6.4.17 CM describes feeling let down and tearful at times, for which a psychological opinion should be considered.

6.5 The Claimant's prognosis

6.5.1 CONDITION AND PROGNOSIS:

6.5.2 10.1.1 Prior to Colposcopy / LLETZ on 26/11/21

6.5.3 10.1.2 Following the first LLETZ procedure on 24/12/20 she had no post procedural symptoms of bladder dysfunction. Just before the second LLETZ procedure CM had no symptoms of stress incontinence, urge incontinence, urgency or nocturia. CM was fit and well from urinary point of view.

6.5.4 10.1.3 Following LLETZ procedure on 26/11/21

6.5.5 10.1.4 CM indicated to me that she started to leak urine as soon as she got home and was immediately incontinent. She stood up from the chair and was flooding urine. She immediately knew that something was wrong.

6.5.6 10.1.5 CM felt ignored and nobody would listen to her. The urine just came away, she had no control and no sensation of the bladder filling or the need to go to toilet.

6.5.7 10.1.6 CM symptoms persisted and on 27/11/21 her GP noted the previous day's procedure and subsequent incontinence of urine; the GP contacted the Gynaecology on-call team who declined admission but was advised to send her to A&E at the hospital. [redacted] also contacted NHS 111 who at 17.32hrs also advised her to attend A&E. She attended at 20.15hrs with 'problem related to vagina' but 'left before clinical assessment'. Did not wait to see clinician, left ED at 21.36. CM attended on 30/11/21, She was seen by an ED Doctor. No pelvic or vaginal assessment was undertaken to identify the location of the leakage. The Gynaecology Registrar advised that her symptoms 'cannot happen' after a LLETZ. There was no gynaecology review or urologist review. Urologist advised to treat as UTI.

6.5.8 10.1.17 CM clearly described symptoms suggestive of constant urinary leakage. As the Serious Untoward Incident report indicates that the failure to entertain a differential diagnosis of VVF on 30/11/21 was 'a missed opportunity to treat' the fistula and that an extended period of catheterisation should have been commenced. There is an argument here that could have resolved the immediate grief and would have assisted in the future diagnosis of fistula. There is also a possibility that the fistula could have healed with prolonged catheterisation [less than 5% - estimate] due to the size of the fistula [large] and the condition of the vulval tissues [poor]

6.5.9 10.1.18. CM indicated to me that she had to purchase incontinence pads, but these were soaking almost immediately and her vulval region had become sore and red despite changing the pads frequently. The usage of pads and consequent rubbing of ammonical urine to the skin exacerbated the situation. Emollients were given by her GP which were of no use in grand scheme of things

6.5.10 10.1.19 CM described that the consequences of these persisting symptoms were:

6.5.11• Social activities was curtailed and ceased completely. This was in relation to the frequent change of pads and clothings within a hour due to urine soaking. She described herself as a sociable and outgoing person who enjoyed going for walks with her friends, and out for meals about once a month.

6.5.12• She used to socialise over coffee at home with her friends and this stopped completely due to the wetness experienced every time she stood up.

6.5.13• She had to rely on her sister and brother for domestic chores. The relatives visited her everyday to assist in household chores such as washing, ironing, cleaning and cooking

6.5.14• CM's sister and brother helped her with shopping and found small errands to local shops left her wet due to constant leakage of urine, and resorted to on-line shopping.

6.5.15• CM described asking a gardener for assistance, whereas previously she was able to undertake that activity enthusiastically herself, and couldn't do so no more due to leakage of urine.

6.5.16• CM said that she was in a relationship at the time, but she was unable to have sexual activities due to the continuous leakage of urine. CM felt that her urinary incontinence and the resulting lack of intimacy was partially the cause of the breakdown in the relationship.

6.5.17• CM's mental health was affected and this was compounded when her sister developed terminal cancer. She found that distressing in that she couldn't visit her due to urinary incontinence.

6.5.18• It may be helpful to obtain a Psychological assessment in addition to this report.

6.6 Please address, to the extent you are able, the Claimant's condition and prognosis, including as set out at in the Schedule of Loss and C&P evidence of [redacted] and confirm the extent to which you agree (if at all). Do you agree there is an increased risk of delayed diagnosis of endometrial cancer and that annual transvaginal ultrasound scan is recommended in light of this? To what extent do you consider there is risk of Claimant's fistula recurring and, if it does, what treatment do you consider would be required? Do you consider a prolonged period of catheterisation would have been successful and have allowed the Claimant's fistula to heal and, if so, that the Claimant would have avoided 18 months of continuous daily incontinence with perineal excoriation, two exploratory operations, fistula repair and closure of the cervix from the vagina? Do you consider the Claimant would always have required surgical intervention?

6.6.1 CONDITION AND PROGNOSIS

6.6.2 11.1 With reference to increased risk of delayed diagnosis of endometrial cancer please request a gynaecologist opinion

6.6.3 11.2 Claimant's fistula recurring: very rare possibility of the fistula recurring [less than 2% in next 5 years - estimate]

6.6.4 11.3 If the fistula recurs an attempt at revision surgery is eminently feasible and the possibility of urinary diversion [stoma] exists

6.6.5 11.4 Even if the fistula recurs, the chances that needed a surgical intervention is very remote [less than 0.25% - estimate], very unlikely to cause any major impact on quality of life [if that recurs would be mild fistulous leakage]

6.6.6 11.5 With reference to the failure to provide a catheter following the complication endured by the LLETZ, the allegation is accepted. There was no effort taken by the clinicians in mitigating the urinary incontinence by offering her a catheter. No attempt were made to provide her contact with the continnce advisors or offered incontinence pads. Therefore, the cost of private incontinence pads etc from 27th November 2021 to 25th July 2022 (35 weeks) @ approximately £15 weekly. Total: £525.00 is admissible.

6.6.7 11.6 To address the specific question of "Do you consider there was a 6 month delay in diagnosing the VVF? Should this have been diagnosed earlier? If so, by when?"

6.6.8 11.7 I consider that there was an estimate of 6 month delay in diagnosing the VVF and this is negligent.

6.6.9 11.8 VVF should have been diagnosed earlier.

6.6.10 11.8 The VVF should have been diagnosed on 30/11/21 and not until 17/5/22 when that was recognised some 18 weeks later.

6.6.11 11.9 To address the specific question of ' On the balance of probabilities, had the LLETZ procedure been performed adequately, would the Claimant have avoided a punctured bladder, uncontrollable incontinence and VVF?'

6.6.12 11.10 This question would best be answered by a gynaecologist, having said that from a urologist point of view, VVF and uncontrolled incontinence is very rare following a LLETZ procedure. The corollary is if performed adequately on balance of probabilities the complication could have been avoided.

6.6.13 11.11 To address the specific question of 'On the balance of probabilities, would early conservative treatment have avoided the need for surgical repair? If so, please detail what conservative treatment and how this would have changed the Claimant’s outcome.'

6.6.14 11.12 On balance of probabilities, early conservative treatment would have avoided the need for surgical repair [less than 5% - estimate due to the large size of the fistula], thereby the claimant would have avoided 18 months of daily incontinence with perineal excoriation, two examination under anaesthetics, and fistula repair and closure of cervix from vagina

6.6.15 11.13 The early conservative method of treatment would be prolonged long-term urethral catheter and anticholinergics such as solifenacin.

6.6.16 11.14 A cystogram to confirm or refute the VVF is necessary and to adopt the conservative method of urethral catheter.

6.6.17 11.15 After 3 months of catheterisation, a repeat cystogram to see whether fistula is healed or not, and if healed then the claimant could have avoided the surgical intervention.

6.6.18 11.16 The claimant would have required surgical intervention if the conservative method of prolonged catheterisation has failed. The surgical exploration estimate would be about 95% [based on the size of the defect, how far away from the bladder neck and the multiplicity of the fistulous track, the health of the vulval tissues]

6.6.19 11.17 To address the specific question of 'Please identify any other failings or potential allegations not yet raised'

6.6.20 11.18 Undertaking a diagnostic LLETZ in a patient with an atrophic narrowed vagina under local anaesthesia is questionable

6.6.21 11.19 On the balance of probabilities, the breach of duty led to the harm.

6.6.22 11.20 If LLETZ was performed adequately, the claimant would have avoided the bladder puncture.

6.6.23 11.21 If LLETZ was performed under general anaesthesia the complications could have been avoided

6.6.2411.22 My contention is any procedure could lead to complications, but the awareness to identify and mitigate the complications post procedure is what was missing, and compounded the claimant's grief.

6.6.2511.23 The failure to recognise from the clinical history and examination suggestive of VVF is negligent

6.6.2611.24 The chances of identifying VVF was provided by the claimant via multiple contacts with the health professionals and they failed in diagnosing the VVF earlier.

6.7 Whether you have identified any pre-existing conditions or injuries which may have impacted on the Claimant's condition and prognosis in any event?

6.7.1 none identified

6.8 Whether you consider the Claimant's current condition and prognosis has any effect on her social and domestic activities?

6.8.1 I would not consider the claimant's current condition and prognosis has any effect on her social and domestic activities.

6.8.2 CM has started to feel much more confident and has got less fear in going out

6.8.3 CM has started her regular domestic activities with no restriction

6.9 To what extent (if at all) the Claimant's prognosis is likely to improve and/or resolve?

6.9.1 Very likely the claimant's prognosis had improved to the level that it should do

6.9.2 CM has had achieved a fairly good quality of life following the corrective urological surgery

6.10 Whether the Claimant's current condition and/or future prognosis could be improved with any treatment and/or therapy. If you recommend any treatment or therapy, please provide details of the costs of such treatment.

6.10.1 15.1. CM should have an initial urological evaluation and 2 years of follow up

6.10.2 15.2 This should include [Private Sector Costs in brackets] - Initial consultation [£250 -300], Renal and Bladder Scan to check emptying of the bladder [£450 - 500]

6.10.3 15.3 I would recommend that CM has two years of urological follow up in clinic [2 x £150] to ensure her mild urinary symptoms settle down

6.10.4 15.4 Without further investigations and treatment CM's mild urinary urgency and the genuine stress urinary incontinence [SUI] are likely to continue at the current level of severity [Mild].

6.10.5 15.5 There is a remote possibility if spontaneous improvement in overactive bladder symptoms [less than 10% - estimate]

6.10.6 15.6 There is a remote possibility of spontaneous improvement in SUI symptoms [less than 10% - estimate]

6.10.7 15.7 CM should have initial urological evaluation and 2 years follow-up as per above suggestion and initially that would consist of patient initiated bladder diary, urinary index score [UI], and Overactive Bladder Score [OAB] charts

6.10.8 15.8 I would recommend a combination of

6.10.9 15.8.1 Fluid intake advice

6.10.10 15.8.1.a. avoid caffeine

6.10.11 15.8.1.b. restrict fluid intake to below 2L/d

6.10.12 15.8.2. Bladder retraining

6.10.13 15.8.3. Drug treatment with anticholinergic medication [e.g., solifenacin] or mirabegron [£30 per calendar month, treatment available on NHS prescription]. I would envisage treatment would need to be sustained for 2 to 4 years.

6.10.14 15.9 CM has mild SUI. This is most likely resolved with supervised pelvic floor physiotherapy. [3/12 course of physiotherapy £400 - 500]

6.10.15 15.10 As for [redacted] query and worry about slight risk of delayed diagnosis of endometrial cancer because of closure of cervix and the annual endometrial thinning ultrasound scan, please refer and request a gynaecological opinion and guidance

7 My Summary

7.1 ABBREVIATIONS

7.2 LLETZ - Long Loop Excision of Transformation Zone

7.3 CDP - Care Delivery Problem

7.4 EWS - Early Warning Score

7.5 EUA - Examination under anaesthetic

7.6 MRI - Magnetic Resonance Imaging

7.7 SUI - Stress urinary Incontinence

7.8 VVF - Vesico Vaginal Fistula

7.9 TZ - Transition Zone

7.10 Factual background

7.11 This claim concerns [redacted] (DOB: 18.05.52) complaint of development of vesicovaginal fistula following a routine diagnostic LLETZ procedure to assess persistent HPV at cervical screening, resulting in urinary incontinence and the need for a corrective urological surgery.

7.12 The Claimant was referred to colposcopy clinic after a cervical smear showed presence of high- risk human papilloma virus. On 27.08.21 the Claimant's cervix was noted to be atrophic, had type 2 transformation zone and demonstrated evidence of HPV virus.

7.13 She attended clinic on 26.11.21 where she was offered either further screening and review or diagnostic large loop excision of transformation zone (LLETZ) procedure. The claimant opted for a diagnostic LLETTZ.

7.14 The Claimant attended ED on 30.11.21 with continuous urine leaking, tingling sensation in perineal area and small amount of blood from vagina. The case was discussed with the gynaecology registrar on call and he consulted with the urology department. The claimant was not clinically assessed by either the Gynaecology or the Urology team. The ED doctor treated the claimant for possible UTI. There is clinical negligence on this day. This clinical contact provided an ideal opportunity to identify the cause of the urine leakage and to offer her a long term urethral catheter that could have mitigated the sufferings.

7.15 23/12/2021 Result discussed at Colposcopy MDT Outcome suggesting offer to cease from screening or repeat screening in 12 months with course of oestrogen MDT discussion involving Gynaecologist (Colposcopist), histopathologist and Nurse Colposcopist. This is a missed opportunity to identify that the biopsies were inadequate and did not represent the transition zone [TZ], rather that involved the vaginal tissue and adipose tissue. Most importantly the pathologist could have high lighted the fact that the biopsies were not from TZ, and there was negligence here. Again the failing of the trust is that the MDT involved no consultant but the coloposcopist [redacted] and this is a severe let down in itself in that the outcome was not challenged enough.

7.16 On 24/1/22, [redacted] [Post CCT Fellow] recorded in relation to the 26/11/2021 colposcopy mainly focussing on the difficulty with the LLETZ and mentioned that the obtained sample was non-diagnostic - This clearly was an missed opportunity to catch up with the patient regarding her well-being particularly the urinary incontinence.

7.17 On 2/2/22 following referral for 'ongoing urinary incontinence and soreness of to urethra and vulva' In [redacted] (Urogynaecologist) clinic she was seen by [redacted] (SpR) who noted ‘no control of bladder since colposcopy – both stress and urge incontinence’ also nocturia and nocturnal enuresis. She ‘has to wear incontinence pads throughout the day’. Prior to the LLETZ she was ‘completely fine with a normal bladder’. On examination ‘ narrow introitus, pale vaginal walls, erythema around the vulva and no stress incontinence’. No pelvic examination was performed. Management was discussed with [redacted] who did not see her himself. Discussed with the consultant to stop Solifenacin and commence Mirabegron. Referred for urodynamic studies for a better assessment. Request for GP to prescribe oestrogen cream for the vulva and pessaries. Management discussed with consultant and follow up arranged. - This clearly is a missed opportunity to link clinical history and examination findings to consider VVF as a differential diagnosis.

7.18 Urodynamic studies was abandoned on 17/5/22. MRI arranged after having had recognised the VVF. Even on this occasion, no urethral catheter was offered that could have mitigated the patient sufferings. Recognition of significance of symptoms and history.

7.19 A MRI was undertaken on 25.05.22 reporting 11mm defect within posterior bladder wall with a resultant vesicovaginal fistula (VVF).

7.20 MRI findings were then communicated and CM underwent an EUA and cystoscopy on 4/8/22 at NNUH that which showed 2 connected fistulae within the bladder. A proposed operation date for repair of the VVF was given for 8/9/22 with a clinic review first. Here again there was a failure to consider the urethral catheter, that might have mitigated the symptoms.

7.21 Discussion in NNUH MDT of the EUA findings on 10/8/2022. Difficult to repair abdominally. Consider urinary diversion. Might be consider second opinion from elsewhere. [redacted] to discuss with UCLH.

7.22 [redacted], Consultant Urologist at UCH, was contacted on 11/8/22 by telephone and offered to undertake a vaginal repair of the fistula at UCH. Further EUA and Cystoscopy performed on 10/1/23 and a subsequent MDT on 25/1/23 indicated that a vaginal repair would be possible but would probably close the cervix. Hysterectomy could be performed at the time of the fistula repair. Here again no one considered the sufferings of the claimant particularly in relation to the urinary incontinence i.e. a urethral catheter might have mitigated the symptoms.

7.23 A Surgical repair of the vesicovaginal fistula was performed vaginally on 9/5/23, using a Martius flap from the labial fat pad, tunnelled into the vagina, and covering the repair. She was discharged on 11/5/23. She returned for trial without catheter on 6/6/23 but this was deferred as fluoroscopy showed a small leak; however, on review of the images the catheter was successfully removed on 13/6/23.

7.24 The claimant is currently enjoying a good quality of life with mild urinary symptoms.

7.25 I have addressed the claimant's condition and prognosis in appropriate section, and after reviewing the schedule of loss and C and P evidence of [redacted] I am able to state the following to the best of my ability and without prejudice, regarding the specific questions for which the answer is being sought:

7.26 (a) Do you agree there is an increased risk of delayed diagnosis of endometrial cancer and that annual transvaginal ultrasound scan is recommended in light of this? - I cannot comment on this, as this is outside my expertise and I recommend a gynaecologist opinion.

7.27 (b) To what extent do you consider there is risk of Claimant's fistula recurring and, if it does, what treatment do you consider would be required? - The chances of the claimant's fistula recurring is slim in the region of less than 2% in next 5 years - estimate

7.28 (c) Do you consider a prolonged period of catheterisation would have been successful and have allowed the Claimant's fistula to heal and, if so, that the Claimant would have avoided 18 months of continuous daily incontinence with perineal excoriation,

7.29 two exploratory operations, fistula repair and closure of the cervix from the vagina? - The prolonged period of catheterisation might have been successful, in the region of less than 5% - estimate due to the large size of the fistula and considering the poor tissue condition of the claimant

7.30 (d) Do you consider the Claimant would always have required surgical intervention? - In my experience and opinion, very unlikely that the prolonged catheterisation would have helped heal the fistula. On balance of probabilities the claimant would have required a corrective urological surgery, anyways.

7.31 (e) Whether you have identified any pre-existing conditions or injuries which may have impacted on the Claimant's condition and prognosis in any event - I could not identify any pre-existing condition or injuries that might have impacted on the claimant's condition and prognosis in any event

7.32 (f) Whether you consider the Claimant's current condition and prognosis has any effect on her social and domestic activities - I could not identify any adverse effect on her social and domestic activities based on the current condition and prognosis after the corrective urological surgery

7.33 Statement of compliance

7.34 I understand my duty as an expert witness is to the court. I have complied with that duty and will continue to comply with it. This report includes all matter relevant to the issues on which my expert evidence is given. I have given details in this report of any matters which might affect the validity of this report. I have addressed this report to the court. I further understand that my duty to the court overrides ant obligation to the party from whom I received instructions.

7.35 Practice Direction 35 para 3.2 (9) (a) and Guidance para 52 [see Appendix 20]

7.36 Declaration of awareness

7.37 I confirm that I am aware of the requirements of Part 35 and Practice Direction 35, and the Guidance for the Instruction of Experts in Civil Claims 2014

7.38 Statement of truth

7.39 I confirm that I have made clear which facts and matters referred to in this report are within my knowledge and which are not. Those that are within my knowledge I confirm to be true. The opinions I have expressed represent my true and complete professional opinions on the matters to which they refer.

7.40 I understand that proceedings for contempt of court may be brought against anyone who makes or causes to be made, a false statement in a document verified by a statement of truth without an honest belief in its truth.

7.41 Practice Direction 35 para 3.3 and Guidance para 53.

7.42 Statement of conflicts

7.43 I confirm that I have no conflict of interest of any kind, other than any which I have already set out in this report. I do not consider that any interest which I have disclosed affects my suitability to give expert evidence on any issue which I have given evidence and I will advice the party by whom I am instructed if, between the date of this report and the trial, there is any change in circumstances which affects this statement

7.44 Signature: Mr Krishnan Anantharamakrishnan; Date 4 August 2024

8 Declaration and Statement of Truth

8.1 I have endeavoured in this report and in my opinion to be accurate and to have covered all relevant issues concerning the matters stated which I have been asked to address.

8.2 I have endeavoured to include in my report those matters which I have knowledge of, or which I have been made aware, that might adversely affect the validity of my opinion.

8.3 I have indicated the sources of all information used. I have not, without forming an independent view, included or excluded anything, which has been suggested to me by others.

8.4 I will notify those instructing me immediately and confirm in writing if for any reason my existing report requires any correction or qualification.

8.5 I understand that my report will form the evidence to be given under oath or given under oath or affirmation, and that I may be cross-examined on my report by a cross-examiner assisted by an expert. I confirm that I understand my duty to the Court and have complied with and will continue to comply with it.

8.6 I also confirm that I am aware of the requirements of CPR Part 35, Practice Direction 35 and the Guidance for the Instruction of Experts in Civil Claims 2014.

8.7 I confirm that I have made clear which facts and matters in this report are within my own knowledge and which are not. Those that are within my knowledge I confirm to be true. The opinions I have expressed represent my true and complete professional opinions on the matters to which they refer.

8.8 I understand that proceedings for contempt of court may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief in its truth.

Dr Krishnan Anantharamakrishnan MBBS, MS, FRCS, MSc, FEBU
Consultant Urological Surgeon
Sherwood Forest Hospitals NHS Foundation Trust, Sutton-in-Ashfield - GMC 4588780