Walsall Healthcare NHS
NHS Trust

Our Ref: RB/CR/MU/ 2017/28914
Your Ref: Regulation 28 Report
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Chief Executive's Office
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Dear Mr Siddique,

Re: Margaret Spencer (Deceased)

Date of Birth: 08/03/1929
Date of Death: 17/12/2017 (88 years old)
Date of Inquest: 22/03/2018

I am writing in response to your report under paragraph 7, Schedule 5, of the Coroners and Justice Act 2009 and regulations 28 and 29 of the Coroners (Investigations) Regulations 2013.

Circumstances of Margaret Jean Spencer death

Margaret Jean Spencer (preferred name Jean) was admitted to Walsall Healthcare NHS Trust (WHNHST) on the 7th November 2017 following a fall at home and remained in hospital until her demise in December 2017.

Precis of history:

Mrs Spencer's medical and social history included: chronic kidney disease with recurrent urinary tract infections (UTI); ischaemic heart disease (stent x2); bilateral macular degeneration (partially-sighted). Her gynaecological history included: a hysterectomy in 1987 with an anterior colporrhaphy in 1995, with insertion of a vaginal shelf pessary in 2014 at WHNHST. Mrs Spencer lived in a bungalow with her husband (diagnosed with dementia) and mobilised with a stick but was mainly bed-bound since October 2017 due to back pain. Social support was provided from family (sister) daily.

On the 2nd of November 2017 Mrs Spencer underwent a flexible cystoscopy for recurrent UTIs under local anaesthetic. Findings noted: a large calcified pessary found in vagina, eroding into urethra. Surgeons were unable to advance the cystoscope past the pessary and therefore the procedure was abandoned and Mrs Spencer later discharged. A follow up plan

of care included: a CT scan with a view to performing a cystoscopy under general anaesthesia (GA) and advice sought from a Consultant Gynaecologist.

On the 3rd of November 2017 Mrs Spencer returned to WHNHST via Accident and Emergency (A&E) feeling unwell. Mrs Spencer was diagnosed with a UTI and subsequently returned to the care of her General Practitioner (GP), with no follow up appointments within the hospital.

Mrs Spencer then returned to WHNHST on the 7th of November 2017 via A&E following a fall at home and concerns of confusion. She was subsequently admitted to hospital, treated for urosepsis and acute kidney injury; initially under the care of the medical team. On the 16th of November, while under the care of the gynaecology, medical and urology team Mrs Spencer underwent a cystoscopy and attempted removal of shelf pessary under GA. The findings indicated that: most of shaft of the pessary was within the bladder and a large fistula was felt behind the pessary. Pessary encrustations were removed by lithoclast; however, surgeons were unable to remove the pessary vaginally; therefore, the procedure was abandoned, and plans were set to acquire a second urology opinion and to consider an open procedure.

On the 23rd of November 2017 Mrs Spencer was considered medically fit for discharge home from WHNHST and to await admission to a tertiary hospital for further treatment (potential open procedure). Discharge home did not occur as additional social support had to be put in place and shortly afterwards Mrs Spencer's health deteriorated (25th November 2017) noting: raised inflammatory markers, poor renal function and a diagnosis of a lower respiratory tract infection leading to hospital acquired pneumonia (HAP) in early December. Subsequently, Mrs Spencer sadly passed away on the 17th of December 2017.

Trust investigation:

Prior to Mrs Spencer's death WHNHST had already commenced an investigation into her care following recognition of the retained shelf pessary; the investigation was subsequently widened following her death. This was reported as a Serious Incident (SI) to the Divisional directors and the CCG, and the final report approved on the 5th of March 2018.

While the cause of death on the certificate was listed as:

1a Acute kidney injury;
b Hospital acquired pneumonia;
c Ischaemic heart disease, frailty, forgotten vaginal pessary,

The investigation team concluded that the root cause of Mrs Spencer's death was a failure to provide appropriate follow up care to support the shelf pessary that was placed insitu in May 2014. The shelf pessary has a limited timeframe of approximately 6 months, when the pessary should be removed and reinserted (if deemed appropriate) by a gynaecologist. However, there were also missed opportunities by her GP, with a failure in the documentation of patient history, noting a shelf pessary; this is an oversight in the GP system and would have alerted the GP that a device was insitu which required follow up care. Mrs Spencer did not receive any further appointments from WHNHST and the pessary inserted in May 2014 remained insitu until her death in December 2017.

As part of the process of being open and honest and learning from incidents, the SI (serious incident) review panel requested that an external review of the case was undertaken. This review was completed by a consultant urologist at a local tertiary unit. The outcome of the report highlighted comparable issues identified in the WHNHST investigation findings; with the main findings of: neglect – due to a failure in the Trust appointment system with no failsafe mechanism to ensure the patient was followed up within an appropriate timeframe and the failure in the GP system to holistically review the patient.

Coroner's concerns:

The conclusion of the inquest on the 22nd of March 2018 was a short narrative outlining that Mrs Spencer: Died after developing complications arising from a failure to remove a pessary that had been put in place in 2014. A failure to do a timely follow up review due to system failures in IT and administrative input errors contributed to a decline in her condition and these failures and omissions were contributed to by neglect.

During the inquest the evidence revealed matters giving rise to concern and a risk that future deaths will occur unless action is taken.

Circumstances of the death:

i. Mrs Spencer was under care of the Manor Hospital Gynaecology clinic at Manor Hospital. She had regular appointments and review after being diagnosed with a prolapse. This was treated with a pessary.
ii. She last saw and was reviewed by her Consultant on the 23rd of May 2014 and a new pessary given.
iii. Due to change in IT systems no follow up review took place and her condition deteriorated with her reporting frequent urinary tract infections during 2017.
iv. This resulted in further hospital admissions and in November 2017 it was discovered that the pessary was eroded through the bladder.
v. Sadly, despite plans for further surgery her condition continued to decline, and she passed away on the 17th December 2017 after developing pneumonia and acute kidney injury.

Preventing Future Deaths – Action for Walsall Healthcare NHS Trust:

ACTION SHOULD BE TAKEN

In my opinion action should be taken to prevent future deaths and I believe you have the power to take such action.

> *You may wish to consider further reviewing the systems in place to ensure that all relevant patients identified during the relevant period have been identified and further treatment offered as needed. In addition, you may wish to review that this IT system change did not result in any other patients across the Trust having their cases closed prematurely.*

<u>Actions Taken:</u>

Gynaecology care and follow up of patients:

The following key actions were taken in response to this incident to reduce the risk of any further incidents of this nature occurring. This section of the response to the coroner takes into consideration the early part of the action required by the coroner, addressing '*all relevant patients identified during the relevant period have been identified and further treatment offered as needed'*.

This section of the response is addressed in 3 phases and describes the actions undertaken moving forward.

NB. All data relies on patients being coded as having a vaginal pessary inserted. In the case of Mrs Spencer, she was not coded as having a pessary inserted; her access plan was closed and therefore she would not appear on the recall list for the calendar year of 2014.

Phase 1: This commenced upon recognition of Mrs Spencer's incident report for the retained shelf pessary.

A report was generated via the Performance and Information Team which identified all the patients that had a pessary fitted during the calendar year of 2014. This report identified 602 patients having a vaginal pessary (ring and shelf) fitted during 2014. Out of these 602 patients, 7 had a shelf pessary fitted and had not received a follow up appointment. All 7 patients were reviewed by a consultant gynaecologist within a short time frame; none of the other 7 patients have been harmed.

Phase 2: This involved the reviewing of all patients receiving a vaginal pessary between January 2015 to 28th February 2018. This list of patients was generated by the same method adopted for phase 1.

This report identified a total of 2,856 having a vaginal pessary (ring and shelf) fitted during the stated period. Out of the 2,856 patients identified, 63 patients had a pessary fitted. Using Lorenzo (IT data) all 63 patients care plans were reviewed by a clinician, identifying 20 patients that required a follow up clinic appointment. The other 43 on double checking had been followed up appropriately; including the one (1) high risk patient with a shelf pessary, with no harm determined.

Out of these twenty (20) patients without a follow up appointment; one (1) patient has declined a follow up appointment: due to fragility with age (96) and history of dementia, this has been agreed with the patient's next of kin. One (1) other patient chose to attend a private consultation, the pessary (inserted in 2015) was removed under GA and further follow up arrangements will be within WHNHST; this patient was incident reported within WHNHST and moderate harm was acknowledged, with no long term sequelae, DoC has been enacted for this patient. Out of the eighteen (18) patients remaining, sixteen (16) have had follow up appointments with no harm determined; the remaining two (2) patients will be reviewed by a consultant gynaecologist, one by the end of May 2018, and the final patient in early June as per patient request.

Should any of these remaining patients, awaiting consultant review, come to harm they will be individually incident reported and investigated accordingly, including disclosure to the patient under the Duty of Candour (DoC).

Phase 3: Following review of the data for the period listed in phase 2 it was noted that a single consultant gynaecologist discharged all their patients receiving a shelf pessary back to the care of the GP, requiring a referral back into the system when the pessary required changing, if the GP was not trained to do so. To provide assurance that these patients had been followed up appropriately **all patients receiving a vaginal pessary between January 2015 to 28th of February 2018, listed under the care of this specific consultant, were reviewed. T**his list of patients was generated by the same method adopted for phase 1.

Fifteen (15) patients were identified as having a shelf pessary. Out of these 15 patients: 5 patients had already received a referral from another consultant gynaecologist for assessment, 6 patients had already had the pessary removed and no further pessary inserted; this includes 1 patient from phase 2 noted as moderate harm to the patient (please refer to phase 2 for detail) . One patient (1) was reviewed by a consultant in April 2018 with a follow up appointment generated. Three (3) patients have appointments booked with a consultant and all will be reviewed by early June 2018.

To date no harm has come to the patients already reviewed by the consultant gynaecologist attending WHNHST. Should any of the 3 remaining patients come to harm they will be individually incident reported and investigated accordantly, including disclosure to the patient under the Duty of Candour (DoC).

Moving forward:

Since recognition of the incident at WHNHST there have been several processes reviewed to generate a safer system to ensure women (and all patients across the Trust) are followed up accordingly to their individual requirements.

From a gynaecological perspective a Multi-Disciplinary Team (MDT) approach has been introduced to support the changes in systems and processes. The MDT has not only reviewed the patients that were not assessed in a timely manner, following insertion of their pessary, but also new systems have been implemented, with regular audits and monitoring of follow up appointments arranged to ensure the revised systems and processes are functional.

The three main changes within the gynaecology department include: the generation of a patient leaflet, which informs the patient in detail as to the expectations of the device they have insitu and relevant follow up care that is required. A *patient passport* is being generated: this is dispensed to the patient, along with the leaflet, before they leave the hospital. The *passport* contains the type of device inserted, the individual identification code of the device, the date of insertion and the expected follow up date/pre-generated appointment date (if this is available at the time of leaving). And, in addition to this, a letter of confirmation of insertion of device and relevant information is automatically distributed to the patients GP; GP information is checked with the patient before they leave the hospital to maintain an updated system.

Lorenzo / Trust perspective Introduction:

Following the implementation of 'Lorenzo', the new patient administration system in 2014, multiple issues with patient level data occurred and the Hospital ceased reporting its National RTT (Referral to Treatment) performance to the Trust Development Authority(TDA) and from April 2016 National Health Service Improvement (NHSI). These problems left significant data quality issues regarding the accuracy of patient waiting lists for new and follow up patients.

The Trust returned to reporting its RTT performance in October 2016, following a number of actions to improve data quality for the Trusts waiting list. This involved the validation of over 30,000 patient's pathways, with support from an external validation company. This included communicating with patients and GPs as part of this process.

There was Board, TDA and subsequently NHSI scrutiny of the improvement plans. In October 2016 the Trust was assured the data was accurate enough to resume reporting to NHSI.

Mrs Spencer's appointment occurred two weeks after the Lorenzo system went live, and this is when Mrs Spencer's access plan was closed in human error by the reception staff. The patient's access plan is in effect the patient's ticket to their next appointment. As this was closed there was no way of our systems being able to track that she needed a follow up appointment and therefore she would be classed as lost to follow up.

The Trust closes on average 500 patient access plans per day when the patients care is concluded. The scale of these closures means that is it not possible to review and validate all historical access plan closures.

Clinical Harm Group

The clinical review and assessment of harm was managed along with the Trust incident reporting system Safeguard with a monthly combined WHNHST and WCCG Clinical Harm meeting which reported to Trust Board. The cases were discussed with both Trust and primary care doctors and the level of harm agreed. These patients were then dealt with by the Trust RCA process.

As of 23rd May:

There are 362 patients on the clinical harm data base of these:

95 relate to 52 week RTT issues,
1 relates 31 day cancer upgrade pathway,
245 relate to 62 day cancer pathway
21 relate to care/lost to follow up issues as in the index case.

221 are closed following review of these the following levels of harm have been applied

No harm 175
Minor harm 136
Moderate harm 6
Major harm 3 all being managed via RCA process and reported through RMC

141 remain open pending review

4 delay, lost to follow up
4 relating to 52 weeks RTT
133 cancer pathway related

The Clinical Harm process continues. There have been no reported deaths.

Trust Outpatient Improvement Process

It was recognised at this time that there were significant issues with data quality in outpatients and for the follow up patient waiting list (held on access plans in Lorenzo) and it was not clear as to the 'true' number of patients exceeding their guaranteed appointment date (GAD).

It was agreed that a program of work to improve outpatient processes and validate the patients recorded as needing a follow up appointment.

A validation pilot was undertaken that focused on reviewing the overdue access plans in the clinical speciality of gastroenterology. This pilot solely used manual systems by the RTT validation team to validation the open follow up access plans.

The results from the pilot showed that majority of problems with the overdue access plans have stemmed from poor outpatient processes -

- Appointments not cashed – clinics not completed on the Lorenzo system
- Outcomes not completed on the same day as appointment
- Follow up appointments not being booked
- Clinicians not completing e-Outcome forms

The first part of the validation process involved a patient by patient review using the Trust's patient management system (Lorenzo) and Fusion (the clinical system) to establish whether patients have had further contact with the Trust since the access plan was created. It was agreed in a meeting between NHSI, NHSE and the CCG to focus on a fixed data position of the 1st January 2017. There is a variation by treatment function (speciality), but the average percent have been identified as spent or duplicate entries exceeds 40%.

The position fixed at 1st January 2018 was 53795 overdue outpatient access plans. The Trust has reviewed to date 46865 access plans. The patient's access plans have been reviewed and the following action has been taken – discharged, seen in clinic or the patient has been written to regarding their care. The project continues to validate the remaining 6930 follow up access plans.

Outpatient processes have been improved across the Trust with the following measures being taken: –

Electronic outcome

This has ensured that appointments have an electronic record of the patient's next steps. Previous to these a paper system was used which was a risk due to being mislaid, patients leaving the clinic with them and the clinicians not completing them. No audit trail was available following the appointment.

The electronic system also provides an alert to which type of appointment is required such as fully booked– patient requires an appointment within six weeks, has a condition of risk such as cancer or device inserted. The system also provides an alert if a clinician has not completed an outcome form for the patient following their appointment so this can be investigated and completed to ensure the patient's next appointment needs are recorded.

This also provides an electronic audit system to review outcomes and ensures the patient has the correct appointment, which delivers an additional safety check against human error.

Outpatient processes Improvement

Every outpatient clinic is now 'cashed up' (patient outcomes completed), this is monitored daily by the central team. Historically this did not happen and had contributed to the overdue access plans and data quality issues experienced in the Trust.

Booking procedures and communication with patients has been improved including introducing a DNA text reminder clinic which has seen an increase in patients attending their appointments.

Patient waiting time reports have been strengthened and validated on a weekly basis by the operational teams to ensure patient receive timely treatment.

Data Quality Metrics

There are a number of monitoring of processes and systems now within WHNHST supported by the RTT Validators and Data Quality team. These teams run a series of reports each month that review the patient systems for data quality or human errors that may that occur. The teams take corrective action and if necessary refer the user back for training and support.

The outpatient receptionists have specific modules for their role based training. Refresher sessions have been regularly delivered to all receptionists since go live to ensure staff remain up to date with the system, receive the same messages and provide further assurances of the required competencies. The training team monitor assessments that were completed during training sessions designed to equip staff with the required competencies to use the system safely and effectively. Any staff that failed to reach an 80% pass mark are re-trained.

Conclusion:

The Trust recognises that the implementation of the Lorenzo processes and the inadequate staff training led to poor performance, a poor patient experience and led to harm significantly contributing to the death of Mrs Spencer and to major harm in 3 other patients.

It is through the above interventions and continued monitoring that the Trust believes that patient pathways in outpatients have been improved and safer for patients which are being closely monitored and assured to Trust Board, TDA and WCCG.

Finally, and on behalf of the Trust, I would like to take the opportunity to offer our sincere condolences to her sister and all Mrs Spencer's family for their loss and apologise for the Trusts failure to follow her care in relation to the insertion of the shelf pessary and subsequent gynaecological appointments.

I trust that the actions set out in this letter will provide you with the assurance that we have responded constructively and with the seriousness required to improve the care we provide.

Yours sincerely

Richard Beeken
Chief Executive