Department of Health & Social Care

From Nadine Dorries MP
Minister of State for Patient Safety,
Suicide Prevention and Mental Health

39 Victoria Street
London
SW1H 0EU

[redacted]

[redacted]

Ms Louise Hunt
HM Senior Coroner, Birmingham and Solihull
HM Coroner's Court
50 Newton Street
Birmingham B4 6NE

14 July 2021

Dear Ms Hunt,

Thank you for your letter of 31 March 2021 about the death of Joan Coley. I am replying as Minister with responsibility for hospital care quality and patient safety and I am grateful for the additional time in which to do so.

I would like to begin by saying how deeply sorry I was to read the circumstances of Ms Coley's death. That Ms Coley's death was contributed to by failings in care is extremely distressing and I offer my most heartfelt sympathies to her family and loved ones. We must do all we can to learn from such tragic incidents to ensure the safety of health services and prevent future deaths.

In preparing this response, Departmental officials have made enquiries with Health Education England (HEE) and the UK Foundation Programme Office (UKFPO); The General Medical Council (GMC); as well as NHS England and NHS Improvement (NHSEI) and the Care Quality Commission (CQC).

I am advised that [redacted], National Director of Education Quality and Medical Director at HEE, and [redacted], Medical Director and Director of Education and Standards at the GMC, have provided detailed responses addressing the matters of concern in your report.

You will therefore be aware that UK medical schools determine the content of their own curricula and that the delivery of these undergraduate curricula are required to meet the standards set by the GMC, which monitors and checks to make sure that these standards are maintained. The standards require the curriculum to be formed in a way that allows all medical students to meet the GMC's *Outcomes for Graduates* by the time they complete their medical degree, which describe the knowledge, skills and behaviour they have to show as newly registered doctors.

The curricula for postgraduate specialty training are set by the Academy of Medical Royal Colleges for Foundation training, and by individual Royal Colleges and faculties for specialty training. The GMC approves curricula and assessment systems for each training programme. Curricula emphasise the skills and approaches that a doctor must develop in order to ensure accurate and timely diagnoses and treatment plans for their patients.

The GMC has explained in its response that procedures using central lines are not included in the GMC's *Outcomes for Graduates* as the GMC considers this to be beyond the level of competence required for newly qualified doctors. However, medical students should be taught about the general risks associated with central lines.

Similarly, the procedure of taking blood samples from central lines is not included in the *Outcomes for provisionally registered doctors with a licence to practice* that all Foundation Year 1 doctors should achieve. It is the view of the GMC that the taking of blood samples from central lines is a procedure undertaken by specialists, or in specialist units and that:

> '*A doctor in training, and especially a recently graduated Foundation Year 1 doctor, should only undertake this procedure on the specific advice of, and under the direct supervision of, a suitably qualified senior colleague. They also must receive specific authorisation and training*'.

You may wish to note that the 2021 Foundation Curriculum, planned for introduction in August 2021, does not contain any specific procedural skills that must be acquired and assessed during the Foundation Programme. Specialty focussed procedural skills must be learnt and performed while supervised before they are undertaken independently. The importance of good supervision is emphasised throughout the Foundation Curriculum.

Doctors in training are expected to acknowledge the limits of their capabilities and understand the risk of performing procedures beyond their level of competence.

In addition, an employer should ensure that there is an appropriate process in place to approve a doctor's competency to undertake specialist and high-risk procedures.

In relation to determining the competency of a trainee doctor, the GMC response explains that its standards state that organisations:

- Must have a reliable way of identifying leaners at different stages of education and training and that learners are not expected to work beyond their competence; and,

- Make sure there are enough suitably qualified staff members to provide learners with appropriate clinical supervision at all times. In particular, Foundation doctors must have on-site access to a senior colleague who is suitably qualified to deal with problems that may arise.

The GMC will continue to work to support local organisations in the West Midlands in their response to Ms Coley's death to improve the quality and safety of the training environment. The GMC has also indicated that it will share learning nationally.

In addition, I welcome the actions that the UKFPO has confirmed it will take in response to the issues highlighted in your report, namely:

- Write to all UK Postgraduate Deans to request that they ensure their induction programmes for Foundation doctors are in protected time; include best practice; and, reinforce the requirements of Foundation Professional Capability 18: *recognises and works within limits of personal competence*;

- Cascade learning from your Prevention of Future Deaths report through the Postgraduate Deans/Foundation Schools, emphasising that:

    - The taking of blood samples from central lines (and any other procedural skill not included in the GMC's '*Outcomes for Graduates*') must only be carried out independently by those who have been trained appropriately and confirmed to be competent to perform the procedure unsupervised; and,

    - That all named clinical supervisors must have appropriate training and fully understand their responsibilities and accountability in undertaking this role. They must ensure an understanding of the competency levels of the trainees for which they are responsible and ensure appropriate supervision is provided at all times.

I hope together these actions provide assurance that action is being taken to learn from the death of Ms Coley.

Finally, you may wish to note that my officials have shared your report with the Healthcare Safety Investigation Branch (HSIB) to support its intelligence monitoring of patient safety risks. The HSIB conducts national patient safety investigations where certain criteria are met. In addition, your report has been brought to the attention of the Kidney Patient Safety Committee, a core structure of the UK Kidney Association which works closely with NHSEI and the Medicine and Healthcare products Regulatory Agency (MHRA), and I am advised that the Committee will consider the circumstances and concerns in your report that fall within its scope.

I hope this response is helpful. Thank you for bringing these concerns to my attention.

NADINE DORRIES

MINISTER OF STATE FOR PATIENT SAFETY, SUICIDE PREVENTION AND MENTAL HEALTH

Aston Medical School
BIRMINGHAM UK

Aston Medical School
Aston University
Birmingham B4 7ET
United Kingdom
[redacted]
medicalschool@aston.ac.uk
astonmedicalschool.com

26 May 2021 [redacted]

Mrs Louise Hunt
Senior Coroner for Birmingham and Solihull
50 Newton Street
Birmingham
B4 6NE

By email

Dear Mrs Hunt

Aston Medical School Response to the Regulation 28 Report to Prevent Future Deaths

I am responding to your Regulation 28 Report dated 31.03.21 following the inquest and your ruling in respect of the death of the late Mrs Joan Coley.

We have noted the six MATTERS OF CONCERN you raised namely:

1. Medical school training
2. Induction programme for FY1 Doctors and assessment of base line competencies
3. How to effectively assess and monitor competencies to undertake procedures
4. Handover of competencies from ward to ward
5. General understanding of the process to follow when taking blood from a central line and the associated risks
6. Standard operating procedures for taking bloods from central lines

As a medical school we have focused our attention on the first and fifth matter of concern and will liaise with Health Education West Midlands, the General Medical Council and Local Education Providers to keep informed of developments in the trainee curriculum.

Following this serious incident senior members of teaching and administrative staff across the MBChB programme at Aston Medical School (AMS) have met to review the School's relevant curriculum and documents, to discuss the practical procedures programme with Sandwell and West Birmingham Hospitals and to discuss your Regulation 28 Report and recommendations. We also met with the medical student involved and read the student's statement to identify gaps in knowledge and understanding and potential weaknesses in our processes.

Re

1. Medical School Training *and*

5. General understanding of the process to follow when taking blood from a central line and the associated risks

The GMC regulates undergraduate medical education and defines the Outcomes for Graduates (GMC, 2018) and the required Practical Skills and Procedures (GMC, 2019). The latter is available at https://www.gmc-uk.org/-/media/documents/practical-skills-and-procedures-a4_pdf-78058950.pdf

Managing and caring for central venous lines is not included in this list for graduating medical schools; Aston Medical School will therefore focus its efforts, from Year 1, on ensuring students have a good understanding of the clinical significance of the physiology of the large central veins and how these differ from peripheral veins. In Year 3, students will be introduced to the risks associated with central lines, supported by case-based learning and throughout Years 3-5 students will be reminded of the causes of air embolism and its emergency treatment.

We will develop or source a standard infogram or picture to succinctly, dramatically and repeatedly inform students that a central line must never have both the clamp and cap open at the same time.

As Year 3 students begin the long clinical placements we shall emphasise the Practical Procedures 3 Question Rule (described in the Action Plan) that students must use to decide if they can undertake procedures on patients, and students will be required to seek agreement from a Specialty Trainee or Consultant if they wish to undertake a procedure not explicitly listed in the curriculum.

The lessons learned from this serious incident must be transferred to other procedures; there is potential for error and harm with respect to other procedures not currently on the GMC list. We will therefore include teaching on generic and specific risks of practical procedures throughout Years 3-5, through videos, lectures, handbooks and discussions of scenarios including serious incidents. We will ensure students understand the risks of procedures within the curriculum and are introduced to the risks of the most common procedures which they may observe but which are outwith the undergraduate curriculum.

As a result of our internal review of materials we have also refined titles and descriptions to highlight the difference between peripheral and central vein procedures.

To maximise the learning and impact of our action plan we will meet with Sandwell and West Birmingham Hospitals (SWBH) within the month to discuss our reports and implications for teaching and practice across the medical school and the Trust. Going forward, we will inform all our Local Education Providers of our developments within Practical Procedures through our meetings, handbooks and training sessions.

We will share our response to your Regulation 28 Report with the Regional Postgraduate Dean West Midlands and meet with his team. Finally the GMC is planning to meet with the University of Birmingham and Aston Medical School together, in the near future, to review the implications of your report and our responses for other medical schools.

Please find attached a more detailed Action Plan in response to your recommendations. It also draws on the AMS internal review of curriculum and documents, review and discussion of the AMS student's statement, and correspondence and discussion with SWBH regarding practical procedures.

Yours sincerely

[redacted]

[redacted]
Interim Head of School
Dean of Medical Education

Cc: GMC; Regional Postgraduate Dean HE West Midlands

UNIVERSITY OF BIRMINGHAM

BIRMINGHAM MEDICAL SCHOOL

Institute of Clinical Sciences
College of Medical and Dental Sciences
Edgbaston Birmingham B15 2TT

Ms L Hunt
Senior Coroner for Birmingham and Solihull

4th June 2021

Dear Madam,

Re: University of Birmingham Coroner Response

We were saddened to hear of the death of Joan Mavis Coley from sepsis contributed to by an air embolus caused by inadvertently leaving a central line unclamped.

At the University of Birmingham Medical School we take the requirement to ensure that upon graduation, all our medical students are able to practice in a safe and competent manner and are able to meet all the requirements determined by the General Medical Council in its document '*Outcomes for Graduates'* and supplementary document '*Practical Skills and Procedures.'* This document in particular, outlines the core set of practical skills and procedures, and minimum level of performance that newly qualified doctors must have when they start work for the first time, so they can practice safely. For each core skill or procedure, the GMC has determined three levels of competence:

1. Safe to practice in simulation
2. Safe to practice under direct supervision
3. Safe to practice under indirect supervision

It is noticeable that this document does not make mention of the need to know or show how to take blood from a central line, the physiology involved or the potential risks.

Nevertheless, it has been a local requirement for several years for medical students at the University of Birmingham Medical School to demonstrate competence in undertaking blood sampling from a central line under direct supervision.

Only students in their final year of study are permitted to undertake this procedure and they are not able to do so unless they have first undertaken a simulated training session and participated in the pre-course learning. Medical students who are not in their final year are not permitted or required to undertake practice in this skill.

Pre-course learning

Consists of a 'storyboard' of how to take blood from a central line, and a twenty-slide power point presentation with the following learning outcomes:

- Recognition and indication of CVAD use
- Understand potential complications and their management (including, notably, air embolism from an uncapped central line port or on line insertion)
- Monitor and manage ongoing care
- Identify relevant documentation
- Understand principles of removal
- Taking and management of bloods

Simulated training session

The content of the simulated training session is reviewed yearly and delivered by a specialist clinical skills team who are part of the Queen Elizabeth Hospital Birmingham. Attendance is mandatory and attendance records are kept. The procedure is demonstrated by the clinical skills team, with an opportunity to undertake the procedure in the clinical skills simulation laboratory. Only when this has been achieved are students permitted to undertake the procedure of accessing a central venous access device in clinical practice, and then only under direct supervision.

Up until July 2021 it has been a requirement of the University of Birmingham Medical School that final year medical students undertake three successful attempts of accessing a central venous access device under direct supervision. Successful attempts are deemed to occur when the clinician supervising the medical student feels that they have adequately followed the correct procedure in a safe manner.

Audit of student procedure practice of accessing a central venous access device

Each student is required to keep an electronic record of their attendance at the clinical skills simulation day and confirm that they have safely and competently demonstrated accessing the device in simulation, signed by a clinical skills trainer. Each time a student undertakes the procedure in clinical practice under direct supervision they will record this in their student clinical skills electronic record, which will be countersigned and dated by the supervising clinician. The University of Birmingham Medical School has determined that only clinicians or healthcare professionals who are familiar and deemed competent with this procedure in normal clinical practice should supervise a final year student in undertaking this skill. It has been our expectation that this would usually be restricted to those clinicians/health care professionals working in intensive care or anaesthesia. All final year students are required to record that they have successfully accessed a central venous device on a minimum of three occasions in clinical practice, under direct supervision. This forms part of the requirement for all final year students to graduate and progress into the foundation training programme and is reviewed by the exam board.

Alterations to training further to the Regulation 28 report to prevent future deaths

It is the intention of the University of Birmingham Medical School to continue to mandate participation of the pre-course learning content and simulated training session all final year students undertake in accessing central venous devices. Emphasis will continue to be placed on recognition and preventing and managing complications. However, it has become increasingly more difficult for students to achieve the previously required number of attempts of procedural practice in this skill as a result of COVID-19. Furthermore, it has been recognised that outside of the critical care environment there are few clinicians who are able to demonstrate the required familiarity with the procedure in order for them to clinically supervise students undertaking this skill. For this reason, whilst we will encourage students to undertake the clinical skills of accessing a central venous device under appropriate direct clinical supervision, where the opportunity arises, it will no longer be a

requirement for students to demonstrate a minimum number of successful attempts in order to graduate.

We trust that this information will help with your enquiry and please do not hesitate to contact us further if we can be of any further assistance.

Yours sincerely

[redacted]
Senior Clinical Lecturer University of Birmingham
Clinical Skills Lead MB ChB Programme

[redacted]

[redacted]
MB ChB Programme Lead
Vice Dean Birmingham Medical School

[redacted]
Dean Birmingham Medical School

Sandwell and West Birmingham Hospitals NHS
NHS Trust

Trust Headquarters
Sandwell Hospital
Lyndon
West Bromwich
B71 4HJ

Mrs Louise Hunt
Senior Coroner for Birmingham and Solihull
50 Newton Street
Birmingham
B4 6NE

[redacted]

11 May 2021

Dear Mrs Hunt

Response to the Regulation 28 Report to Prevent Future Deaths – the late Joan Coley

I am in receipt of your Regulation 28 Report following the inquest and your ruling on 30 March 2021, in respect of the late Mrs Joan Coley. This letter will be copied to Mrs Coley's family and I would extend, through you, my condolences once again for their loss.

Recognising that a number of the recommendations focus on training of doctors and the networks which support this, there are steps we can take to further support medical staff joining and rotating within the Trust and protect our patients. These steps are a collective view following discussion with the Medical Education Director, Undergraduate and Postgraduate tutors. Conversations have also been had with leaders from HEWM to whom a copy of this report will be sent for consideration of the factors that we will be putting in place and how this might link with any wider learning or advice for trainee supervision at other organisation.

1. **Medical school training**
   Whilst not a Medical School, Sandwell & West Birmingham Hospitals NHS Trust ("the Trust") is affiliated with two Medical Schools at Birmingham University and Aston University and, as such, provide opportunity for Medical Students and Doctors to develop their skills on patients safely. The GMC have produced guidelines regarding the level of competence expected of newly qualified doctors (Appendix 1, pages 3-5). Central venous catheter lines are not included in this list as it is an aspect of training considered appropriate and delivered at Core Medical Training (CMT) level (more than 2 years after qualifying)(Appendix 2, page 22). At CMT level, theoretical training, skills lab and supervised training is provided over a 3 year period. Competence is documented in the trainee's e-portfolio by their designated clinical supervisor. Prior to this stage of training, junior doctors and medical students are not expected to interact with central venous catheter lines due to their inherent complexity and risks. These are national guidelines produced by the Joint Royal College of Physicians Training Board.

At the Trust, this guidance will be re-enforced to trainees, with the only exception to this being for those doctors in training undertaking specialist training on the intensive care unit. In this specialised setting, theoretical and practical training will be given during Foundation Years posts and competence confirmed by the trainees clinical supervisor in the trainee's e-portfolio.

In light of the Coroner's Inquest findings, as part of their induction to the Trust, procedural risks related to central venous catheter lines will be introduced to the 3rd year medical student themed week case based discussions, to 3rd, 4th and 5th years and Foundation Year Doctors.

Foundation Year doctors will be trained in the theoretical use of central lines but will not be allowed to undertake blood sampling, flushing, insertion nor removal of central venous catheter lines. During meetings between doctors in training and their educational supervisor, working safely within their competence level will be emphasised. Progress with the acquisition of competence in procedural skills appropriate to that level of training, will be assessed at each meeting. All doctors and medical students will be advised to avoid any clinical practical procedures that are not specifically documented in their clinical skills portfolio appropriate for their level of training.

2. **Induction programme for FY1 Doctors and assessment of baseline competencies**
Foundation year doctors will not be allowed to take blood from central venous catheters at this Trust.

This will be the remit of fully trained and competent nursing staff, outreach ITU nurse/medical team or a medical registrar (a doctor more than 4 years since qualifying).

Theoretical training will be provided to the foundation year doctors in preparation for later stages of their training, including a simulation based session on a cardiac arrest resulting from an air embolism during central vein catheter blood sampling. CMT level will receive theoretical training, skills lab and supervised training over a 3 year period. Competence is documented in the trainee's e-portfolio by their designated clinical supervisor. This is in line with national guidelines produced by the Joint Royal College of Physicians Training Board.

3. **How to effectively assess and monitor competencies to undertake procedures**
We will liaise with HEE to determine the optimal strategy for assigning competence to a range of clinical skills and a requirement that trainees do not undertake clinical procedures without supervision until they have been signed off as being competent, as long as these skills are included within their e-portfolio requirements for their level of training.

Any clinical skills not considered appropriate for their stage of training must be avoided. The use of central lines is part of the CMT curriculum and is formally assessed during their training after theoretical, simulated and supervised practice.

The Trust will look at identifying a list of discussion points around the previous week, focusing on procedure risks, event information, learning from others and safety advice during the weekly meetings held between Clinical Supervisors and Foundation Year Doctors.

4. **Handover of competencies from ward to ward**

   A summary of clinical skills competence will be forwarded to clinical supervisors on each rotation of junior doctors (by the junior doctor following an exit review by their current clinical supervisor) to ensure there is an awareness of skills competence and areas of lack of training.

   There will be a requirement for all supervising consultants to check documented competency when assigning tasks in the clinical environment. No doctor will be allowed to undertake any procedure unsupervised, at any level of training, unless they have been signed off as being competent in that clinical skill/procedure.

5. **General understanding of the process to follow when taking blood from a central line and the associated risks**

   Additional training and education will be introduced into our undergraduate and postgraduate teaching portfolio, including Trust induction, to highlight safety issues related to central venous catheters. An email has been sent to all doctors at the Trust clearly stating the precautions required when dealing with a central venous catheter including the risk of air embolism.

   Documents exist on the Trust's intranet describing the correct use of central venous catheters, the risks of air embolism and how to avoid this. Additional theoretical training will be introduced to medical students and Foundation year doctors as to the risks related to using central venous catheters.

6. **Standard operating procedures for taking bloods from central lines**

   Documents exist on the Trust's intranet clearly describing the correct use of central venous catheters with particular note to the risk of air embolism and how to avoid this complication.

   All staff have been sign posted to the pre-existing guidance which has been re-enforced. A new guideline will be written with the benefit of the inquest findings to include additional pictorial emphasis to avoiding uncapping and unclamping at the same time.

   Health Education England will liaise with the GMC to qualify the following GMC statement, 'It is important to remember that newly qualified doctors who enter the Foundation Programme will work under educational and clinical supervision and in a multidisciplinary team. In accordance with the Foundation Programme Curriculum, they will need to demonstrate that they are refining their skills and that they are able to take responsibility appropriately whilst recognising and working within the limits of their competence.'(Appendix 1, page 3)

   This should ideally state, 'All practical procedures not documented as appropriate for that stage of training, in the trainees portfolio should be avoided unless fully supervised by a fully competent trainer who has made the assessment that the trainees involvement in the procedure is appropriate and safe. Trainees should not be involved in any practical procedure unsupervised until they have been designated as being fully competent in that procedure by their clinical supervisor.'

The Patient Safety page on the intranet will evidence a 'Learning Alert', a pictorial reminder of the safe way of sampling from central lines, with intermittent communications on the correct processes being 'pushed' to doctors and nursing staff (where appropriate)

As well as addressing the specific points raised, following the Inquest hearing, we consider that there is wider learning with regard to other procedures. The risks of undertaking similar procedures or around certain incidents will be highlighted through a series of short films, recorded power points, pushed out to the doctors and loaded onto our Intranet page for quick referral.

In reviewing this procedure, and the way the system let down both our junior doctor and Mrs Coley, the appropriateness of delegation was considered and reiterated to Consultants. This will be further emphasised across the Trust to all disciplines.

I attach the implementation plan for those actions which resulted from the serious incident investigation and your ruling.

Yours sincerely

Interim Chief Executive

Cc Family of Mrs Joan Coley
NHS England
CQC
Regional Medical Examiner,
Birmingham and Solihull CCG
Black Country and West Birmingham CCGs
Health Education West Midlands

General Medical Council

3 Hardman Street
Manchester M3 3AW

Email: gmc@gmc-uk.org
Website: www.gmc-uk.org
[redacted]

25 May 2021

Louise Hunt
HM Senior Coroner for Birmingham and Solihull

Dear Mrs Hunt

Regulation 28: Report to Prevent Future Deaths

I was really sorry to hear of the tragic circumstances that led to the death of Joan Mavis Coley. I extend my sincere condolences to Joan's family and all others affected.

You raise six concerns in your report. Before I turn to those, let me summarise the role of the GMC as a regulator and how it relates to the education and training of medical students and doctors. Then I will explain our involvement in the case prior to your letter, and finally I will respond to the important questions and recommendations you raise.

Our role as a medical regulator

Our powers in medical education, as set out in the Medical Act 1983, are two-fold: to set the outcomes for graduates of UK medical schools leading to entry on to the medical register and to approve the curricula for postgraduate training of doctors. We quality assure both aspects of medical training against our standards for the management and delivery of medical education and training. The principle of patient safety drives our work.

Undergraduate education

Our powers don't extend to mandating specific content in undergraduate curricula, but we determine and publish the high-level outcomes all medical students are required to demonstrate in order to graduate and be awarded a Primary Medical Qualification (PMQ). We updated our *Outcomes for graduates* in 2018 after extensive consultation. This is supplemented by a set of core *Practical skills and procedures* graduates must have achieved when they start work for the first time so they can practise safely.

Foundation Programme

All doctors enter the two-year Foundation Programme after graduating from a UK medical school. It provides new graduates with a range of essential interpersonal and clinical skills for managing acute and long-term conditions. The Academy of Medical Royal Colleges develops the Foundation Programme curriculum, which describes specific outcomes all Foundation doctors should demonstrate on completion of the programme. Our regulatory role is to approve the curriculum.

The Foundation Programme curriculum requires first year trainees (FY1) to meet the outcomes we have set out in *Outcomes for provisionally registered doctors with a license to practise*, which includes fifteen core clinical and procedural skills. This enables the trainee to apply to the GMC for full registration and a license to practise, which is a requirement of entry to the second year of the Foundation Programme.

Quality assurance of education and training

We also have a duty to make sure medical education and training in the UK is meeting our standards. We expect organisations responsible for educating and training medical students and doctors in the UK to meet the standards set out in *Promoting excellence: standards for medical education and training.*

We quality assure medical schools, postgraduate deaneries and local offices, and local education providers (such as NHS trusts and health boards) to check they are meeting our standards. Our quality activities are risk based, which means we look at our evidence and decide which areas are likely to be of concern. We provide feedback to organisations on how well we think they are meeting our standards.

If we are concerned about something, we ask for more information to seek assurance that any issues are being dealt with appropriately, and if we're not satisfied with the response we can intervene.

We can place organisations providing postgraduate training under 'enhanced monitoring', which we do to promote and encourage local management of concerns about quality and safety. This involves more frequent progress updates and we can provide representation on a locally led visit to investigate a concern or check on progress. Where possible we work with all organisations to address the concern and develop a sustainable solution. Sometimes we need to work with other regulators to make improvements.

We also approve new medical schools, which we subject to an extensive period of quality assurance to ensure their programmes will deliver *the Outcomes for graduates* and meet the *Promoting Excellence* standards.

Our response to this incident

Since being notified of the incident by Aston Medical School in December 2020, we have been engaging with local organisations regarding the immediate and long-term measures that will be taken to protect patients and to support those involved.

Our West Midlands Employer Liaison Adviser has met with Sandwell and West Birmingham NHS Trust to discuss the incident and their response. He has also held discussions with Health Education England West Midlands (HEE WM). We will work with both organisations to monitor the situation and ensure appropriate measures are being implemented.

Aston Medical School is subject to the enhanced quality assurance measures we apply to all new medical schools, we will continue to liaise with Aston about this incident and their response to your report will feed into this quality assurance activity.

We will organise a meeting with local organisations to ensure that the issues identified in your report are being satisfactorily addressed. We will also share our response to your report with local and national organisations to reinforce the learnings from this incident to prevent a similar incident happening again locally or nationally.

Addressing your specific concerns and recommendations

Against the general background of our regulatory powers and the specific actions taken already, I will now address each of the recommendations in your report.

In doing so I will refer to our standards, which state that learners' responsibilities for patient care must be appropriate for their stage of education and training. Supervisors must determine a learner's level of competence, confidence and experience and provide an appropriately graded level of clinical supervision.

Medical school and Foundation Year 1 training

You recommend urgent action is taken to review the training provided to medical students. The inquest heard there is limited training on taking bloods from a central line, the physiology of the procedure and its potential risks, and that the FY1 doctor felt she did not have adequate understanding of the risks of performing this procedure.

Procedures using central lines are not included in our *Outcomes for graduates* as we consider it to be beyond the level of competence required for newly qualified doctors. However, medical students should be taught about the general risks associated with central lines. It would be unsafe for them to access these lines given their complexity and the high level of risk involved.

You have advised that we should also consider including the procedure on the checklist of tasks for junior doctors. The inquest heard that the procedure is not on the checklist, which meant there was no process in place to determine individual competency.

Taking bloods from central lines is not included in our *Outcomes for provisionally registered* doctors that all FY1 doctors must achieve. It is a procedure undertaken by specialists or in specialist units, and it would be inappropriate for this to be a requirement for all Foundation Programme doctors. A doctor in training, and especially a recently graduated FY1 doctor, should only undertake this procedure on the specific advice of, and under the direct supervision of, a suitably qualified senior colleague. They also must receive specific authorisation and training.

Doctors in training are expected to acknowledge the limits of their capabilities and understand the risk of performing procedures beyond their level of competence. However, there must be effective systems, policies, and processes for determining their competency to undertake procedures, whether they have received appropriate training, and the level of supervision needed to ensure patient safety.

Systems for determining trainee competency

In the absence of a formal system for assessing a doctor's competence to undertake a particular procedure, a doctor's agreement to perform a task was taken as an indication of their competency. This put the onus on to the doctor to decline tasks beyond their competency or ensure an appropriate level of clinical supervision was provided.

The more senior doctor in training and FY1 doctor both lacked an appropriate level of understanding of the procedure and the competency to perform it unsupervised, although neither realised this when the task was delegated. The doctor in training determined that the FY1 doctor was competent and could, with the assistance of the medical student, undertake it safely. An appropriate employer process should be in place to approve a doctor's competency to undertake specialist and high-risk procedures.

Your report notes the absence of a system to share information about trainee competency between wards. The FY1 doctor was shadowing the ward and the consultant had no understanding of the FY1 doctor's competencies, as no such system was in place.

Our standards state that organisations must have a reliable way of identifying learners at different stages of education and training. They must also make sure all staff members take account of this, so that learners are not expected to work beyond their competence.

Our standards also require organisations to make sure that there are enough suitably qualified staff members to provide learners with appropriate clinical supervision, at all times. Supervisors must determine a learner's level of competence, confidence and experience and provide an appropriately graded level of clinical supervision. Foundation doctors must have on-site access to a senior colleague who is suitably qualified to deal with problems that may arise during the shift.

We will continue to work with employers, HEE WM and the medical schools to monitor the actions being taken, and to ensure sustainable changes are made that will improve the quality and safety of the training environment.

Awareness of all doctors and proposal for a standard operating procedure

Your report recommends that consideration is given to ensuring all doctors are fully aware of the basic principles and risks when taking bloods from a central line. This includes the development of a national standard operating procedure that could be linked to training and assessment of competency. As any such measures would be aimed at all doctors employed across the UK's health services, rather than those currently within GMC-regulated training programmes, national service and education providers such as HEE and NHS England would be best-placed to comment on such proposals.

Specialist associations or representative bodies may also be able to assist with these recommendations. As an example of where these bodies have responded to earlier incidents, the removal of dialysis lines was reported to the National Patient Safety Agency in 2018 and the Renal Association, British Renal Society, and Intensive Care Society set out advice and an action plan in response. This recommended a number of precautions and monitoring measures and indicated national guidelines would be developed.

Final reflections

We welcome the publication of this Report to Prevent Future Deaths as an important measure to raise awareness of the incident with those who can take action to prevent future deaths. We have carefully considered your concerns. I hope this information provides reassurance of the actions we have been taking and will take with local and national organisations to ensure a similar incident does not happen again.

Yours sincerely

[redacted]
Medical Director and Director of Education and Standards
[redacted]
[redacted]

General Medical Council

Regent's Place
350 Euston Road
London NW1 3JN

Email: gmc@gmc-uk.org
Website: www.gmc-uk.org
[redacted]

11 June 2021

Louise Hunt
HM Senior Coroner for Birmingham and Solihull

[redacted]

Dear Mrs Hunt

Regulation 28: Report to Prevent Future Deaths – Joan Mavis Coley

Further to my letter of the 25th May 2021 regarding the tragic circumstances that led to the death of Joan Mavis Coley, we have spoken to Birmingham Medical School regarding their response to you of the 4th June. They had stated:

"it has been a local requirement for several years for medical students at the University of Birmingham Medical School to demonstrate competence in undertaking blood sampling from a central line under direct supervision."

I wanted to make you aware that they have agreed that this will now cease, but I will write to you again shortly with a more detailed response indicating further actions we will take.

Yours sincerely

[redacted]
Medical Director and Director of Education and Standards
[redacted]
[redacted]

Copied to: [redacted], Vice Dean for Medicine and programme director for the medicine degree programme [redacted]