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NHS
Mid Yorkshire Teaching
NHS Trust

[redacted]

[redacted]
Chief Medical Officer
Trust Headquarters and
Education Centre
Pinderfields Hospital
Aberford Road
Wakefield
WF1 4DG
[redacted]
[redacted]

Date: 31 August 2023

Mr Kevin McLoughlin
HM Senior Coroner
West Yorkshire (Eastern District)
HM Coroner's Service
71 Northgate
Wakefield
WF1 3BS

[redacted]

Dear Mr McLoughlin

Re Inquest of David Barnet WILSON (dcd) – 26.03.1955 to 31.12.2022 – [redacted]

I am responding on behalf of Mid Yorkshire Teaching NHS Trust (MYTT; the Trust) to the Regulation 28 Report to Prevent Future Deaths that you issued on 8 June 2023 upon the conclusion of the abovenamed inquest.

The Matters of Concern raised in your report were:

1) *The Consent form signed by Mr Wilson was a standard pre-printed form. It did not attempt to provide any statistical rating for the risks identified, which would have enabled Mr Wilson to evaluate the risks.*

2) *No attempt was made to interpret or tailor the risks inherent in the procedure in the light of his extensive medical history and co-morbidities.*

3) *The Consent Form did not refer to the risks of death, which befell him. He was thus not in a position to make a truly informed consent to undergo the sigmoidoscopy.*

4) *The Consent Form did not identify those clinicians involved in discussing the decision with him, save for* [redacted] *who obtained his signature at a time when he was under the influence of morphine sedation.*

The objective of the Consent process should be to demonstrate a patient has made a truly informed decision at a time when he is able to evaluate the risks clearly.

I would like to thank you for bringing these matters to MYTT's attention. We have carefully considered and discussed the concerns you've raised and their implications for the Trust. Following a review of our processes, we will implement a number of measured actions in response.

Pre-printed consent forms and inclusion of statistical ratings of risks; advising patients of increased risks and the risk of death

The Trust utilises a bank of consent forms for the most common procedures performed. The consent forms used in MYTT are based on national guidance issued by the Department of Health and Social Care. Of note, we currently have generic forms and hundreds of procedure-specific consent forms across all specialties. The procedure-specific consent forms are pre-populated with the most frequently associated risks for the particular procedure. The forms are reviewed and amended as required to align with contemporary medical knowledge and practice.

Up to now, the Trust has typically not included the statistical chances of a specific risk occurring. However, as a form comes up for review, it will be updated to include whether the chances of a specific risk occurring is: very common (1 in 10); common (between 1 in 10 and 1 in 100); uncommon (between 1 in 100 and 1 in 1,000); rare (between 1 in 1,000 and 1 in 10,000); and very rare (between 1 in 10,000 and 1 in 100,000). These ranges adopt World Health Organization classifications.[1]

As it is proposed to include risk ranges, to a certain degree these will inherently account for varying medical histories and co-morbidities of patients. But in instances where a specific risk is greater due to a particular patient's unique circumstances, this medical advice will be clearly noted. We will also update and strengthen our consent process through our internal policy to reflect this requirement (see below).

The Trust also appreciates that the risk of death is a possibility in every procedure that is undertaken, and that even if it is a remote possibility, the risk of death would be a material consideration for patients in assessing whether to go ahead with a procedure.[2]

To date, it has been the Trust's practice to leave the decision about discussing the risk of death to the clinical judgement of its clinicians when evaluating the specific circumstances of their patients. However, the Trust will work with clinical teams to encourage its clinicians to undertake these discussions at an earlier stage, and we will introduce an additional specific risk of death as a risk that is required to be canvassed as part of our consent process (see below).

Identifying clinicians involved in the consent process; and capacity to consent

I fully concur with your statement that "the objective of the Consent process should be to demonstrate a patient has made a truly informed decision at a time when he/she is able to evaluate the risks clearly".

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1 Whilst these ranges will be a starting point for all consent forms, a specialty may choose to be more explicit in detailing the specific risks of a particular procedure.

2 In accordance with *Montgomery v Larnarkshire Health Board* [2015] SC11 [2015] 1 AC 1430

[redacted] [redacted]

As you are aware, the process of consenting a patient for a procedure is an ongoing one that starts with a conversation with the patient about treatment options and **culminates** with the signing of the consent form. The form itself is merely the final "ok" from the patient to go ahead after a number of steps have taken place over a length of time, to obtain fully informed consent from the patient.

The consent process regularly involves a number of staff from the clinician undertaking the initial conversation with the patient about the procedure and placing the patient on a waiting list; to others providing follow-up advice, e.g. in response to pre-procedure questions from the patient after reading the relevant patient information leaflet; to those involved in the pre-admission process; and finally to the clinician and/or assistant who will perform the procedure on the day.

As these are all clinical conversations, the Trust expects staff to have appropriately documented an accurate record of them in the patient's medical notes, which would also include a note of any patient information leaflets that have been provided. When reviewing the patient's records pre-procedure, this documentation provides assurance to the clinician performing the procedure that the patient understands, and is fully cognisant of the risks and benefits of the procedure, and has consented to it.

Ideally the final consent form would list all MYTT staff who have been involved throughout the entire consenting process of the patient for a particular procedure. Unfortunately, time and resource constraints make this suggestion impracticable for implementation by the Trust.

In relation to the capacity to consent, the Trust will work with clinical teams to ensure that as part of the consent process, the question of a patient's capacity – regardless of the circumstances – is considered, taken into account, and properly documented. The issues surrounding capacity will also be further highlighted in the Trust's internal policy (see below).

Other actions

Of course, the Trust regularly offers training to staff on consent as well as having an internal policy that provides guidance on consent to examination and treatment. The consent policy undergoes a planned review every three years unless it is updated earlier, i.e. "refreshed", when new guidance becomes available. Previous iterations have incorporated, amongst other matters, refusal of treatment and advance decisions; consent for transfusion; the *Montgomery* ruling; and latterly the General Medical Council's Guidance on professional standards and ethics for doctors: *Decision making and consent* (November 2020).

Overall, I concur that the matters of concern you've raised regarding how we consent our patients require action on our part and I thank you for bringing these to the Trust's attention. Accordingly we undertake to address these matters (as outlined above) and "refresh" our consent policy ahead of its triennial review, currently scheduled for March 2024.

In closing, I acknowledge that your concerns arose out of your investigation into the death of Mr Wilson, and on behalf of Mid Yorkshire Teaching NHS Trust, I would like to take this opportunity to offer our sincere condolences once again to Mr Wilson's family in relation to his sad death.

[redacted] [redacted]

Yours sincerely

[redacted]

[redacted]
Chief Medical Officer

[redacted] [redacted]