ANNEX A

REGULATION 28: REPORT TO PREVENT FUTURE DEATHS (1)

*NOTE: This form is to be used **after** an inquest.*

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** **The Chief Executive Cwm Taf Morgannwg University Health Board** **Dr. N. Lyons Medical Director, Executive Directorate, Cwm Taf Morgannwg University Health Board**
1	**CORONER** I am Dr. Sarah - Jane Richards, HM Assistant Coroner, for the coroner area of South Wales Central.
2	**CORONER'S LEGAL POWERS** I make this report under paragraph 7, Schedule 5, of the Coroners and Justice Act 2009 and regulations 28 and 29 of the Coroners (Investigations) Regulations 2013.
3	**INVESTIGATION and INQUEST** On 30th April 2019 I commenced an investigation into the death of Darren John GODDARD. The investigation concluded at the end of the inquest on 22nd January 2020. The medical cause of death provided by the Royal Glamorgan Hospital was: 1(a) *Multi-organ Failure;* and 1(b) *Sepsis (escherichia coli) following prostatic biopsy 1/4/19.* The Coroner's conclusion at the end of the Inquest was a Narrative Conclusion: *The deceased died from a recognised complication of sepsis following an elective medical procedure. Medical intervention failed to recognise the urgency required for the diagnosis and treatment of sepsis although the impact of this upon the deceased's survival is unclear.* The family's concerns at inquest were: i) Advice received prior to consenting to the Trans Rectal Ultrasound biopsy (TRUS) procedure was that sepsis was a rare post-procedure occurrence i.e. the consent form stated a risk of "*rarely sepsis*" (*Sepsis is a recognised complication following TRUS biopsy occurring in less than 1% of biopsies despite antibiotic cover*). Conversely, transient flu-like symptoms were stated as more commonly experienced. This information led Mr. [redacted] Goddard to believe the shivers and symptoms he experienced on 1st April 2019 post-operatively were, more likely than not, to be the more common adverse effects of flu-like symptoms rather than the more insidious symptoms of sepsis. The family consider emphasising flu-like symptoms was misleading as they can overlap with the grave symptoms of sepsis thereby minimalizing patient concern and avoiding seeking prompt intervention.

	ii) Subsequent to Mr. Goddard's death, the family question how this data i.e.1% is generated and whether or not it is a reliable reflection of the incidence of sepsis following TRUS. iii) On 29 March 2019, prior to his TRUS procedure, Mr. Goddard was provided a prescription of 4 doses of the antibiotic Ciprofloxacin 750mg. This was considered as being contraindicated for Phenytoin, the anti-epileptic medication prescribed long-term to Mr. Goddard. In the event, and following discussion between the Pharmacy, the Urology Consultant and Nurse Practitioner, it was agreed that Ciprofloxacin was safe to be taken with Phenytoin. The British National Formulary does not list this antibiotic as a contra-indicated medication for Phenytoin. iv) Mr. Goddard received his antibiotic prescription which he took as prescribed in order to be provided antibiotic prophylaxis for the procedure he was to undergo. The family now have concerns whether the interaction between Phenytoin and Ciprofloxacin 750mgs which was subject of discussions between the pharmacist and Consultant related to any diminished efficacy of the antibiotic. v) Mr. Goddard underwent TRUS on 1 April 2019 at 1100 hours. He was advised the procedure had been conducted without complication and was discharged at 1300 hours with the warning that he may suffer flu-like symptoms and advised to drink plenty of water. He was discharged from the post-op recovery unit after demonstrating he could tolerate fluids; could produce urine; and had no *per rectal* bleeding. He was observed for approximately 1 hour post-operatively whereas the recommended observation period was for longer. Had Mr. Goddard been observed for the full recommended period of time his family consider that his early symptoms of sepsis would have been noted in the recovery unit with a good chance of rapid diagnosis and treatment. vi) The following day, on 2nd April 2019 Mr. Goddard suffered a headache, shaking became incoherent, was bleeding *per rectum* and in a state of collapse. [redacted] fearing sepsis rushed her husband to A&E at Royal Glamorgan Hospital. A full account of the TRUS procedure and risk of sepsis was provided to the Nurse at Triage yet there was no sense of urgency with progressing Mr. Goddard for antibiotic treatment and significant delays occurred with being reviewed by a doctor and being administered antibiotics (a delay of 1 hour 40 minutes later than required with the current sepsis 6 management bundle). These delays represented missed opportunities for successfully treating Mr. Goddard. vii) There was a further significant delay (around 7 hours) in escalating Mr. Goddard for Critical Care by which time he was at risk of heart failure, sepsis and septic shock from a high lactate level (risen to 20). viii) Although colloidal IV fluids were administered in A&E these were not the recommended fluids for treatment of hypovolaemic shock.
4	**CIRCUMSTANCES OF THE DEATH** These were recorded as :- Darren John Goddard 52 years underwent an elective, trans-rectal ultrasound of his prostate gland. A risk associated with the procedure is sepsis. The following day he became acutely unwell and was admitted to the Royal Glamorgan Hospital where upon sepsis was diagnosed but with significant delays with providing intervention. When treatment was provided it was not always the recommended treatment. Medical intervention failed to improve his condition and he passed away on 18 April

	2019. The Inquest focused upon:- a. The practices & procedures of the elective surgery of TRUS and information provided concerning sepsis as an adverse effect. b. Failures within A&E at triage through to critical care to expedite appropriate treatment for sepsis even though warnings of the lethality of sepsis was advertised through public warning notices displayed in the A&E department.
5	**CORONER'S CONCERNS** During the course of the inquest the evidence revealed matters giving rise to concern. In my opinion there is a risk that future deaths will occur unless action is taken. In the circumstances it is my statutory duty to report to you. The **MATTERS OF CONCERN** are as follows. – (1) TRUS elective surgery 'consenting' and information provision (oral and in written format) places a misleading emphasis on flu-like symptoms as adverse effects. (2) The accuracy of the 1% risk of sepsis incidence provided. (3) Premature discharge post-operatively from the recovery unit with the missed opportunity to recognise the adverse effect of sepsis when they occurred. (4) The failure at triage to escalate this referral to seeing a doctor within 10 mins of admission. (5) Subsequent failure to provide timely and appropriate fluids and antibiotics. (6) Delay in admission to Critical Care.
6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe you and your organisation have the power to take such action. • Review and provide definite warnings (oral and written) of sepsis when consenting patients to TRUS and upon their discharge. • Avoid patients being discharged prematurely. • Further training of Triage nursing staff and doctors of the Sepsis 6 bundle and ensure the training is kept current.
7	**YOUR RESPONSE** You are under a duty to respond to this report within 56 days of the date of this report, namely by 10 May 2020. I, the Coroner, may extend the period upon request. Your response must contain details of action taken or proposed to be taken, setting out the timetable for action. Otherwise you must explain why no action is proposed.
8	**COPIES and PUBLICATION** I have sent a copy of my report to Mr. Mark Drakeford, First Minister of Wales, Mr. Vaughan Gething, Minister for Health and Social Services, and the family who may find it useful or of interest. I am also under a duty to send the Chief Coroner a copy of your response. The Chief Coroner may publish either or both in a complete or redacted or summary form. He may send a copy of this report to any person who he believes may find it useful or of interest. You may make representations to me, the coroner, at the time of your response, about the release or the publication of your response by the Chief Coroner.

9	9 March 2020 **SIGNED:**  Dr. Sarah - Jane Richards, Assistant Coroner for **South Wales Central**