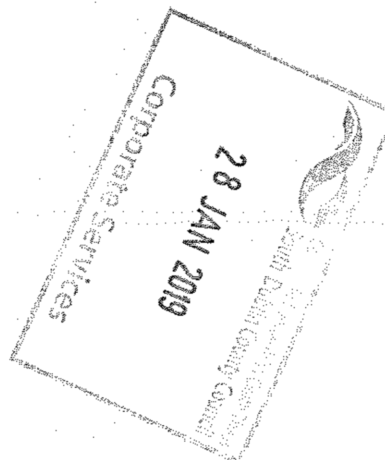
**An Roinn Sláinte**
Department of Health




25 January 2019

Mr Colm Murphy
Meetings Administrative
Corporate Services
South Dublin County Council
msomers@SDUBLINCOCO.ie

Dear Mr Murphy

The Minister for Health, Simon Harris, T.D., has asked me to thank you for your recent correspondence concerning Standing 4 Women. Your ref: M15/1218

**Open Disclosure and Patient Safety Legislation**
The Department of Health is committed to driving openness and transparency to ensure patient safety. All staff must be open and honest with patients. Patient safety is fundamental to the delivery of quality healthcare and to public confidence in the health system and open disclosure is an integral element of patient safety incident management and learning.

Open disclosure is about an open, honest and consistent approach to communicating with patients and their families when things go wrong in healthcare. This includes keeping the patient informed, providing feedback on investigations and the steps taken to prevent a recurrence of the incident and it may include, depending on the particular circumstances involved, an apology for what happened.

In line with international best practice, the Department has been driving a progressive legislative framework to build an open and just culture for patient safety which balances the need for an open and honest reporting culture that facilitates a learning environment, and quality healthcare with accountability for both individuals and organisations. Disclosure and reporting are opportunities to learn, to improve, to address errors that have happened and to apply the lessons to make the service safer for the next patient and the patient after that.

Part 4 of the Civil Liability (Amendment) Act 2017 provides the process and procedures for open disclosure. The Act of 2017 covers the open disclosure of all patient safety incidents, unintended and unanticipated, including near misses. It provides provisions to create a safe space for staff to be open and transparent with patients in order that they would be given as much information as possible, as early as possible, including an apology where appropriate. The Commencement of Part 4 of the Act and the Civil Liability (Open Disclosure) (Prescribed Statements) Regulations 2018, came into effect on 23rd September 2018.

**Bloc 1, Plaza Miesach, 50 - 58 Sráid Bhagóid Íochtarach, Baile Átha Cliath, D02 XW14**
Block 1, Miesian Plaza, 50 - 58 Lower Baggot Street, Dublin, D02 XW14
T +353 1 635 4148 I ministersoffice@health.gov.ie
www.health.gov.ie

During the Report Stage debate of these provisions, the Minister also committed to examining how legislation could be expedited to provide for mandatory open disclosure to patients of serious incidents.

The general scheme for the Patient Safety Bill provides the legislative framework for a number of important patient safety issues, including: mandatory open disclosure of serious patient safety incidents and the notification of same, clinical audit guidance against explicit clinical standards on a national basis and the extension of the Health Information Quality Authority remit to private hospitals.

The General Scheme of the Patient Safety Bill is intended to provide clarity and assurance with regard to the requirement for open disclosure to patients and or their family with regard to serious patient safety incidents, the management of the incident itself and the need to ensure the dissemination of any learning from the review of the incident across the whole health system. This is further facilitated by the requirement for mandatory external reporting of those same incidents by health service providers to the appropriate regulatory authority and the State Claims Agency. The general scheme of the Patient Safety Bill underwent pre-legislative scrutiny at the Oireachtas Joint Committee on Health on the 26 September 2018 and is currently being drafted by the Office of the Parliamentary Counsel.

**Findings of the Scally Report**
Provision for mandatory open disclosure has been further reinforced by Dr Gabriel Scally's final report of the Scoping Inquiry into the CervicalCheck Screening Programme. The Scally Report clearly identified significant deficits in the current HSE open disclosure policy and HSE/State Claims Agency guidelines and these account for 5 of the 50 recommendations in the Report. The Report also makes recommendations in relation to the open disclosure policies of both the Medical Council and CervicalCheck. The Implementation Plan for these recommendations was published on the 11th of December.

Recommendation 33 refers specifically to Open Disclosure and the Medical Council and their Guide to Professional Conduct and Ethics for Doctors (2016):
"The Department of Health should enter into discussions with the Medical Council with the aim of strengthening the guide for registered medical practitioners so that it is placed beyond doubt that doctors must promote and practice open disclosure".

Officials in the Department of Health met with the heads of the post-graduate medical training bodies on the 19th of September 2018 to discuss a whole system response to the Scally Report, in line with his specific focus on implementation in order to apply all the recommendations and lessons learnt. The Department has also had exchanges with the Medical Council on this issue.

The Department will shortly establish a new Independent Patient Safety Council. The first task of the Council will be to undertake a detailed review of the existing policies on

Open Disclosure across the whole healthcare landscape, in line with Dr Scally's recommendations. The resulting policy will have legislative underpinning, will operate across the whole health service and its implementation will in turn be overseen by the Independent Patient Safety Council. The Independent Patient Safety Council will include strong patient and public representation and international patient safety expertise.

**Independent Clinical Expert Panel Review**
In addition to Dr Scally's work, the Minister commissioned an independent clinical expert panel review to examine all cases of cervical cancer in women who had a screening history through CervicalCheck. This review is being conducted by the Royal College of Obstetricians and Gynaecologists (RCOG).

The review includes those women who have developed cervical cancer, whose diagnosis was notified to CervicalCheck or registered with the National Cancer Registry at the beginning of May 2018, and who had been screened by CervicalCheck prior to their diagnosis.

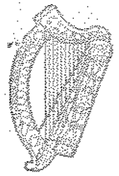
In light of the sensitivities surrounding this matter, all women whose slides could be reviewed are being contacted to ask for their consent to be included if they wish. Where the woman has, sadly, died, their next of kin are being contacted to seek consent for inclusion. Over 1,700 women or their next-of-kin have been written to, and approximately 1,100 have given their consent to be included.

**Laboratory Services and Primary HPV Testing**
Currently cervical screening samples undergo cytology screening as the primary screening test and following the move to HPV testing, cervical screening samples will undergo a HPV test as the primary screening test and women whose samples show HPV infection will be triaged using cytology to determine if there are any abnormal cell changes.

The Minister approved the switch to HPV testing as the primary screening mechanism for the CervicalCheck programme in February. Work on implementing this switch is well underway. While it is likely that a tendering process will be needed to meet at least some of the HPV testing requirement, the potential to use public laboratories in Ireland to carry out testing for the programme is being carefully assessed as part of the planning of this major project. As this procurement process is underway, it is not possible to give any details on these on-going negotiations. However, Dr Scally made several recommendations in relation to procurement and quality assurance, and these will be implemented going forward.

Funding to implement the switch to HPV screening has been allocated in Budget 2019, along with funding to implement the recommendations of Dr Gabriel Scally's inquiry in to the CervicalCheck Screening Programme, illustrating the Government's commitment to these essential projects.

.....



It is important to be clear, however, that the Report of the Scoping Inquiry into CervicalCheck, published on 12 September on the website of the Department of Health, provides welcome reassurance on the quality management processes of all laboratories currently contracted to provide services for CervicalCheck, including the private laboratories contracted both in Ireland and America (Medlab Pathology and Quest Diagnostics, respectively) and the Coombe Women and Infants University Hospital in Dublin.

I hope this is of assistance to you.

Yours sincerely

Paula Smeaton

Paula Smeaton
Private Secretary

.....