"MISS DIAGNOSIS": THE INADEQUACIES SURROUNDING THE PATIENT SAFETY (NOTIFIABLE INCIDENTS AND OPEN DISCLOSURE) ACT 2023 AND WOMEN'S HEALTH IN IRELAND IN LIGHT OF THE CERVICALCHECK DEBACLE

ROISIN CUNNINGHAM*

Introduction

"I don't want your apologies. I don't want your tributes. I don't want your aide-de-camp at my funeral. I don't want your accolades or your broken promises. I want action. I want change. I want accountability."

These were the sentiments of the late Vicky Phelan after she publicly exposed the reality of the cervical screening programme in Ireland.[1] Along with over 221 women, she had been ensnared in one of the most significant concealments in the history of the Irish State.[2] Her refusal to comply with a proposed and recommended non-disclosure agreement unveiled what was to become known notoriously as the CervicalCheck Scandal. Under a HSE cervical cancer screening scheme, scores of women later diagnosed with cervical cancer were not informed that their smear test results, initially indicating no abnormalities, were

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* Roisin Cunningham is in 3rd year Law and Human Rights at the University of Galway and would like to thank Cian O'Carroll (medical negligence solicitor) and Ceara Martyn (221+ support group manager) for their contributions, as well as the editorial board for their help and feedback, in particular, Maddy and Holly. The author dedicates this piece to her mother, Maebh, and to all the women and families affected by the CervicalCheck debacle.

[1] '221+ Statement on the Passing of Vicky Phelan' (221+ Cervical Check Patient Support Group, 14th November 2022) <https://221plus.ie/lorem-ipsum-dolor-sit-amet-consectetur-adipiscing-elit-11/> accessed 30 November 2023.

[2] ibid.

inaccurate.[3] Furthermore, the revised results of the retrospective audit were withheld from them for several years.[4] This meant that in some women's cases, they passed away from their cancer without ever knowing the full truth behind their diagnoses.[5]
Requiring an unsuspecting patient to uncover the truth about the CervicalCheck screening programme highlights a deeply flawed system in need of reform. Significant adjustments and improvements have been made in the Irish healthcare system as a result of the scandal, however, there is much work to be done. This article will outline the relevant statutes and case law regarding patient safety, provide a comparative analysis of this legislation with other jurisdictions, and propose solutions for the development of a more humane health system.em.

I. "Nuns don't get cervical cancer": The Turbulent History of Women's Health in Ireland

It could be said that part of womanhood in Ireland is dealing with the inefficiencies, shame, and stigma that surround women's reproductive health. According to Scally, one of the most disturbing accounts of a patient-consultant interaction under the CervicalCheck scheme, is that of a relative of an already deceased woman, who was told that 'nuns don't get cervical cancer.'[6] Such occurrences are characteristic of a system that inculcates a gendered shame in its patients.[7] Sundstrom details an interview with an Irish legal expert concerning the scandal, in which the expert said, 'it would be better if victims and women in particular just shut up.'[8]

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[3] Gabriel Scally, 'Scoping Inquiry into the CervicalCheck Screening Programme: Final Report' (Department of Health, 2018).
[4] ibid.
[5] ibid.
[6] ibid.
[7] Beth Sundstrom '"Nuns Don't Get Cervical Cancer": A Reproductive-Justice Approach to Understanding the Cervical-Cancer Prevention Crisis in Ireland.' (2021) 56(3) Éire-Ireland 292, 319.
[8] ibid.

It is no coincidence that the majority of healthcare scandals in Ireland surround women's healthcare issues[9]. The CervicalCheck scandal, regrettably, is just one manifestation of the broader issue of systematic sexism in women's health. Take, for instance, the death of Savita Halapannavar, which was caused by a lack of safe and basic care after she was denied an abortion following a prolonged miscarriage.[10] The thalidomide scandal was yet another example of women's health being neglected. The drug was prescribed for the treatment of nausea in pregnant women without adequate testing, resulting in severe birth defects in thousands of children.[11] The controversies of the mother and baby homes reaffirm the ongoing systemic issue that is the neglect of women's health and its deep-rooted history in Ireland. These examples represent the disconnect in acting on the health priorities of women.[12] Professor Brian MacCraith in his HSE-commissioned review of the CervicalCheck Screening Programme recommended the adoption of a 'women-first' approach to healthcare, but it appears that little to nothing has been done to implement this.[13] Ceara Martyn, 221+ CervicalCheck Patient Support Group manager, said that women's health needs to be

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[9] Geraldine Walsh, 'Women Feel Unheard and Dismissed When it Comes to Health' (*The Irish Times*, 14 July 2021) <https://www.irishtimes.com/life-and-style/health-family/women-feel-unheard-and-dismissed-when-it-comes-to-health-1.4597239> accessed 10 March 2024.

[10] Health Information and Quality Authority, *Investigation into the safety, quality and standards of services provided by the Health Service Executive to patients, including pregnant women, at risk of clinical deterioration, including those provided in University Hospital Galway, and as reflected in the care and treatment provided to Savita Halappanavar* (7 October 2013) <https://www.hiqa.ie/sites/default/files/2017-01/Patient-Safety-Investigation-UHG.pdf>.

[11] James Kim, 'Thalidomide: The Tragedy of Birth Defects and the Effective Treatment of Disease' (2011) 122(1) Toxicological Sciences: An Official Journal of the Society of Toxicology 1.

[12] Walsh (n 9).

[13] Brian MacCraith, 'Independent Rapid Review of Specific Issues in the CervicalCheck Screening Programme' (Health Service Executive, 6 August 2019) 41 <https://www.rte.ie/documents/news/2019/08/independent-rapid-review-of-specific-issues-in-the-cervicalcheck-screening-programme.pdf?app=true> accessed 16 March 2025.

'treated holistically' instead of permitting the situation to escalate to a crisis point before being dealt with accordingly.[14]

A pattern has appeared: a scandal involving women's health is exposed, followed by government assurances to improve legislative protections, which result in short-term solutions. Over time, the system tends to revert to its original state. Take, for example, the creation and subsequent disappearance of the Women's Health Council.[15] In 1987, the Women's Health Council was established for the purposes of promoting women's health through the development of expertise and women's health services. Its ephemeral existence came to an end when it was integrated into the Department of Health and Children in 2008, ultimately resulting in its vanishing.[16] The rise and fall of the Women's Health Council demonstrates the government's great hesitation in achieving sustained improvements in the provision of women's health services.

A) Steps for Improving Women's Health Standards

In response to Dr Gabriel Scally's recommendation, the Women's Health Taskforce was established in 2019. While seemingly a positive development, this Taskforce, unsurprisingly, is not fit for its intended purpose. The taskforce rolled out the Women's Health Action Plan 2022-2023, which put forth strategic plans, as well as the allocation of €31 million for innovative advancements, for improving women's health in Ireland.[17] This initiative was originally slated for a two-year duration, however, no provision for women's health expenses was mentioned in Budget 2024. This is yet another example of the State's flawed approach to

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[14] Interview with Ceara Martyn, 221+ CervicalCheck Patient Support Group Manager (Galway, 13 March 2024).
[15] Scally (n 3).
[16] The Women's Health Council (Establishment Order) 1997.
[17] Department of Health, 'Progress on women's health in 2022 under the Women's Health Action Plan' (23 December 2022) <https://www.gov.ie/en/press-release/8d535-press-release-progress-on-womens-health-in-2022-under-the-womens-health-action-plan/> accessed 10 March 2024.

implementing long-term solutions for women's health issues.[18] The Department of Health stated that regular reports from the Taskforce would be available on their webpage.[19] However, the latest update available from the taskforce regarding the implementation of the 2022-2023 action plan, details that only 60% of the intended actions have been 'completed' or are 'in progress.' There have been no updated reports published since.[20] This appears to be another example of the cycle of women's health initiatives falling to the wayside, just as the Women's Health Council did.

The decision to outsource the review of cervical samples to private laboratories abroad represents another shortcoming in the State's approach to women's health care. According to reports from a HSE whistle-blower, this decision was made because the cost of outsourcing was a third of testing costs in Ireland.[21] This resulted in a loss of expertise in this field in Ireland which will be challenging to restore.[22] It is concerning that the review of samples of women undergoing HSE provided screening are still outsourced to the same laboratories that the High Court deemed to be in breach of their duties of care, following their failing to disclose abnormalities in smear tests.[23] Although a National Cervical Screening Laboratory has been established in Ireland, the HSE only aims to send 10% of samples to this domestic service

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[18] Department of Finance, 'Budget 2024' (24 September 2024) <https://www.gov.ie/en/publication/fd255-budget-2024/> accessed 16 March 2025.

[19] Department of Health, 'Women's Health Taskforce' (25 September 2019) <https://www.gov.ie/en/campaigns/-womens-health/> accessed 10 March 2024.

[20] ibid.

[21] Maeve Sheehan, 'Renewed calls for review of smear test outsourcing' (*The Irish Independent*, 11 December 2022) <https://www.independent.ie/irish-news/renewed-calls-for-review-of-smear-test-outsourcing/42210870.html> accessed 16 March 2025.

[22] Dáil Debate 7 December 2022, vol 1030, no 6.

[23] Health Service Executive, 'Cervical screening tests to resume at National Cervical Screening Laboratory at The Coombe Hospital' (23 October 2023) <https://www2.healthservice.hse.ie/organisation/nss/news/latest-news-update-from-the-nss-26-october-2023/> accessed 20 March 2024.

for review.[24] The new National Screening Laboratory is not without issue; it experienced a pause in its services from March 2023 until late October, due to delays in filing final accreditation documentation. No domestic screening took place during this period.[25] Going forward, the State must focus on implementing protective measures and fostering confidence that such occurrences will not reoccur.

II. Legislating Healthcare in Ireland

A) Mandatory Open Disclosure and Notifiable Incidents: To Say Nothing is to Say Something.

i. What is open disclosure?

Open disclosure is defined by the HSE's Open Disclosure Policy 2013 as:

> An open, consistent approach to communicating with service users when things go wrong in healthcare. This includes expressing regret for what has happened, keeping the service user informed, providing feedback on investigations and the steps taken to prevent a recurrence of the adverse event.[26]

The concept of voluntary open disclosure was given legal authority in part 4 of the Civil Liability (Amendment) Act 2017, where in the case of all patient safety incidents, including 'near misses'[27] and 'no harm'[28] events, 'the health services provider may make, in accordance with this Part, an open disclosure of the

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[24]Health Service Executive, *'Sample processing pause at the Coombe Hospital'* (29 March 2023) <https://www2.healthservice.hse.ie/organisation/nss/news/sample-processing-pause-at-the-coombe-hospital/> accessed 10 March 2024.
[25] ibid.
[26] Health Service Executive, *Open Disclosure Policy* (2013).
[27] Jim Smith, *Building a Safer NHS for Patients: Improving Medication Safety* (National Health Service (NHS), 2001).
[28] ibid.

patient safety incident.'[29] The term 'may' was quite problematic, as it granted free reign to healthcare professionals in deciding whether to disclose the details of patient safety incidents on a voluntary basis. Without statutory obligation or incentive to report these safety incidents, patients are not fully appraised of facts when choosing their healthcare providers. In May 2023, the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 (the Act) made mandatory open disclosure in the case of a notifiable incident a legal requirement. This is a welcome change, albeit restricted, due to the limited scope of what qualifies as a 'notifiable incident.' This narrow scope will be examined in the following subsection.

Despite this restricted scope, significant advancements have been made in the area of open disclosure. The recent incorporation of Dr Gabriel Scally's recommendation to the Medical Council regarding the phrasing of their guidelines for registered medical practitioners is an example of this. In his final 'Scoping Inquiry' report, Scally recommended the implementation of guidelines to ensure, 'beyond doubt that doctors must promote and practice open disclosure.'[30] The Medical Council's 'Guide to Professional Conduct & Ethics for Registered Medical Practitioners' for 2016 stated:

> When discussing events with patients and their families, you should: acknowledge that the event happened; explain how it happened; apologise, if appropriate; and assure patients and their families that the cause of the event will be investigated and efforts made to reduce the chance of it happening again.[31]

Their updated 2024 guidelines provide that medical professionals must promote and support a culture of open disclosure, rather than the previous wording suggesting they 'should.'[32] Although accepted six years after the proposal of this

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[29] Civil Liability (Amendment) Act 2017.
[30] Scally (n 3).
[31] Irish Medical Council, *Guide to Professional Conduct & Ethics for Registered Medical Practitioners* (8th edn, 2016).
[32] Irish Medical Council, *Guide to Professional Conduct & Ethics for Registered Medical Practitioners* (9th edn, 2024).

change, this is a positive development, indicating that sufficient patient safeguards are being introduced with respect to open disclosure. The nature of patient safety, especially in dealing with sick and sometimes terminal patients, creates an exceptionally time-sensitive need for rapid implementation of recommendations, which the State should endeavour to take into consideration when prioritising policy changes.

ii. The Limited Scope of Notifiable Incidents

Schedule 1 of the Act provides a list detailing what qualifies as a notifiable incident which, in tandem with the relevant regulations in Section 8, allow the Minister to prescribe notifiable incidents in some cases. Although Section 8 allows for expansion of Schedule 1, these criteria are limited, with nearly every incident requiring an outcome of death to qualify.[33] Consider the Health Information and Quality Authority's estimate that one medication error occurs per Irish hospital patient per day.[34] This amounts to nearly three million errors a year, illustrating the sheer volume of mistakes that occur and do not necessarily result in death.[35] While notifying patients in every instance of mistake is perhaps too onerous an obligation to place on healthcare providers, the criteria per Schedule 1 should be broadened beyond the requirement of death. A middle ground must be found. An example of such is seen in England and Wales, where the terms "severe", "moderate" or "prolonged psychological harm" effectively extend the range of what qualifies as a notifiable safety incident without creating too heavy a burden on healthcare providers.[36] This will be further discussed at a later stage.

The foundations of open disclosure should be built upon respect and willingness to inform patients of adverse events that may have occurred to them – regardless of the outcome of such

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[33] The Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023, sch 1.
[34] Health Information and Quality Authority, 'Recommendation to promote a national strategic approach to reduce the amount of medication errors in public acute hospitals' (1 February 2018) <https://www.hiqa.ie/hiqa-news-updates/hiqa-recommends-promoting-national-strategic-approach-reduce-amount-medication> accessed 16 March 2025.
[35] ibid.
[36] Health and Social Care Act 2008 (Regulated Activities) Regulations 2014/20.

events. To leave patients unaware of such incidents, gives rise to a broader question about the constitutionality of such acts, particularly that of patients' unenumerated right to bodily autonomy per article 40.3.1 of the Irish Constitution.[37]

A) Ireland's Complaints Mechanism: Don't Judge Clinical Judgements.

i. The Health Act 2004: A Legal Denial of Justice

Section 48.1 of the Health Act 2004 states that:

> A person is not entitled to make a complaint about any of the following matters: …a matter relating solely to the exercise of clinical judgment by a person acting on behalf of either the Executive or a service provider.[38]

This section prevents patients who believe the judgements of their health service provider to be flawed from voicing their concerns. However, if the floodgates were to be opened to any and all patient complaints, legitimate concerns may arise as there is potential for capricious, ill-informed or frivolous claims. Not allowing for any complaints is too drastic a protection and leaves important concerns unaddressed. A more nuanced approach could include safeguards against abuse, all the while prioritising patient output. This would allow for a more responsive and accountable system, rather than simply provide an ultimatum: remain silent or pursue legal action.

Although it may be understood that the court system is the primary means of seeking justice, it cannot be viewed as a preferable option for lower-scale complaints. Moreover, Ireland is the only jurisdiction in Europe in which there is a legislative prohibition on clinical complaints.[39] Ideally, an independent body such as the Health Service Executive should have an "adequately

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[37] Art 40.3.1*; Ryan v Attorney General* [1965] IR 294 (SC).
[38] The Health Act 2004, s (48)(1).
[39] Gabriel Scally, *Review of the Implementation of Recommendations of the Scoping Inquiry into the CervicalCheck Screening Programme* (Department of Health, 2022).

constituted clinical complaints system" in place to eradicate the requirement of legal action.[40] This has not been addressed in the Patient Safety Act 2023 and is carried into the HSE complaints procedure, generating a flagrant denial of justice concerning those who may not wish to pursue the time-consuming, prohibitively expensive, 'gladiatorial courts.'[41] As aforementioned, clinical complaints often relate to time-sensitive issues, and lengthy court processes may delay justice. A dedicated HSE complaints system could provide a faster, more efficient alternative, ensuring timely resolution and accountability.

According to Dr Gabriel Scally, and congruent with common belief, 'the court system is not the right place to achieve a resolution that is imbued with grace and compassion.'[42] In their response to Scally's 2022 review of implementations, the 221+ support group agreed that: 'litigation is a sad indictment of any system for dealing with possible clinical errors.'[43]

The need for a more compassionate healthcare system, with an aim to alleviate the stress of patients rather than adding to the severe pressure they are under when dealing with their sicknesses or diagnoses, is undeniably urgent.

B) The "Part 5 Review"

Under the Act, a patient retains the right to request a review, termed a 'Part 5 review.'[44] Individuals who develop cancer after participating in a population screening program, namely BowelScreen, BreastCheck, or CervicalCheck, can request a review of their screening. Section 36 states that:

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[40] ibid.

[41] 'Patient Safety Bill: next steps for medical transparency' (RTE Radio 1, 17 February 2023) <https://www.rte.ie/radio/radio1/clips/22214394>/ accessed 15 February 2024.

[42] Scally (n 3).

[43] 221+ CervicalCheck Patient Support Group, 'Statement from 221+ in Response to Dr. Gabriel Scally's Review of the Implementation of Recommendations of the Scoping Inquiry into the CervicalCheck Screening Programme – Implementation Review Report' (23 November 2022) <https://221plus.ie/lorem-ipsum-dolor-sit-amet-consectetur-adipiscing-elit-12/> accessed 10 March 2024.

[44] The Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 s 5.

> A health services provider shall, in relation to a patient in respect of whom a cancer screening is to be or is being carried out, inform the patient in writing, either before or at the time the cancer screening service carries out the cancer screening on that patient, of his or her right to make a request for a Part 5 review…[45]

Although the new establishment of a right to request such information may easily be interpreted as an advancement, this provision is, in essence, meaningless. It lacks substantive legal effect in terms of communicating the entitlement to request a review of their screening results. This is because the sole obligation it imposes on a healthcare provider is to notify the patient either before or at the time of screening, rather than post-diagnosis.[46] In an interview with Cian O'Carroll, medical negligence solicitor, he explained that if a patient were to receive a subsequent cervical cancer diagnosis years later, no legal obligation would exist to reinform their right to review, although the probability of their remembering being informed initially is likely minuscule.[47] Additionally, the patient is informed in writing, and the clinician is not obligated to ensure that they understand. Furthermore, it imposes a positive obligation on a patient to make a complaint, without which there is no onus on the service provider to inform the woman of a discordant slide, in the case of a retrospective review.[48]

There is a difference between a service provider or clinician being obligated to provide information upon request, if desired by a patient, versus a patient having to initiate the process and undergo a Part 5 procedure to obtain information.[49] It is ironic that a Part 5 Review only has relevance after a diagnosis of cancer. For section 36 to be effective, it must be amended to include an obligation on healthcare professionals to ensure professionals ensure their patient understands their right initially, in writing perchance, and to reinform their patients at a suitable time, post-

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[45] ibid s 36.
[46] Interview with Cian O'Carroll, Medical Negligence Solicitor (Galway, 21 March 2024)
[47] ibid.
[48] Dáil Deb 7 December 2022, vol 1030, no 6.
[49] ibid.

diagnosis, of their right to request a review. A clear explanation of the purpose of the review should be provided in an appropriate and timely manner, considering the sensitivity of receiving a diagnosis.

Director of the Gender Studies programme at University College Dublin, Mary McAuliffe in an interview with CNN about the CervicalCheck scandal said that:

> It should not be left up to individual women to basically shame the government into doing something right. We are part of this society and deserve the best. The fact we have to campaign for it over and over again is not acceptable.[50]

This statement, unfortunately, beholds a poignant truth. There is no excuse for a developed society to repeatedly fall so far behind on such an important issue. In the words of Ceara Martyn: 'Patient voice needs to be in the room, but more specifically, women's.'[51] There is a severe need for the amplification, reception and implementation of the concerns and recommendations voiced by first-hand users, as they are uniquely positioned to identify the shortcomings.

C) Morrissey v HSE

Perhaps the most significant advancement in improving patient safety standards surrounding the CervicalCheck scandal was arguably that of the adoption of the test outlined by Clarke C.J. in *Morrissey v HSE* that established the appropriate safe practice in cervical cytology.[52] The test effectively quashed the claims of the National Screening Service and Jerome Coffey, head of the National Cancer Control Programme in a briefing to the then Minister for Health, that the discovery of Vicky Phelan's discordant slides did not constitute a patient safety incident, but

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[50] Kara Fox, 'A scandal over cervical checks is a sign of a bigger problem in Ireland' (*CNN,* 5 October 2019) <https://edition.cnn.com/2019/10/05/europe/ireland-cervical-check-scandal-intl/index.html> accessed 10 March 2024.

[51] Interview with Ceara Martyn, 221+ CervicalCheck Patient Support Group Manager (Galway, 13 March 2024).

[52] *Morrissey v Health Service Executive* [2020] IESC 6.

was rather a result of the known limitations of cancer screening.[53] The *Morrissey* test has allowed for the settlement of many cases, provided they can satisfy the 3-step criteria outlined therein:

i. What was to be seen in the slides?
ii. At the relevant time could a screener exercising reasonable care have failed to see what was on the slide?
iii. Could a reasonably competent screener aware of what a screener exercising reasonable care will observe on the slide treat the slide as negative?[54]

It may be argued this standard had always existed among clinicians, however, it was not being used as benchwork for examining liability until the courts endorsed it, demonstrating the reluctance of the judiciary to permit the State to evade, in most cases, evident liability.

III. Comparative Analysis – United Kingdom

A) The English Approach

A more effective approach to patient safety can be seen in English legislation, whereby a broader definition of patient safety incidents is adopted. The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 defines a notifiable safety incident as:

> any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a healthcare professional, could result in, or appears to have resulted in — the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition, or severe

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[53] Department of Health, 'CervicalCheck: Briefing Note for Minister Harris' (30 April 2018) <https://www.gov.ie/en/publication/dacdfc-cervicalcheck-briefing-note-for-minister-harris/> accessed 16 March 2025.
[54] *Morrissey v Health Service Executive* [2020] IESC 6.

harm, moderate harm, or prolonged psychological harm to the service user.[55]

Moderate harm is defined as including significant harm, such as 'unplanned return to surgery, an unplanned readmission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area.'[56] When contrasted with the overly restrictive approach in Ireland, this method of open disclosure is broader and more encompassing – particularly in relation to the 'psychological harm' provision, of which there is no mention in the Irish Act. Establishing the umbrella threshold for 'severe' or 'moderate' harm exemplifies England's proactive stance in fostering a culture of transparent disclosure, in contrast to the more reserved approach observed in Ireland. That being said, the incident must be 'unexpected' to ensure the scope of open disclosure is not overly broad, limiting it in cases of recognised potential harms where the programme is operating within agreed standards.[57] As discussed below, the Irish State should consider adopting a methodology of this sort by replacing the Schedule 1 criteria with a similar definition to create a more honest, open, and humane system.

i. Candour in England

The introduction of the duty of candour in England, as is often the case, stemmed from several tragic events; one being the avoidable death of Robbie Powell. The failure to treat suspected Addison's disease and falsifying records ultimately led to his demise, and highlighted the need for a duty of candour following his parents'

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[55] The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014/20.

[56] ibid.

[57] Public Health England, 'Guidance: Duty of Candour' (5 October 2020) <https://www.gov.uk/government/publications/nhs-screening-programmes-duty-of-candour/duty-of-candour#:~:text=1.1%20Duty%20of%20candour%20and%20NHS%20screening%20programmes&text=the%20person%20with%20or%20without,from%20bowel%20rupture%20following%20colonoscopy> accessed 15 January 2024.

unsuccessful appeal to the European Court of Human Rights.[58] In this case, it was recognised that the absence of such duty in English legislation meant that:

> Doctors have no duty to give the parents of a child who died as a result of their negligence a truthful account of the circumstances of the death, nor even to refrain from deliberately falsifying records.[59]

Although Robbie's case exposed the initial legislative lacuna, no further action was taken until the Francis Inquiry led to the establishment of a legal duty subject to criminal penalties under regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.[60] Candour is defined in the Francis Inquiry as:

> ensuring that patients harmed by a healthcare service are informed of the fact and that an appropriate remedy is offered, whether or not a complaint has been made or a question asked about it.[61]

This duty applies in relation to the manifestation of notifiable incidents under regulation 20(7), as outlined above, but does not apply to harm below moderate harm, including near misses, due to legitimate fears about the bureaucratic burden of such a duty. Ireland and England have a near analogous common law basis for the doctrine of informed consent. Building from the preceding UK case of *Sidaway v Governors of the Royal Bethlehem Hospital*[62], and the Irish case of *Walsh v Family Planning Services Ltd*[63], the High Court in *Geoghegan v Harris*[64] formally adopted the view that all material risks should be disclosed to a patient before

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[58] *William and Anita Powell v the United Kingdom* App No 45305/99 (ECtHR, 4 May 2000).
[59] ibid.
[60] Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.
[61] Robert Francis, *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry* (2013) 75.
[62] *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871.
[63] *Walsh v Family Planning Services Ltd* [1992] IR 496 (SC).
[64] *Geoghegan v Harris* [2000] 3 IR 536 (HC).

medical intervention. This doctrine was formally adopted in the UK in *Chester v Afshar*[65], and reaffirmed more recently by the UK Supreme Court in *Montgomery v Lanarkshire Health Board*[66] under the same principles. Therefore, the idea of both jurisdictions adopting a similar view on open disclosure and a statutory duty of candour should not be considered too radical.

IV. Proposed Solutions

A) Ethical framework of nondisclosure

Kant's philosophy of honesty being a 'perfect duty', i.e. one that cannot be overridden by other values, would imply that there are no valid arguments against full disclosure.[67] Many of the strongest arguments in favour of full open disclosure are deontological in nature, therefore there exist consequentialist counter-arguments that may appear to be more favourable from a legal and policy-making standpoint.

Scheirton analogises: 'Information is powerful; it can turn a sugar pill into an effective pain killer. For the same reason that information can empower patients, it can also confuse and crush them.'[68] The concept of full disclosure may seem purely advantageous, however, an ethical question arises regarding the necessity of disclosure in circumstances where the consequences may not necessarily benefit the patient. This argument is referred to as the 'therapeutic exception' and suggests that in cases where non-disclosure has no grave material consequences for the well-being of the patient and could either cause distress for them or diminish their trust, it may be ethically justified to withhold

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[65] *Chester v Afshar* [2004] UKHL 41, [2005] 1 AC 134.

[66] *Montgomery v Lanarkshire Health Boar*d [2015] UKSC 11, [2015] 2 All ER 1031.

[67] Miriam Schulmann, 'Truth and Consequences' (*Santa Clara University*, 10 November 2015) <https://www.scu.edu/character/resources/truth-and-consequences/> accessed 15 January 2024.

[68] Linda Scheirton, 'Proportionality and the View from Below: Analysis of Error Disclosure' (2008) 20(3) Hec Forum 215.

information in order to maintain the therapeutic relationship.[69]

The issue of whether or not to disclose certainly places medical professionals at a moral crossroads. However, why should the burden of determining a patient's reaction lie with them? Medical professionals should not have the right to assume the responsibility of estimating the material consequences of truth-telling to their patients. How can they, while maintaining a strictly professional relationship, predict their patient's reaction? The entitlement to the truth is an inherent right of the patient, regardless of any potential outcome.

B) Addressing Victim Blaming Culture in Healthcare

The healthcare system should be built upon values of honesty, genuine care, and openness. However, it is more prevalent than ever that this is not the case, where there has been reported fear from patients that by speaking up, they may become the 'unpopular patient', and that voicing their genuine concerns may negatively affect the quality of the care they receive going forward.[70] Patients should be able to trust their healthcare providers, but there must be valid cause for doubt if the system is making patients feel this way. Accounts from victims of the CervicalCheck scandal regarding their treatment in the system include being made to feel like 'second-class citizens.'[71] One woman recounted being 'treated like a leper' after being questioned by a clinician about any affiliation with the 221+ group.[72] According to cervical cancer campaigner Lorraine Walsh, there are cases of victims being refused treatment by clinicians and having their consultants tell them they cannot treat them anymore after informing them of their association with 221+.[73]

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[69] Fred Rosner and others 'Disclosure and Prevention of Medical Errors' (2000) 160(14) Archives of Internal Medicine 2089.

[70] Patricia Daly, 'Explaining the HSE's complaints procedure' (*Irish Legal News*, 16 July 2021) <https://www.irishlegal.com/articles/patricia-daly-explaining-the-hse-s-complaints-procedure> accessed 10 January 2024.

[71] Scally (n 3).

[72] ibid.

[73] Cate McCurray, 'Clinicians Refused to Treat Women Associated with CervicalCheck Support Group' (*BreakingNews.ie*, 24 November 2022)

This is problematic as it illustrates the victim-blaming view held by medical professionals in Ireland and discourages patients from being honest with the clinicians they depend on for future care. It is evident from these accounts that these professionals are not willing to recognise previous shortcomings and would rather leave patients untreated than admit failure. As articulated by Scally: "If you can't bring yourself to acknowledge past failings, why would anyone trust you today?".[74] No matter how far open disclosure policies and training develop, it is all for nought if there is an epidemic of distrust in the system. Measures need to be implemented to ensure that healthcare professionals maintain a relationship built on honesty, such as a statutory duty of candour, which will be further discussed below.

C) Call for a Statutory Duty of Candour

i. The Need for Legal Recognition.

The Patient Safety Act certainly legislated for welcome changes concerning being open and promoting honesty within the healthcare system, but contrary to multiple recommended amendments, it is lacking a crucial element: a statutory duty of candour.[75] There are certain limited incidents in which a healthcare provider must disclose the truth, however, there remains an absence of a general legal duty upon healthcare professionals to be candid in all circumstances. The Medical Council's Guide to Professional Conduct & Ethics for Registered Medical Practitioners begins by detailing what good medical practice is. It states that building doctor-patient relationships:

> depends on establishing trust, providing patient-centred care, working collaboratively with patients and colleagues,

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<https://www.breakingnews.ie/ireland/clinicians-refuse-to-treat-women-associated-with-patient-advocate-group-1396914.html> accessed 12 March 2024.

[74] Scally (n 3) 3.

[75] The Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023.

> advocating for patients and communicating effectively with patients, colleagues and others.[76]

Although candour is encouraged on an ethical basis, there is still a need for a statutory duty to be implemented. Evidence exists to suggest that the main barriers to enhancing candour, including toxic work environments of blame and defensiveness, and fear of complaints and litigation, remained static in the absence of a legal duty.[77] When it comes to candour, guidelines and policies are not as effective as a law that imposes a positive obligation on healthcare providers.[78] Medical professionals are also less likely to disclose errors that are not apparent to patients and errors that could result in more serious consequences for the practitioner.[79] A relationship of trust cannot be safeguarded and enshrined in the healthcare system when no legal duty exists to be open and transparent with clients. In a public inquiry chaired by Robert Francis QC into the failings in care at Mid Staffordshire NHS (The Francis Inquiry), he stated:

> For all the fine words printed and spoken about candour, and willingness to remedy wrongs, there lurks within the system an institutional instinct which, under pressure, will prefer concealment, formulaic responses and avoidance of public criticism.[80]

The imperative for patients to be fully informed about their health and this duty should underpin all interactions between health services, health professionals, and patients. As Scally said, honesty with patients should be 'as natural as breathing.'[81]

ii. Challenges in Implementing a Statutory Duty of Candour

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[76] Medical Council, *Guide to Professional Conduct & Ethics for Registered Medical Practitioners* (9th edn, 2024).
[77] Oliver Quick, 'Duties of Candour in Healthcare: The Truth, the Whole Truth, and Nothing but the Truth?' (2022) 30(2) Medical Law Review 324.
[78] ibid.
[79] Catherine Kelly and Oliver Quick, 'The Legal Duty of Candour in Healthcare: The Lessons of History?' (2019) 70(1) Northern Ireland Legal Quarterly 77.
[80] Francis (n 61).
[81] Scally (n 39).

Arguments against the implementation of a statutory duty of candour include that the legislation may have the capacity to produce an abundance of notifications and administrative tasks, potentially resulting in clinician frustration and public confusion.[82] As mentioned previously, the duty does not extend in the UK to harm regarded as minor or near misses, so as not to create a bureaucratic burden.[83] The intention of the phrase "could result in harm" in Regulation 20 is not to include near miss events as notifiable safety incidents, rather it is meant to account for harm that may not be visible immediately after the incident but could appear later.[84] Regulation 20.1 states that 'registered persons must act in an open and transparent way with relevant persons in relation to care and treatment provided to service users in carrying on a regulated activity.'[85] It is, therefore, important to realise the overarching aspect of the duty of candour is always applicable: healthcare providers must be open and transparent about what happened, whether or not something is a notifiable safety incident.[86] It must also be noted that the duty is imposed on 'registered persons', i.e. registered providers and registered managers, rather than individuals themselves, which reduces the burden placed on individual clinicians.[87] A balanced approach to candour would include taking inspiration from the UK and expanding notifiable incidents to include incidents of 'moderate', 'severe' or 'prolonged psychological' pain, alongside a general statutory obligation on registered persons to be open and honest.[88]

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[82] Don Berwick, *A Promise to Learn – A Commitment to Act: Improving the Safety of Patients in England* (National Advisory Group on the Safety of Patients in England, 2013).
[83] Kelly and Quick (n 79).
[84] 'Regulation 20: Duty of candour' (*CareQuality Commission,* 30 June 2022) <https://www.cqc.org.uk/guidance-providers/all-services/regulation-20-duty-candour> accessed 6 March 2025.
[85] Health and Social Care Act 2008 (Regulated Activities) Regulations 2014/20.
[86] 'Regulation 20: Duty of candour' (CareQuality Commission, 30 June 2022) <https://www.cqc.org.uk/guidance-providers/all-services/regulation-20-duty-candour> accessed 6 March 2025.
[87] ibid.
[88] Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, reg 20.

iii. Apologies

Clinicians also tend to fear the threat of legal and disciplinary action as a result of them saying too much due to mandatory disclosure law.[89] Section 2 of the Compensation Act 2006 in England and Wales ensures that: 'an apology, an offer of treatment or other redress, shall not of itself amount to an admission of negligence or breach of statutory duty.'[90] Irish legislation employs a similar protection. Section 10 of the Patient Safety Act states:

> Information provided, and an apology where it is made, to a patient or a relevant person … by a health services provider at a notifiable incident disclosure meeting … (a) shall not constitute an express or implied admission of fault or liability.[91]

However, this provision only applies in Ireland to notifiable incident disclosure meetings, which are, as aforementioned, highly restricted. The Care Quality Commission in their Regulation 20 guidance to providers stated:

> In many cases it is the lack of timely apology that pushes people to take legal action. To fulfil the duty of candour, you must apologise for the harm caused, regardless of fault, as well as being open and transparent about what has happened.[92]

In Michigan, USA, implementing a culture of candour has been shown to cut medical negligence litigation costs in half.[93] After a shift from a culture of 'deny and defend' to one of openness

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[89] ibid.

[90] Compensation Act 2006, s 2.

[91] Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023, s 10.

[92] 'Regulation 20: Duty of candour' (CareQuality Commission, 30 June 2022) <https://www.cqc.org.uk/guidance-providers/all-services/regulation-20-duty-candour> accessed 6 March 2025.

[93] David A Stephenson, 'The Scottish Statutory Duty of Candour' (2016) 20 Edinburgh Law Review 224.

and transperancy medical negligence claims dropped by 50% in Illinois.[94] This further backs the CQC's claim that an apology is a 'crucial part' of the duty of candour.[95] Berlinger suggests that statements of sympathy are insufficient, and analogises that 'I am sorry your father died', is not the same as saying, 'I am sorry for my error that contributed to your father's death.'[96]

iv. Soft law mechanisms

In order for a culture of candour to exist in the healthcare system staff must feel supported and comfortable to be honest about medical harm. Too broad an approach to candour goes beyond clinicians having to admit personal mistakes to also informing patients about issues related to hospital resources and health system management.[97] This is evidently problematic, as it creates a conflict of loyalty between clinicians' patients, colleagues and their employer, with professional guidance suggesting that the protection of patients should be the priority.[98] The statutory duty in Scotland requires healthcare providers to train and support staff in communicating candidly or managing the emotional challenges associated with such work.[99] These supports, known as soft law mechanisms, should be legislated for alongside a balanced approach to candour to create an open environment in which clinicians feel comfortable to disclose the truth.[100] It is imperative to remain mindful of the rationale behind this proposed legislation and its objectives, striving to enhance patient safety and mitigate the secondary harm stemming from mishandling the aftermath of clinical incidents.[101] Instances

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[94] ibid.
[95] 'Regulation 20: Duty of candour' (CareQuality Commission, 30 June 2022) <https://www.cqc.org.uk/guidance-providers/all-services/regulation-20-duty-candour> accessed 6 March 2025.
[96] Nancy Berlinger, 'After Harm: Medical Error and the Ethics of Forgiveness' (2005) 331(7528) BMJ 1343.
[97] Kelly and Quick (n 79).
[98] Kelly and Quick (n 79).
[99] Oliver Quick, 'Duties of Candour in Healthcare: The Truth, the Whole Truth, and Nothing but the Truth?' (2022) 30(2) Medical Law Review 324.
[100] ibid.
[101] JD Wijesuriya and D Walker, 'Duty of candour: a statutory obligation or just the right thing to do?' (2017) 119(2) British Journal of Anaesthesia 175, 178.

involving medical harm are arguably the most delicate and potentially detrimental for patients and their families. They warrant the utmost communication, empathy, and attention.[102]

D) A New Complaints System

It may be disputed that full open disclosure would lead to increased litigation arising from higher levels of complaints, but it has been widely reported that patients want to avoid legal proceedings where possible and usually want three things:

1. a comprehensive explanation of the errors and their causes,
2. a sincere acknowledgment of responsibility by involved clinicians, including an apology where warranted,
3. and assurance of concrete measures being implemented to prevent recurrence and safeguard future patients from harm.[103]

The Independent Patient Safety Council's research further supports this claim, listing: "an apology; an explanation of what went wrong; acknowledgement of responsibility (and) commitment to prevent reoccurrence" as the expectations from patients regarding the open disclosure process.[104]

Proportionality is key in deciding whether a revised complaints system is necessary. While it may potentially lead to a hypothetical rise in legal action, the disproportionate denial of patients' rights to voice complaints about their care is glaringly apparent. It is imperative to revise the currently flawed system. It should also be considered that although disclosing an error may lead to legal action being taken, so too can failure to disclose, as seen in the case of the CervicalCheck Scandal.[105] A potential model for complaints systems might include the formation of an independent statutory body such as the Ombudsman dedicated to the HSE alone, similar in nature to the Garda Ombudsman. It is, at present, possible to file a general Ombudsman complaint regarding the HSE, however, it is limited in its power by the

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[102] ibid.

[103] ibid.

[104] Albert Wu and others, 'Disclosure of Adverse Events in the United States and Canada: An Update, and a Proposed Framework for Improvement' (2013) 2(3) Journal of Public Health Research 186.

[105] Scheirton (n 68).

prohibition on clinical judgement complaints.[106] An independent complaints system should be established to ensure an unbiased, prioritised review and the Health Act should certainly be amended to remove the "outrageous" clinical complaints ban.[107]

Conclusion

It cannot be disputed that patient safety, open disclosure, and women's health have each made notable advancements, so too it cannot be disputed that there is much work left to do. Stephen Teap, founding member of the 221+ CervicalCheck patient support group, whose wife, Irene, tragically passed away before the discovery of her discordant results, said that Irene: 'would have wanted to know the truth, whether she found out three weeks or three minutes before she passed away.'[108] Healthcare professionals should not unilaterally determine what information is disclosed to patients. The time has come to put an end to the 'ethically embarrassing' debate on whether or not to disclose patient safety incidents.[109]

To summarise, the limited scope of what constitutes a notifiable incident must be amended to a broader definition, as is seen in England and the need for the introduction of an autonomous complaints mechanism is urgent. Restrictions on clinical judgments must be removed with immediate effect and a new long-term women-centric healthcare approach should be adopted as repeatedly recommended by adopting the aforementioned measures. A legal obligation on healthcare

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[106] The Ombudsman 'The Ombudsman and Complaints about Health and Social Care Services' (2023) <https://www.ombudsman.ie/publications/information-leaflets/the-ombudsman-and-the-hea/index.xml> accessed 15 February 2024.

[107] 'Patient Safety Bill: next steps for medical transparency' (RTE Radio 1, 17 February 2023) <https://www.rte.ie/radio/radio1/clips/22214394>/ accessed 15 February 2024.

[108] Olivia Kelleher, 'Husband Pays Tribute to Cervical Cancer Victim Irene Teap on Fifth Anniversary' (*Irish Examiner*, 27 July 2022) <https://www.irishexaminer.com/news/arid-40927595.html> accessed 16 March 2025.

[109] Lucian Leape and Donald Berwick, 'Five Years after To Err Is Human: What Have We Learned?' (2005) 293(19) Journal of the American Medical Association 2384, 2388.

providers to conduct and ensure patients are aware of their rights regarding reviews needs to be imposed, and a statutory duty of candour should be legislated for. These represent just a fraction of the prevailing issues that must be dealt with promptly due to the time-sensitive nature of patient safety.

In the words of Dr. Scally, "ticking the box doesn't make the change!".[110] The Irish legal and healthcare systems must address historical shortcomings with respect to women's healthcare and implement a more accessible remedial framework. Legal arguments aside, the majority of the persisting issues could be mitigated if the main priority were to cultivate a humane and honest system. The legal arguments support this claim, and it comes as no surprise that Ireland's healthcare system is internationally regarded as a 'morality tale.'[111] While there is still hope for improvement, time is of the essence to enact necessary changes.

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[110] Scally (n 3).

[111] Patrick Heavey, 'The Irish Healthcare System: A Morality Tale' (2019) 28(2) Cambridge Quarterly of Healthcare Ethics 276.