An tSeirbhís Náisiúnta Scagthástála
National Screening Service

Report of the Legal Framework Group on interval cancers

Recommendations on the legal and ethical requirements for population cancer screening in Ireland

October 2023

Contents

Executive summary

In September 2022, the National Cancer Registry Ireland (NCRI) published a report on national trends for cancers with population-based screening, namely breast, bowel, and cervical cancer. All three cancers showed favourable trends in incidence, stage, survival and/or mortality consistent with improvements in early detection and outcomes, with clear evidence for additional or more recent benefits of screening. Screen-detected cancer cases were, on average, detected at a substantially earlier stage than other cases diagnosed at the same ages. Survival has improved for all three cancers, with the biggest improvements seen in the age-groups targeted by the national screening programmes. Death rates of all three cancers have fallen significantly. Decreases in the mortality rates in the age-groups targeted for screening have been more substantial than the overall decreases for all three cancers. From a public health perspective, population cancer screening programmes are delivering on their stated outcomes.

The purpose of cancer screening is to detect pre-cancer or early-stage cancer in individuals who do not have symptoms so that timely confirmatory diagnosis and early treatment can be offered and where this treatment can lead to better outcomes for some people. The aim of a cancer screening programme is either: (a) to reduce mortality and morbidity in a population by early detection and early treatment of a cancer (for example, breast screening) or (b) to reduce the incidence of a cancer by identifying and treating its precursors (such as cervical and colorectal screening). While the population will benefit, not every individual within the screened population will benefit from participation in a population screening programme. This apparent paradox reflects the fact that screening programmes are limited in what they can achieve. For example, cervical screening has limited sensitivity. This in effect means that even in best-in-class screening programmes the test will only ever detect 65-70% of cancers and will fail to detect cancer in approximately 30% of cases where people are screened. It is also recognised that some participants will receive a false positive result which leads to anxiety and in some cases can lead to unnecessary treatment.

Since 2018, there have been significant challenges faced by Ireland's population screening programs particularly CervicalCheck – The National Cervical Screening Programme. These include; trauma as a result of failures within the services experienced by participants, families and healthcare professionals; reduced trust between the public and other material stakeholders; difficulty with staff recruitment and retention in an increasingly adversarial medico-legal environment; widespread confusion around the purpose of clinical audits, incident reviews, look back reviews and patient-requested reviews; the increased costs of mitigation against the risk of litigation; and the overall cost-impact to the public taxpayer arising from legal cases and the level of awards.

Individuals diagnosed with cancer, having participated in a screening programme, are very likely to experience a range of distressing emotions. Details within the *'Scoping Inquiry into the CervicalCheck Screening Programme'* illustrate the range of emotions and hurt experienced by women which was compounded by the failures and confusion in communication with respect to delays in reporting outcomes of the retrospective audit of cervical cancer and the manner of delivery of these results to

some individual patients. Discussions with the Legal Framework Group Patient Advisory Forum (a sub-set group commissioned by the Legal Framework Group Chair) reiterated that some of the hurt was generated from the realisation of a missed opportunity for them personally but also by the way some of the results of the audit were communicated. Unfortunately, this cruel *'what if'* and *'if only'* realisation, with life-limiting consequences for some, is, and will always remain, an integral part and harm of population screening programmes.

Population cancer screening is neither a simple nor a diagnostic test. There is a need to continually educate the public and all material stakeholders that there are benefits but there are also known and accepted harms associated with population cancer screening. It is a complex public health programme incorporating an entire pathway of care that requires significant resources, infrastructure, and coordination underpinned by quality assurance methodologies. There is a clear need to give equal emphasis on communicating harms as well as benefits and to allow individuals to make an informed choice before participating.

During its discussions, the Legal Framework Group was struck by the reality of misinterpretation and/or misunderstanding of ambiguous language, inconsistent definitions, and the use of terminology generally when discussing screening programmes. For example, it is not uncommon for a clinical audit done for the purposes of learning to be confused with an incident review, a look-back review, or a healthcare record review, all of which involve separate and specific responses and differing protocols and interactions with the individuals who have participated in screening. Similarly, there is neither an international reference nor a definition for the term 'programmatic audit' in the context of cancer screening, or a consistent understanding or application of the term. It is critical that a standardised use of language and terminology be applied when discussing population cancer screening.

Interval cancers - cancers diagnosed in between routine screening episodes - are an inevitable part of any population screening programme. While rare in the context of the total number of individuals screened and the number of lives saved through screening, they are nonetheless a painful and upsetting reality and a known 'harm' for any individual participating in a cancer screening programme. Measuring the interval cancer rate will allow for international comparison and give a good indication of whether the screening programme in question is performing within standard and in line with its peers internationally. The occurrence of an interval cancer in a previously screened individual is a statistical certainty and, as such, cannot be automatically attributable to the negligence or failure on the part of the relevant screening programme. Ireland has seen an unprecedented growth in the extent of litigation brought by participants in cancer screening programmes, and in the level of awards. Irish personal injury compensation levels are high when compared with most other jurisdictions and Ireland is a clear outlier when compared to other population screening programmes internationally. An ideal cancer screening test would perfectly separate people who have cancer from those who do not. Screening tests cannot do this. They can only suggest the likelihood that a person is at risk (or risk-free) of cancer. Even with the best technology, there will always be people whose cancer is not detected by the screening test (i.e., given a false-negative result) and people who do not have cancer but are given an abnormal result (i.e., a false-positive result).

The last two years, and again appearing to be unique to Ireland, has seen significant growth in the number of litigation cases related to actual screen-detected cervical cancer cases based on an argument and a belief that the cancer detected by screening should have been detected at an earlier stage. This is a fundamental contradiction to the very purpose of a cervical cancer screening programme and what it can achieve. There is now a need to have a discussion with Irish society to decide how we manage the limits of the performance of cancer screening programmes.

Under the current medico-legal environment, there is a risk that new cancer screening programmes in Ireland will be considered too high risk for clinicians and too costly for the state irrespective of any independent evidence-based recommendation to do so.

Currently, the only means of determining whether there was actual negligence in any interval cancer case will involve findings of fact by a judge based on evidence. Each case will, necessarily, depend, to a significant extent, on its own facts. However, it is very rare for cases to be heard to completion by a judge (only 2 cases to date in Ireland). Most cases are in fact settled, most without admission of liability. Nonetheless, whether settled out of court or not, for all those involved the legal route is adversarial, expensive, and traumatic. The current Irish legal environment in which the screening programmes operate is not suited to resolving disputes that have arisen over the last 4 years in cancer screening and will remain insoluble unless alternative measures are introduced.

Reviews of individual interval cancer cases are not without significant difficulty. They are associated with what is termed 'hindsight bias'. Hindsight bias is a phenomenon common to us all but is particularly evident in clinical negligence cases and specifically in screening cases. It occurs where experts are asked to review medical cases and to give an opinion on negligence when the outcome is already known, for example, the expert will know whether the person has died, survived with impairments or is healthy. This advanced knowledge of the patient's condition is more likely than not to lead the expert to scrutinise those cases with a poor outcome with a prior bias that something must have gone wrong when seeking to attribute error as opposed to ignoring the same issue had the patient survived unharmed. In screening cases, no matter how closely any review panel tries to reproduce the original screening conditions, the conditions of the subsequent review will always be different – the fact that a review will include the records of a patient known to have a serious condition such as cancer, will inevitably heighten a reviewer's vigilance and will increase reports of abnormality. While it may be intuitively difficult to understand, finding discrepancies on review, up to 40% in cytology reviews for example, does not imply that the same findings could or should have been made under routine screening programme conditions. It does though make clear that a cytology smear test is subjective, prone to significant observer variability, and as such cannot be considered a diagnostic test, nor can it provide absolute certainty that it rules out precancerous changes.

> *"… it is not simply a case of inferring from the fact that someone obtained a clear result but subsequently was diagnosed with the relevant disease that there was necessarily negligence on someone's part"*
>
> *(Former Supreme Court Justice Frank Clarke)*

There remains a concern that the specific legislative reference to screening in the 'Patient Safety (Notifiable Incidents and Open Disclosure)' Act will be interpreted by the public as meaning that something went wrong that should not have gone wrong and that the screening programme was at fault, and in so doing set unrealistic expectations of performance that run contrary to international standards. As per the Expert Reference Groups Reports the full disclosure of the results of any patient-requested reviews is an inherent component of the NSS patient-requested review process irrespective of any legislative requirement. The universal application of patient-requested reviews arising from legislation is without precedent, untested, and most notably has not been evaluated in terms of patient experience, expectations, process outcomes and the potential benefits and harms for all those participating in such a review. There is a very real risk of unknown and unintended consequences arising from its incorporation into legislation prior to any evaluation, peer review and publication of the entire patient-requested review process.

After the completion of the work of the Legal Framework Group, the World Health Organisation's International Agency for Research on Cancer (IARC) published *'Recommendations on best practices in cervical screening programmes: audit of cancers, legal and ethical frameworks, communication and workforce*

competencies (2023)' (see report executive summary in chapter 10). It is an invaluable addition to the literature and some of its key messages are important to highlight as they align and endorse many of the recommendations presented by the Legal Framework Group.

- Audit of cervical cancers aims to evaluate the programme (i.e., the whole pathway) and not individual health professionals or what happened to an individual participant. In any programme, some cancers will be missed. Some interval cancers are due to fast-growing tumours that could not be detected through screening at the specified interval.
- An [invasive cervical cancer] audit looks at the extent to which cervical cancer could be further prevented in the population by avoiding human or systematic errors, and not at whether the failure to detect a cancer in a particular woman was a result of human error.
- Although the practice standards have not been well defined in cytology, a systematic review reported that even in countries with organized screening programmes, 20–55% of women who developed cervical cancer had had false- negative smear test results within 6 years before the diagnosis.
- An individual [cancer] case review should be distinguished from an [invasive cervical cancer] audit and should be planned and implemented differently, because the two processes have different objectives. An individual case review is not based on quality assurance principles of improving the programme. Instead, it is an attempt to determine how or why a specific individual developed cancer despite participating in screening. Although it may be intuitively difficult to understand, finding discrepancies on review (e.g., up to 40% in cytology reviews) does not imply that the same diagnoses should have been made under routine screening programme conditions.
- Successful claims for negligence should concern errors that are not merely inevitable consequences of the limitations of the screening process. A test result is not necessarily negligent just because a different screener would have formed a different opinion. Many of the legal and ethical complexities in cervical cancer screening arise from the fact that the screening process is not diagnostic. Most legal and ethical frameworks in the health-care sphere were developed in the context of diagnosis and treatment. Screening tests do not naturally fit into this approach. It is not possible to achieve a zero-error rate in screening. Cytology is highly subjective, and even in a quality-assured screening programme there are a significant number of false-negative test results.
- Regarding legal liability for errors in screening, it should be possible to make a claim for negligence with respect to cervical screening, but the standards applied by courts in assessing such claims should accommodate and reflect the reality of cervical screening, including hindsight bias in an audit of cancers. The determination of whether the particular screening error was serious enough to be categorized as negligent and/or serious enough to entitle the participant to compensation needs to consider the inherent limitations of cervical screening.
- Uncontrolled and unjustified litigation poses a serious threat to current screening programmes and to the establishment of new screening programmes.

For the first time the IARC Report produced a definition of an interval cancer in cervical cancer screening programmes.

- Any cancer (including microinvasive cancer [stage IA]) diagnosed in a woman between her most recent screening episode and her next screening round, at an interval stipulated by the programme, who had either (i) no abnormal screening test result or (ii) an abnormal screening test result but a negative triage test result or a negative diagnostic test result.

In conclusion, cancer screening in Ireland has reduced morbidity and mortality across breast, cervical and colorectal cancer. However, the many contradictions in population screening are laid bare in this report. There are known limitations and harms associated with the delivery of these

population-based cancer screening programmes. The current cost of these harms in Ireland - in terms of retention of staff and the cost of the programmes, including the opportunity costs - may now outweigh the benefits for the majority. The work of the Legal Framework Group has clearly identified that clinical negligence litigation results in lengthy, costly and often traumatic experiences for both plaintiffs and defendants. The current system is not working for anyone, particularly patients. It is inarguable that the advantages of pre-action protocols and case management would bring considerable benefit and relief to participants not least of which would be the early resolution of the dispute and the preservation of the therapeutic doctor-patient relationship. This could be achieved with the commencement of the new Part 2A of the Civil Liability and Courts Act, 2004. But this is only part of the answer. While most people will benefit from screening, some will be harmed or at least will not benefit from a screening programme in any way. Population cancer screening programmes find themselves in an invidious position and must constantly strive for balance between maximising benefits and minimising harms. They are inextricably linked and unfortunately harm is not wholly avoidable. This report advocates for a wider public consultation and engagement on a new legal framework for screening, in order to protect the future of all current and proposed screening programmes.

Acknowledgement

The Legal Framework Group has sought to underpin its discussions and recommendations with published and verifiable data, peer reviewed publications and reports of the lived experience of individuals who have participated in screening programmes. The Legal Framework Group fully acknowledges the difficulties all screening programmes face in balancing the known benefits with the known harms, and the hurt participants face when screening has not found their cancer. The Legal Framework Group is aware, in the context of its recommendations, of its responsibilities to the current and future eligible populations for all population cancer screening programmes in Ireland.

The Legal Framework Group also acknowledges that many of the recommendations made in this report are already progressing, both those within the remit of the NSS and beyond.

Recommendations

1. The Legal Framework Group recommends transparency in the communication of the benefits and harms of population cancer screening programmes incorporating informed consent; continued engagement and improved education with key stakeholders, including the public, media, healthcare professionals, legal community, patient representatives, advocates, and politicians; and information campaigns, training, and education to re-build trust and confidence in population cancer screening in Ireland.

2. The Legal Framework Group recommends the full adoption and use of the *HSE National Centre for Clinical Audit Nomenclature – A Glossary of Terms for Clinical Audit.*

3. The Legal Framework Group recommends ceasing the use of the term 'programmatic audit' for population screening programmes and that any clinical audit should be given a full descriptive title to ensure clarity of purpose and consistency of understanding.

4. The Legal Framework Group recommends the drafting of NSS operational guidance on the management of true patient safety incidents in population screening programmes to align with the current *HSE Incident Management Framework and Guidance (2020)* and the HSE Open Disclosure Policy.

5. The Legal Framework Group recommends that in the context of interval cancers in population cancer screening programmes, the most appropriate and internationally recognised measure of quality is the interval cancer rate in BreastCheck and CervicalCheck and the post-colonoscopy colorectal cancer rate in BowelScreen.

6. The Legal Framework Group recommends that personal data obtained during the operation of cancer screening programmes should be retained and managed in line with the HSE policy on retention periods for personal data.

7. The Legal Framework Group endorses the ERG recommendation that in the event of a cancer diagnosis, a patient-requested review should be an option available for all participants in cancer screening programme.

8. The Legal Framework Group recommends that an independent evaluation of the structures, process and outcomes of patient-requested reviews should be commissioned after the first full year of operation by the National Screening Service.

9. The Legal Framework Group recommends that future retrospective audits [of invasive cancer] should only be undertaken on an anonymised basis and published in aggregate format. Audits should be carefully designed by an overarching NSS multidisciplinary Steering Committee (or equivalent) that includes a patient/public representative and international research representative.

10. The Legal Framework Group urges the Government to commence new Part 2A of the Civil Liability and Courts Act, 2004 as a matter of urgency. This will enable pre-action protocols to be introduced in relation to clinical negligence claims, and will enable case management rules to be introduced, so that such claims can be progressed more expeditiously and at far less cost to the parties involved in a dispute.

11. The Legal Framework Group has noted the long-established position that the "Dunne principles" are the appropriate legal test for medical negligence in Ireland. In order to ensure that the Dunne principles in claims arising from CervicalCheck are strictly adhered to, the Legal Framework Group's position, having taken advice is as follows:

(a) Recommend that the expert(s) engaged by a plaintiff to review a slide for the purpose of establishing that the course the defendant's screening technician took was "one which no medical practitioner of like specialisation and skill would have followed had he been taking the ordinary care required from a person of his qualifications" (see Dunne principle 2) must be another screening technician, and not an expert in a different area of specialisation such as a consultant cytopathologist who may never have worked as a screening technician.

(b) Recommend that any review of the allegedly mis-read slide carried out on the part of a plaintiff is conducted as far as practicable under the same conditions as it was originally reviewed by the defendant's technician – i.e., being one of perhaps 30 slides being read by a typical screening technician during the course of his/her day's normal work, rather than a review of a single slide in isolation.

(c) Recommend the need to avoid 'hindsight bias', and lead evidence from an expert on the effects of 'hindsight bias'.

(d) Recommend that where a plaintiff's expert is someone other than a screening technician, and who examines the suspicious slide under different working conditions, make appropriate submissions to the Court that lesser weight should be attached to that evidence than the evidence attached to that of any blind review that is undertaken.

(e) Recommend that any third-party review be "blind" – in other words the slide should be unmarked, and anonymised – again, to reduce and ideally avoid any risk of 'hindsight bias'.

12. The Legal Framework Group recommends that a further examination with appropriate expert advice, of the feasibility of a non-adversarial alternative dispute resolution process for interval cancers diagnosed as part of participation in population cancer screening programmes.

13. The Legal Framework Group recommends that an assessment, with appropriate expert advice, of the most appropriate economic evaluation of population cancer screening programmes in Ireland should be completed in 2023 with a view to completing an economic evaluation in 2024.

14. The Legal Framework Group recommends the involvement of a Citizens' Assembly (or a viable independently commissioned alternative, such as a Citizens' Jury) to engage debate within society on all aspects of population cancer screening.

1. Background

1.1 The Expert Reference Groups' (ERG) Interval Cancer Reports published in 2020[1], set out a new and comprehensive approach to reviews of interval cancers in people who have been screened by Ireland's breast, bowel, and cervical cancer screening programmes. They affirm that population screening programmes must balance participant trust with staff recruitment, retention and affordability, and that interval cancers are a statistical certainty and an inherent feature of any population screening programme.

1.2 The Legal Framework Group was established in March 2021. Membership of this group is broad, including representation from the Department of Health (DOH), Legal Experts, Health Ethics, Health Economics, Public Health, National Screening Service (NSS) Clinical Directors and Patient Advocacy. The group set out to develop clear recommendations around the conduct and participation in population screening programmes, based on current legal instruments such that the public, political, medical, and legal interpretation of screening are clearly defined and understood.

1.3 Despite the evidence of population benefit in Ireland[2], not every individual within a screened population can or will benefit, and some will even be harmed by participating in a population screening programme. This is not unique to Ireland and reflects the experience in every population screening programme all over the world. It is internationally acknowledged that cervical screening for example provides protection from cervical cancer of around 70%. The level of protection depends partly on the regularity of screening and age, with younger women deriving slightly less protection than older women. Screening has been shown to be associated with a 60% reduction in cancer in women aged 40, and this reduction increases to 80% by age 64. This means around 30% of cervical cancers are not detected by screening[3].

2. Terms of Reference

(a) Assessment of the current legal framework under which screening operates

(b) Consideration of the proposed interval cancer implementation plans and the likely effect on the future medico-legal environment for patients and medical staff

(c) Development of clear recommendations around the conduct of screening and participation in screening based on current legal instruments such that the public, medical, legal, and political interpretation of screening (positives and limitations) are clearly defined and understood

(d) In the event of a gap identified in legal instruments, production of a risk assessment and proposals to develop an alternative legal environment to support the structure under which screening operates

(e) Consideration of alternatives to legal action through the development of a proposed methodology for independent review and/or future clinical care management of screening participants who develop an interval cancer

(f) Collaboration with other key groups to support the implementation of specific relevant recommendations

(g) Assessment of and planning for the implications of the Patient Safety Bill (if within the timescale of the overall interval cancer project)

(h) The provision of progress reports on the status of implementation of recommendations or any other significant developments to the Interval Cancer Steering Group

(i) Identification and escalation of risks and/or issues to Interval Cancer Steering Group

(j) To comment on the ethics of resource allocation in healthcare with reference to Cancer Screening Services

3. Methodology

3.1 The Legal Framework Group has held 18 meetings during the course of its tenure. In addition, there have been two patient advisory forum meetings. The approach taken included an analysis of the recommendations arising from the ERG reports[1], discussion and debate on the ERG recommendations in the context of the current screening and medico-legal environment, the input of a data security and technology expert and four areas of commissioned research and advice consisting of:

1) The benefits and limitations of population screening with respect to mortality and morbidity; see Supplement 1

2) Ethical considerations in relation to population screening with specific attention to the balance between the benefits and harms of screening and the limitations of participation; see Supplement 2

3) An analysis of the current legal environment in Ireland and benchmarking that against the operational environment of other international population screening programmes; see Supplement 3

4) Advices on the Legal Framework Group Interim Report. Supplement 4.

4. Communications – the benefits and harms of screening

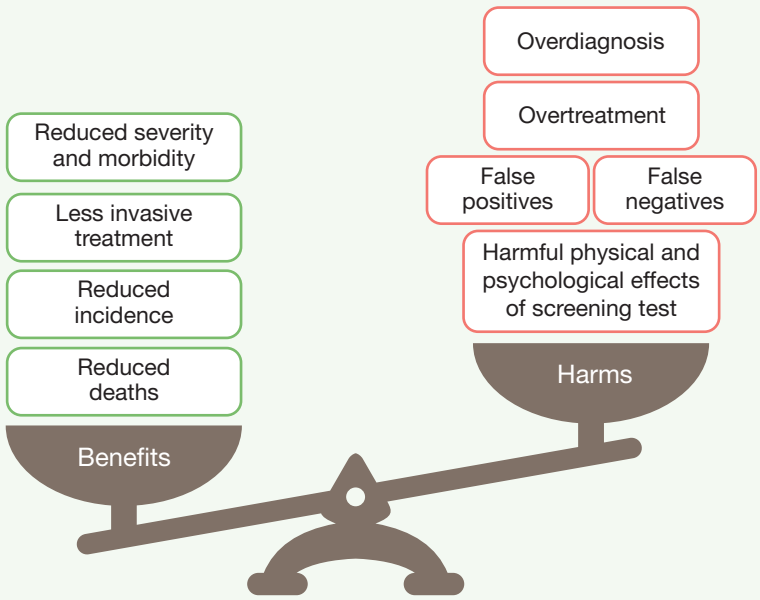
4.1 Population cancer screening is neither simple nor just a single test. On the contrary, it is a complex public health programme incorporating an entire pathway of care that requires significant resources, infrastructure, and coordination underpinned by robust quality assurance.

4.2 The purpose of cancer screening is to detect pre-cancer or early-stage cancer in asymptomatic individuals so that timely confirmatory diagnosis and early treatment can be offered and where this treatment can lead to better outcomes for some people. The aim of a cancer screening programme is either: (a) to reduce mortality and morbidity in a population by early detection and early treatment of a cancer (for example, breast screening and cervical screening) or (b) to reduce the incidence of a cancer by identifying and treating its precursors (such as cervical and colorectal screening).

The modelled impact of screening on the incidence and mortality of breast, colorectal and cervical cancer incidence is presented in Supplement 1. The earliest indications of success in a population screening programme are typically a stage shift in the cancers reported. It is noteworthy that this can be seen to be the case in the recently published NCRI report.[1]

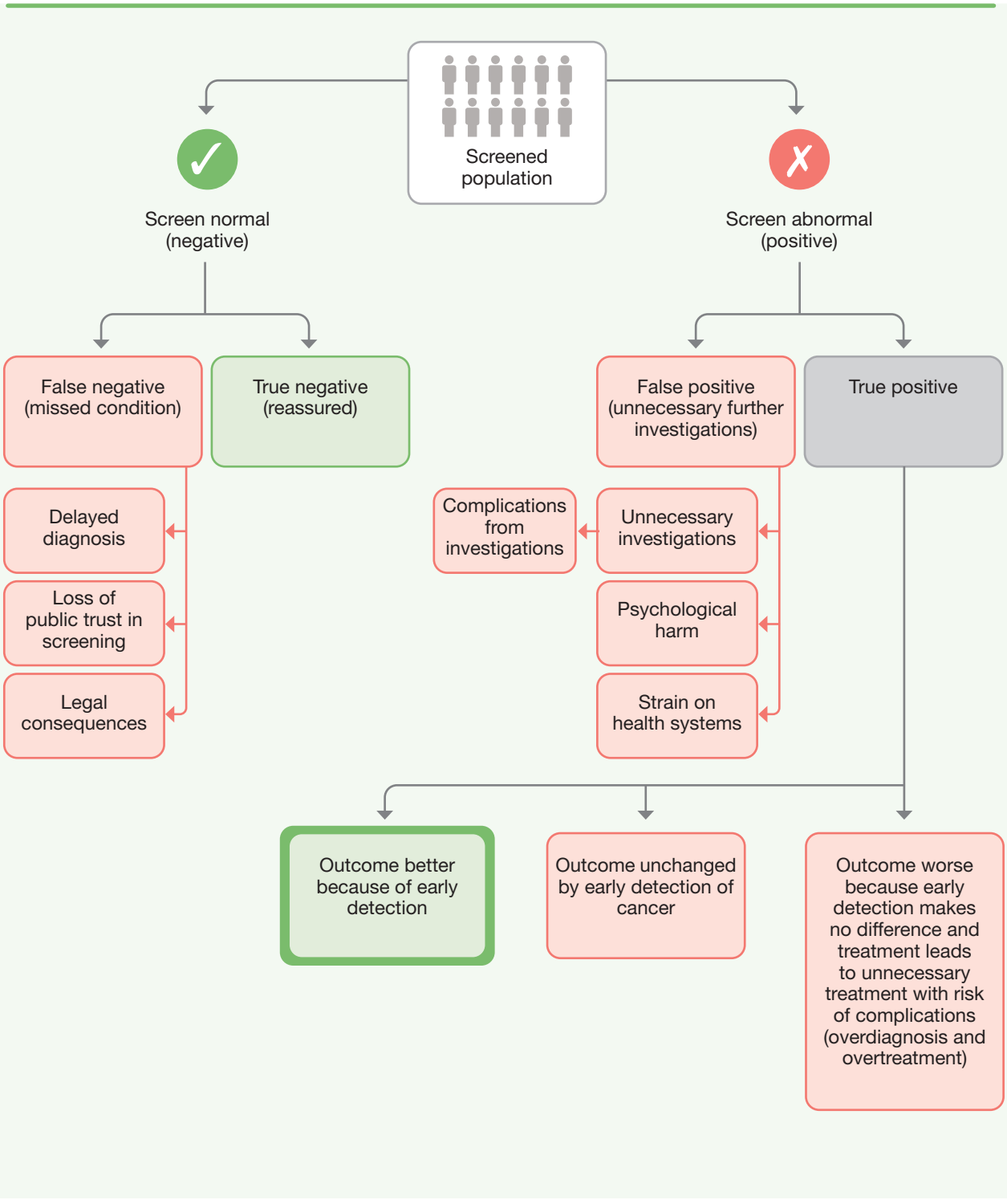
4.3 The benefit of evidence-based screening is to detect cancer at an early or pre-cancerous stage to reduce the incidence or mortality and morbidity associated with the cancer. Other benefits may be the use of less aggressive interventions because treatment can be provided at an earlier stage and may lead to improved quality of life. However, most people who participate in screening are asymptomatic and/or do not have cancer, so many people may be exposed to the harms of screening without benefit. See Figure 1 below[4].

Figure 1. Benefits and harms of population-based screening programmes



4.4 The ideal cancer screening test would - 100% of the time - perfectly separate people who have cancer from those people who do not. In real life, however, screening tests cannot reach this performance level – they can only suggest the likelihood that a person is at risk (or at reduced risk) of cancer. Even with the best technology, the best people, and the best QA Programme and oversight there will always be individuals whose cancer is not detected by the screening test (i.e., given a false-negative result) and other individuals who do not have cancer but are given an abnormal result (i.e., given a false-positive result). This is illustrated in Figure 2 below[4].

Figure 2. The possible consequences for an individual participating in a cancer screening programme



4.5 Population screening programmes must strive for balance between maximising benefits and minimising harms. They are inextricably linked. Figure 2 illustrates the dilemma that faces every cancer screening programme and indeed every individual entering such a programme. A screening programme could in theory reduce the number of false negatives by increasing the sensitivity of the test i.e., by being more conservative and recalling more people for further follow up and investigation. However, it will come at a significant cost to some individuals in the screened population. To find more cases of what are relatively small number of abnormalities in the screened population means that we would have to send increasing numbers of healthy people onwards for further investigations in the full knowledge that we would be subjecting the majority of them to unnecessary investigation, the complications from these investigations, over-treatment, negative psychosocial consequences, and physical complications. Such an approach would not give due regard to the ethical principle of non-maleficence and *primum non-nocere* (first, do no harm).

The Legal Framework Group recommends transparency in the communication of the benefits and harms of population cancer screening programmes incorporating informed consent; continued engagement and improved education with key stakeholders, including the public, media, healthcare professionals, legal community, patient representatives, advocates, and politicians; and information campaigns, training, and education to re-build trust and confidence in population cancer screening in Ireland.

5. Communications – the impact of language and terminology

5.1 The term 'programmatic audit' has become synonymous with the CervicalCheck audit that became the subject of the *Scoping Inquiry into the CervicalCheck Screening Programme (2018)*[6]. The term continued in use throughout the work of the *Expert Reference Groups Interval Cancer Report [1]* and is commonly used in public debate and discourse. It has become clear through the work of the Legal Framework Group that there is neither an international reference nor a definition for the term 'programmatic audit' in the context of cancer screening, or a consistent understanding or application of the term.

5.2 The CervicalCheck audit which was the subject of the Scoping Inquiry into the CervicalCheck Screening Programme (2018)[6] is more accurately described as a *'retrospective audit of invasive cervical cancers'* i.e., only after cases of cervical cancer were diagnosed and treated were they then included in the audit and an examination of the full screening care pathway examined in each case. This type of audit was not without precedent at the time and was similar in its aim to the *NHS Cervical Screening Programme Audit of Invasive Cervical Cancer: National Report 2009-2013*[7].

5.3 There is considerable risk for misinterpretation and/or misunderstanding of ambiguous language, inconsistent definitions, and use of terminology such as 'programmatic audit'. In addition, a clinical audit should not be confused with an incident review, a look-back review, or a healthcare record review, all of which involve separate and specific response processes from health service providers. It is critical that a standardised use of language and terminology is applied across the HSE.

- An **incident review** takes place after an individual patient safety incident has occurred (e.g., administration of the wrong dose of chemotherapy to a cancer patient). It involves *"a structured analysis and is conducted using best practice methods, to determine what happened, how it happened, why it happened, and whether there are learning points for the service, wider organisation, or nationally"*[8].
- A **look-back review** is *"a process that is initiated where it has been determined that a number of people have been exposed to a specific hazard (e.g., recipients of a contaminated blood product). The process seeks to identify if any of those exposed to the hazard have been harmed and what needs to be done to ameliorate the harm. This process consists of three key stages: preliminary risk assessment, audit, and recall"*[8].
- A **healthcare record review** (or chart review or case review) *"is where pre-recorded and person-centred data are used to answer one or more questions. The review is not part of direct patient care. It may be carried out for a number of purposes, including clinical audit, research, or incident review"*[8].
- A **patient-requested review of screening** is a cancer review process for any individual with cancer which incorporate full and open disclosure of all findings of the review[1].

5.4 Population screening programmes have unique components when compared with individual doctor-patient interactions. Population screening is an entire pathway and not just a single test. A screening programme is likely to encompass different clinical departments, organisations, multiple healthcare professionals and even geographical boundaries. As with any other type of medical practice, there is a real risk of harm and there is an ethical responsibility to do as little harm as possible. The population-based nature of screening means that even apparently minor incidents for an individual could (a) have a major impact due to the large number of people screened (b) may involve several organisations and (c) affect public confidence in screening services.

5.5 It is correct to state, that in the same way as an adverse reaction to medication or complications following surgery, there are recognised harms of a screening programme and as such they are not 'unexpected' if the programme is operating within agreed performance and quality standards. For this reason, they are not automatically categorised as 'patient safety incidents.' But equally, this does not mean that they should be dismissed. There needs to be clear and specific guidance on how to define and investigate true patient safety incidents in cancer screening programmes and provide detailed information on the appropriate procedures to apply at each stage of this process including open disclosure in line with current legislation and HSE policies.

The Legal Framework Group recommends the full adoption and use of the *HSE National Centre for Clinical Audit Nomenclature – A Glossary of Terms for Clinical Audit*.[8]

The Legal Framework Group recommends ceasing the use of the term 'programmatic audit' for population screening programmes and that any clinical audit should be given its full descriptive title to ensure clarity of purpose and consistency of understanding.

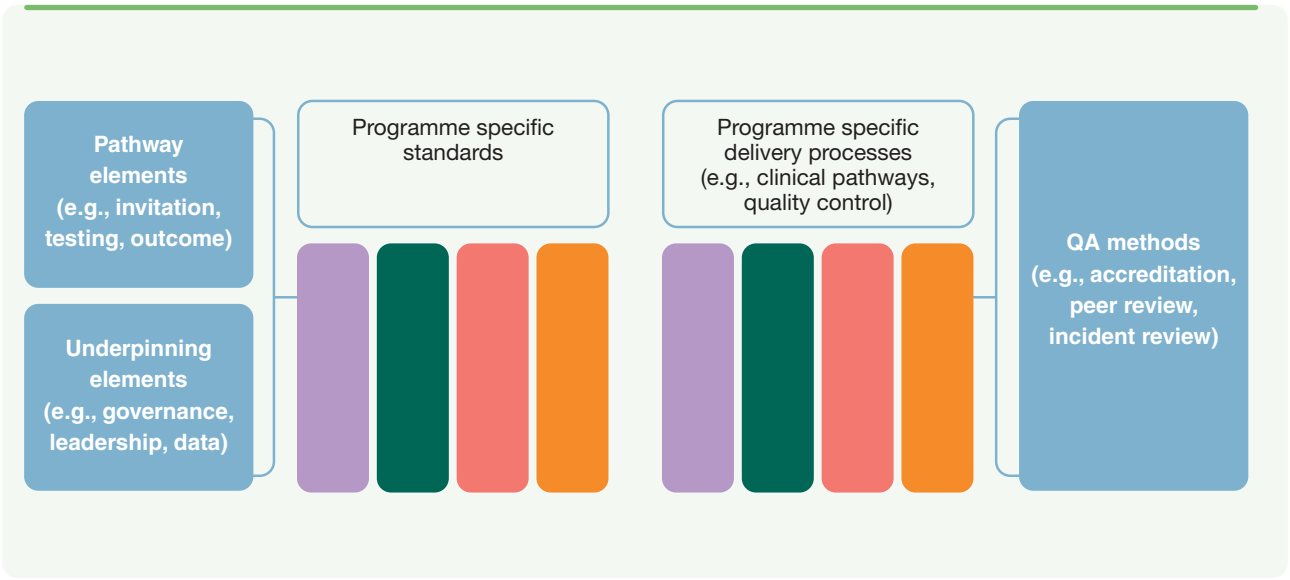
The Legal Framework Group recommends the drafting of NSS operational guidance on the management of true patient safety incidents in population screening programmes to align with the current HSE Incident Management Framework and Guidance (2020)[9] and HSE Open Disclosure Policy.[10]

6. Quality assurance and clinical audit

6.1 Quality assurance in population screening programmes is an ongoing process comprising a multitude of component parts. The NSS Quality Assurance Policy Framework (Q-Pulse NSS/S&F-1) describes the comprehensive suite of quality assurance and quality improvement processes underpinning the four national population screening programmes.

6.2 Figure 3 illustrates how the elements, common to all programmes, can be categorised (i.e., the blue boxes). Descriptions of these components are to be found in a variety of screening programme documents including their Quality Assurance Standards, Quality Assurance Committee's terms of reference, Clinical Advisory Groups, multi-layered performance oversight mechanisms including national and international experts, and formal arrangements with third party providers through service contracts, service level agreements (SLAs) and memoranda of understanding (MOUs). All commissioned partners sign up to these stringent oversight mechanisms.

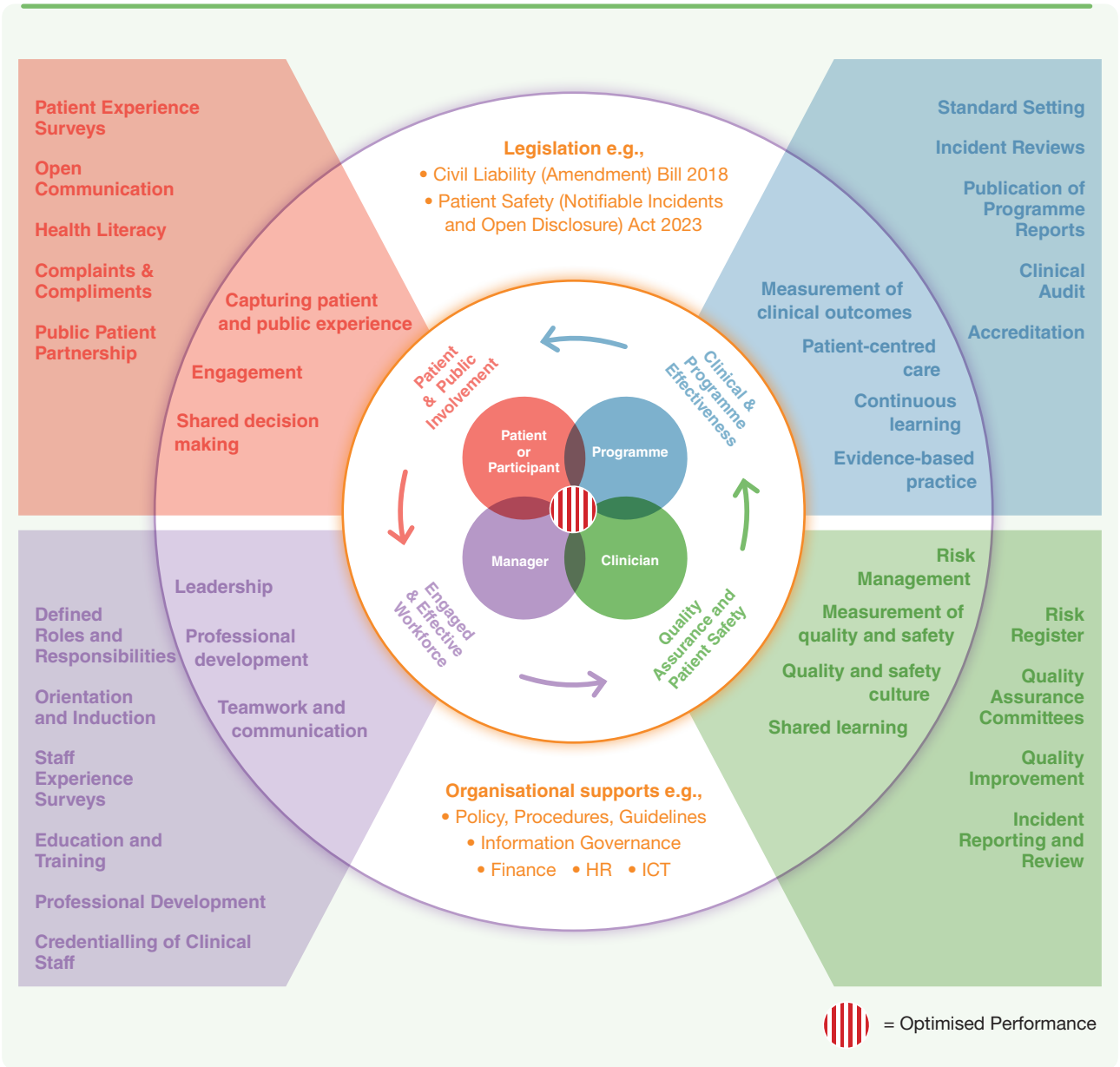
Figure 3. An illustration of common and programme-specific aspects of quality assurance



6.3 Programme specific standards, key performance indicators (KPIs) and delivery processes (i.e., the coloured columns) are unique to each screening programme and dependent on the relevant clinical pathway(s) and are measured (i.e., audited) against defined programme standards. QA covers the entire screening [clinical] pathway which runs from identifying who is eligible for screening, being screened and onward referral (if screen positive) into diagnostic and treatment services. Ultimately selected KPIs and specific quality measures are the basis for facilitating international comparison of outcomes and effectiveness of screening programmes.

6.4 Figure 4 below illustrates this whole of programme clinical governance framework utilised by the National Screening Service.

Figure 4. QA Clinical Governance Framework for Screening



6.5 Clinical audit is a clinically-led quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and acting to improve care when standards are not met. While clinical audit should always remain a component part of a comprehensive clinical governance framework, it is not the single or even the most important determinant of the quality or effectiveness of any clinical service. Rather clinical audit is about a continuing evaluation and improvement process by health professionals, working towards delivery of safe, high-quality care for patients.

"Clinical audit is a clinically-led quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and acting to improve care when standards are not met. The process involves the selection of aspects of the structure, processes and outcomes of care which are then systematically evaluated against explicit criteria. If required, improvements should be implemented at an individual, team, or organisation level and then the care re-evaluated to confirm improvement"[5]

6.6 The Legal Framework Group endorses this definition of clinical audit for use in the NSS. Clinical audit has always been and will continue to be a regular component of each of the programmes. The data is typically collected, analysed, and reported in aggregate format and used solely for the purposes of improving patients' safety and quality of services.

6.7 The Legal Framework Group has concerns that the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 provides a very limited degree of protection for clinical audits. To avail of those protections, the clinical audit in question must come within the precise definition and comply with the conditions set out in Sections 57, 58 and 59 of the Act and constitute the pre-requisites for obtaining protection under Section 60 (i.e., not subject to FOI) and Section 61 (i.e., not admissible in civil proceedings). This could prove to be overly complex, difficult, and burdensome to implement.

6.8 Given the current adversarial nature of medico-legal claims in Ireland there is also a risk that in a clinical negligence case, that the defence will be required to prove that they have met every condition/criterion attached to the definition of 'clinical audit' which may result in clinical staff (and patients) becoming embroiled in stressful, lengthy, and time-consuming arguments about the status of the audit in question. The failure to 'prove' any one of the highly prescriptive conditions contained in Sections 57, 58 and 59 would possibly deprive the audit of the protections set out in the Act. There is a risk that this could ultimately lead to a reduction in the number of clinical audits being conducted to the detriment of quality of care, patient safety and improving outcomes for patients across a multitude of healthcare settings and not just screening.

6.9 The Legal Framework Group has carefully considered the additional value of re-commencing retrospective audits of invasive cervical cancer. The following are the key points that informed the discussion.

6.9.1 The absence of an international consistent approach to audit of interval cervical cancers or to disclosure of audit results[16].

6.9.2 The final report on the Implementation of Recommendations of the Scoping Inquiry into the CervicalCheck Screening Programme[18] reported that there is now an *excellent system of Quality Assurance (QA) for laboratory service provision in place, with a robust operating procedure developed by a QA steering committee with international and national expertise.*

6.9.3 The final report[18] also concluded that there is good evidence of robust implementation of the operating procedures with meaningful QA visits and regular surveillance data being monitored for both laboratories, together with robust follow-up of any non-compliance.

6.9.4 The report of the Expert Panel Review of Cervical Screening (RCOG)[15] stated that there was clear evidence from falling death rates that the CervicalCheck programme is working effectively and that the programme was also functioning well from an operational point of view in terms of population coverage, laboratory turnaround times and the predictive value of abnormal smears. Their conclusion was that women could have confidence in CervicalCheck and that regular participation in screening remains the most effective means of protecting women from cervical cancer.

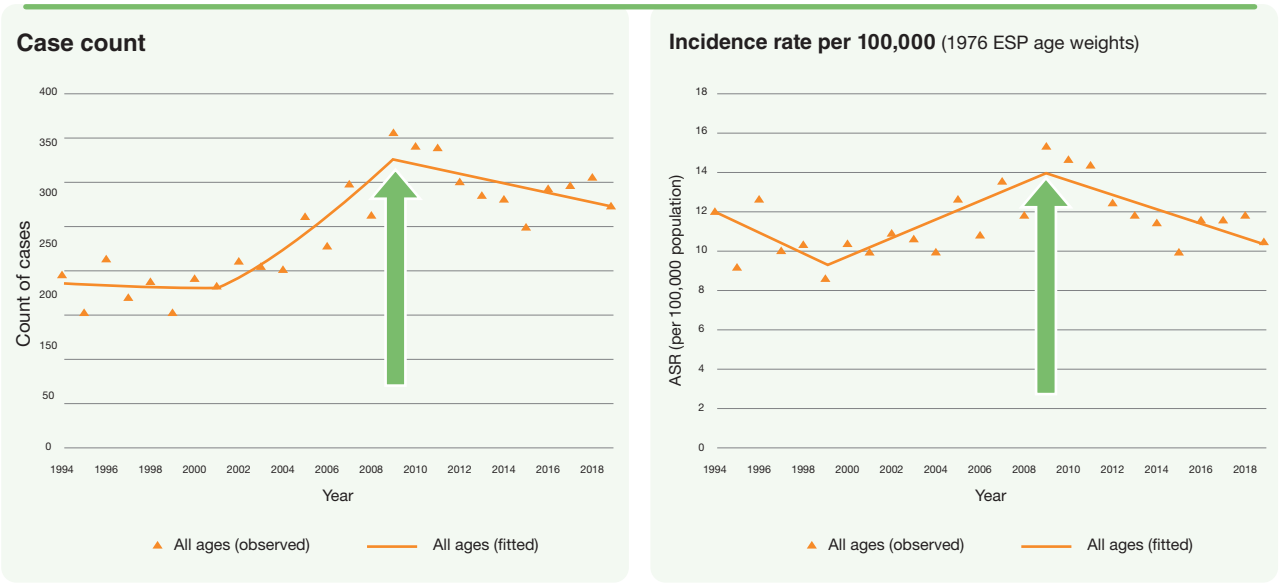
6.9.5 The development and implementation of a Patient-Requested Review Process that will document protocols and timelines on how the NSS will engage with the patient, how the review will be conducted and how and when the results will be presented back to the patient.

6.9.6 It is the view of the Legal Framework Group that the degree of protection for clinical audits offered by Patient Safety (Notifiable Incidents and Open Disclosure) Act is limited. To avail of those protections, the clinical audit must come within the definition and comply with the conditions set out in Sections 57, 58 and 59 of the Act and constitute the pre-requisites for obtaining protection under Section 60 and Section 61 and could be overly complex, difficult, and burdensome to implement.

6.9.7 In the context of interval cancers, the most appropriate quality measure should be on a population basis and allow for international comparison. That measure is the interval cancer rate for BreastCheck and CervicalCheck and the post-colonoscopy colorectal cancer rate in BowelScreen.

6.9.8 The NCRI[2] has reported that breast, bowel, and cervical cancers all show favourable trends in incidence, stage, survival and/or mortality consistent with improvements in early detection and outcomes, with clear evidence for additional or more recent benefits of screening. From a public health perspective population cancer screening programmes are working and achieving their objectives. The impact on the incidence of cervical cancer in Ireland in 2008 is particularly noteworthy since the introduction of a population-based screening. See Figure 5 below.

Figure 5. Incidence trend in cervical cancer during 1994-2019



6.10 Taking account of 6.9.1-6.9.8 the Legal Framework Group does not see the immediate re-commencement of retrospective audits of invasive cervical cancer as adding additional value to (a) the introduction of a patient-requested review process (b) the publication of an interval cancer rate and (c) evidence of an excellent system of Quality Assurance systems and processes and (d) the clear evidence of the impact of the programme on women's health in Ireland since 2008.

6.11 Any future retrospective audits of invasive cancer should only be conducted and published in an aggregate and anonymised format periodically. Until there is a fully integrated (as in Belgium) system of screened and cancer detected individuals or a technical option (not currently available) to aggregate and anonymise data reliably this cannot be done. It is important that any future audits of invasive cancer (breast, bowel, or cervical cancer screening) should be carefully planned, with a robust methodology, have ethical approval and strong academic/research oversight.

6.12 The NSS is conscious of its information governance responsibilities with regard to QA Clinical Governance structures and processes and the conduct of clinical audit. In summary, the NSS has two primary responsibilities towards the screening participant. Firstly, to respect and safeguard their constitutional rights to bodily autonomy, and secondly to respect and safeguard their privacy rights in relation to the processing of their personal data. The Legal Framework Group in its deliberations discussed information governance including data retention and concluded that the retention of data, a unique health identifier and the processing of personal data confers many benefits for participants and the health service, including the facilitation of clinical audit and quality assurance.

The Legal Framework Group recommends that in the context of interval cancers in population cancer screening programmes, the most appropriate and internationally recognised measure of quality is the interval cancer rate in BreastCheck and CervicalCheck and the post-colonoscopy colorectal cancer rate in BowelScreen.

The Legal Framework Group recommends that personal data obtained during the operation of cancer screening programmes should be retained and managed in line with the HSE policy on retention periods for personal data.

7. Patient-requested reviews and hindsight bias

7.1 A patient-requested review [of an interval cancer] is obviously retrospective in nature i.e., it looks back after the diagnosis. Any type of retrospective review will be associated with what is termed hindsight bias. Hindsight bias is known to play a significant role in the evaluation of an antecedent event and has long been demonstrated in both medical and judicial settings[11]. The recognition of a poor outcome can bias the ability to pass judgment on a less apprised perspective, heightening the perception of preventability[12]. This might lead to an unjustified evaluation, based disproportionately on a poor outcome, and not because care was poor[13]. Interval cancers, cancers that are diagnosed in between routine screening episodes, are an inevitable part of any population screening programme.

7.2 Cervical cancer screening deserves specific mention here. It is internationally acknowledged that screening programmes provide protection from cervical cancer at around 70%. The level of protection depends partly on the regularity of screening and age, with younger women deriving slightly less protection than older women. This means that around 30% of cancers are not detected by screening[3].

7.3 *The NHSCSP Audit of Invasive Cervical Cancer: National Report 2009-2013* [7] reviewed cancers detected in England between 2009-13. Of note was the finding that the original slide result and the review slide result disagreed (i.e., was discordant) in 40% of cases. This is hindsight bias in action. Public Health England (PHE) published its most recent audit in October 2019, reporting on the 2013-2016 period and demonstrated, in an unblinded audit of cytology, that the previously negative findings in patients aged 25-49 who had interval cancers were upgraded in 42% of cases[14]. This in effect set the auditable standard for retrospective cytology reviews. An *Independent Review of Cervical screening in Cases of Cervical Cancer in Ireland between 2008 – 2018* revealed a discordance of 30% between original and reviewed slides[15].

7.4 A recently conducted survey of 22 international population-based cervical screening programmes identified varying methodologies for conducting a retrospective cytology review. Most countries/regions do not even discuss interval cancer audit with participants and only 3 of 11 programmes (27%) actually inform women when a cervical cancer audit takes place. Disclosure is limited and variable. In summary there is currently no consistent approach to audit of interval cervical cancers or to disclosure of audit results[16].

7.5 The Legal Framework Group endorses the recommendation of the Expert Reference Groups that those patients who develop cancer should have access to a patient-requested review of their screening data should they so wish and determine whether a patient has suffered avoidable harm.

- **7.5.1** However, the operational requirements for a patient-requested review should not be underestimated and will require significant planning and investment of time and resources.
- **7.5.2** In Ireland, the universal application of patient-requested reviews in cancer screening, arising from legislation is novel, untested and has not

been evaluated in terms of patient expectations, process outcomes and the potential benefits and harms for all those participating.

7.5.3 What is also unknown and of relevance to the current medico-legal environment in Ireland is the unknown impact of the outcome of such patient-requested reviews on a patient's decision or the decision of their legal representatives to proceed to litigation.

7.5.4 It is entirely predictable that between 30-40% of slide reviews [from cervical screening] will reveal discordant results. Invasive [cervical cancer] audit categorisation is subject to bias, with the potential for considerable intra- and inter-observer variation calling into question both the consistency and reproducibility of review findings[17]. Most of these discordant results will be categorised as *'satisfactory within the known limitations of screening'* and a small percentage (approx. 5% of all reviews) will be categorised as *'unsatisfactory'.*

7.6 The Legal Framework Group has concluded that any planned patient-requested review process should:

(a) Be resourced appropriately with dedicated and appropriately trained staff

(b) Be conducted on the principle that the patient fully understands how the review will be performed and how the results of the review will be presented back to the individual patient.

(c) Be agreed by all stakeholders prior to commencement

(d) In the case of a review of cytology slides make clear that it may find a discordant result in up to 40% of cases

(e) Incorporate the disclosure of the results of the review to the patient as an integral component of the process

(f) Make clear that a patient-requested review process will not be able to attribute negligence on someone's part

(g) Make clear that if the patient requires an assessment of whether there was negligence that, in the current Irish legal environment, this can only involve findings of fact by a judge based on evidence submitted to court.

(h) Make clear that the discovery of any identified patient safety incident will be managed in line in the HSE Incident Management Framework (2020)[9] & HSE Open disclosure Policy[10].

The Legal Framework Group endorses the ERG recommendation that in the event of a cancer diagnosis, a patient-requested review should be an option available for all participants in cancer screening programmes.

The Legal Framework Group recommends that an independent evaluation of the structures, process and outcomes of patient-requested reviews should be commissioned after the first full year of operation by the National Screening Service.

The Legal Framework Group recommends that future retrospective audits [of invasive cancer] should only be undertaken on an anonymised basis and published in aggregate format. Audits should be carefully designed by an overarching NSS multidisciplinary steering committee (or equivalent) that includes a patient/public representative and an international research representative.

8. Legal Instruments – Patient Safety (Notifiable Incidents and Open Disclosure) Act, 2023

8.1 The Legal Framework Group discussed at length the evolution of Patient Safety (Notifiable Incidents and Open Disclosure) Bill 2019 (Bill 100 of 2019), as it progressed through the Oireachtas.

8.2 The Legal Framework Group in its interim report (2022) questioned whether it was necessary to refer specifically to screening in legislation. The concern was that this presented the very real risk that any legislative reference to screening in a Bill entitled 'Patient Safety (Notifiable Incidents and Open Disclosure)' will be interpreted by the public as meaning that something went wrong that should not have gone wrong and that the screening programme was at fault, and in so doing set unrealistic expectations of performance that run contrary to international standards.

8.3 The Bill was signed into law by the President on 2 May 2023 and awaits a commencement date. Referred to as a 'Part 5 review' in the Patient Safety (Notifiable Incidents and Open Disclosure) Act, a patient-requested review carried out by CervicalCheck, BreastCheck and Bowel Screen, will be subject to mandatory open disclosure ensuring patients have access to comprehensive and timely information.

8.4 There is a risk of misinterpretation by the requirement for "Open Disclosure" for all patient-requested review results irrespective of their outcome, when the term "Open Disclosure" has, up until now, been reserved for patient safety incidents, a term which will not be applicable to the vast majority of patient-requested reviews. As was the intention of the Expert Reference Groups Reports[1] the Legal Framework Group has always understood that full disclosure of the results of patient-requested reviews was a given and an inherent component of the NSS patient-requested review process irrespective of any legislative requirement.

8.5 It must be acknowledged that the universal application of patient-requested reviews in cancer screening programmes, arising from legislation is novel, untested and has not been evaluated in terms of patient expectations, process outcomes and the potential benefits and harms for all those participating. There is a very real risk of unknown and unintended consequences arising from their incorporation into legislation prior to an evaluation and/or peer review.

8.6 The Legal Framework Group is clear that any identified patient safety incident during the operation of population cancer screening in Ireland is defined as per the Civil Liability (Amendment) Act 2017 and investigated in the same manner as any other suspected patient safety incident occurring in the provision of any health service to a patient in Ireland and as described in the HSE Incident Management Framework (2020)[9].

8.7 The Legal Framework Group agrees that open disclosure is a core professional requirement which is anchored in professional ethics. Communicating effectively with persons affected in a compassionate, empathic, and thoughtful manner, especially when providing information about a patient safety incident, is a crucial part of the therapeutic relationship and, if done well, can mitigate anxiety and enhance the patient's and the relevant person's trust in the staff, the organisation, and the health care system. It is important to communicate compassionately in relation to all adverse events that affect a patient even if they are not designated a patient safety incident, as this is a critical part of the healing process.

1. A patient safety incident, in relation to the provision of a health service to a patient by a health services provider, means "an incident which occurs during the course of the provision of a health service" which: (a) has caused an unintended or unanticipated injury, or harm, to the patient (b) did not result in actual injury or harm to the patient but was one which the health services provider has reasonable grounds to believe placed the patient at risk of unintended or unanticipated injury or harm or (c) unanticipated or unintended injury or harm to the patient was prevented, either by "timely intervention or by chance", but the incident was one which the health services provider has reasonable grounds for believing could have resulted in injury or harm, if not prevented.

9. Legal Instruments – relevant legislation

9.1 The Irish legal system is grounded in Bunreacht na hÉireann (the Constitution of Ireland). All legislation and all actions of the State must accord with the Constitution. The Constitution guarantees a range of individual rights relevant to the issue of legal liability/ compensation in respect of interval cancers. Of relevance to this report are the right to access the court (Art. 34 and Art. 37) and the personal rights to equality Act. 40.1) and to bodily integrity/autonomy (Art. 40.3.1). This means that an action in negligence is not just a private matter but also involves a constitutional element.

9.2 However, the scope of constitutional requirements regarding negligence claims has not been determined by the courts. Authoritative sources have indicated constitutional concerns with some ways in which clinical negligence might be addressed. The introduction of a no-fault compensation scheme for example in respect of clinical negligence could be unconstitutional if it tries to restrict a person's right to bring a legal action. The Law Reform Commission has also raised questions about the constitutionality of the legislative imposition of caps on damages in at least some circumstance (2019)[19].

9.3 In February 2010 the then President of the High Court established a *'Working Group on Medical Negligence and Periodic Payments'.* In March 2012, under the chairmanship of Ms. Justice Mary Irvine, a report on pre-action protocols and draft rules was published[20]. In April 2013, also under the chairmanship of Ms. Justice Irvine, a further report dealing with case management of medical negligence claims and draft rules was published[21].

9.4 In June 2018, as part of a commitment in the Programme for Government, the Minister for Health and the Minister for Justice and Equality, in association with the Minister for Finance, established an Expert Group (under chairmanship of Mr Justice Charles Meenan) to consider an alternative mechanism to the court processes for resolving clinical negligence claims and other matters, including the impact of current tort legislation on patient safety[22]. The Legal Framework Group noted in the *'Meenan Report'* that;

"The Expert Group has considered, in detail, a number of alternative systems. Any alternative system has to operate in an area defined by the provisions, both express and implied, of the 1937 Constitution. A clinical negligence claim involves not only laws of negligence and breach of duty but also, more fundamentally, the Constitutional rights of the parties involved. The 1937 Constitution expressly limits the jurisdiction of bodies other than the Courts to determine the types of issues that arise in such claims. The scope for non-court bodies to resolve clinical negligence claims is very limited. Any reforms to our current legal system, which are undoubtedly required, must have regard to the Constitutional rights of both claimants and defendants" (Executive Summary; para 2: page 5)

9.5 In the non-litigation sense, Meenan[22] is clear that the scope for non-court bodies to resolve clinical negligence claims is very limited.

9.6 The Legal Framework Group noted that the Meenan Report found, the procedural framework to address clinical negligence claims in Ireland is poorly developed[22].

'The fact that our current system fails to have practices and procedures, that are necessary and suitable for the taking and hearing of clinical negligence claims, has been recognised for many years.'

'Unfortunately, despite recent progress, the fact that some seven to eight years after the delivery of these reports[21,22], they still remain to be implemented is disappointing to say the least.'

9.7 While the Government has gone some way already to introduce mandatory pre-action protocols in clinical negligence cases, the recommendations from the Meenan Report are to be welcomed. The Oireachtas has enacted s. 219 of the Legal Services (Regulation) Act, 2015 which has inserted a new Part 2A into the Civil Liability and Courts Act, 2004 to give the Minister for Justice the power, inter alia, to make regulations for a mandatory pre-action protocol in clinical negligence claims to be complied with by all parties to such claims. However notwithstanding that this legislation was passed into law at the end of December 2015, disappointingly Part 2A (as inserted) has not yet been commenced by Government.

9.8 With the commencement of Part 2A, it can reasonably be expected that lengthy, complex and costly clinical negligence cases would be determined more expeditiously with consequential benefits to both plaintiff and defendants. This surely is a desirable objective for the Government given that in most of such cases it is the State which bears the ultimate liability not only for the damages awarded, but the litigation costs of all parties. It can equally be anticipated that such reforms would see a greater number of clinical negligence cases being settled at an early stage, thereby:

- reducing the anxiety and stress of lengthy legal engagement for patients
- saving the State the burden of bearing an unnecessary level of legal costs
- alleviating the pressure on the courts where there is already significant delay in getting dates for the hearing of such cases which typically require several weeks to be set aside for a single case.

9.9 It is worth noting that such reforms in clinical negligence cases have been in place in the courts of England and Wales since the so-called Woolf Reforms in 1999, and in Northern Ireland since February 2013. The Annual Reports of NHS Resolutions (equivalent of the State Claims Agency in Ireland) consistently report a significant reduction in legal costs pay out, even in the face of an increase in the number of clinical negligence claims being brought. They report also that most of the claims are settled either before action or pre-trial. This is made possible in part at least by the principles of early and open disclosure and transparency mandated by the pre-action protocols which have been in place for over 20 years in England and Wales.

9.10 In his Administration of Civil Justice Review Report in October 2020, Mr Justice Peter Kelly, former President of the High Court, recommended the early introduction of regulations in respect of pre-action protocols in clinical negligence cases[23]. This 2020 Report also recommended the introduction of case management rules which would see clinical negligence cases proceeding along a separate track from ordinary personal injury cases, and where case progression would be directed and overseen pre-trial by Masters and Deputy Masters of the High Court, thus ensuring that once proceedings were commenced, they proceeded to a determination without the sort of lengthy delays that regularly occur under the present regime. This new efficiency would lead to more timely resolution of such claims at far lower cost.

9.11 The Legal Framework Group has noted that only one case in CervicalCheck and one case in BreastCheck has come before a judge for their determination of negligence. Nearly all cases are invariably settled without admission of liability on the part of the plaintiff. The Legal Framework Group has noted the contents of a recent judgment in May 2020 delivered by then Chief Justice Frank Clarke[24]

"… even screening processes which operate at the very highest standards can give rise to different results by competent screeners. In addition, a retrospective review of the screening process after someone has been diagnosed may well give different results, possibly influenced by the difficulties encountered with hindsight. It is thus possible that a competent screener exercising ordinary care might give a clear result, even in circumstances where it might transpire with the benefit of hindsight that there could have been suspicious material on the slide. For these and doubtless other reasons, it is not simply a case of inferring from the fact that someone obtained a clear result but subsequently was diagnosed with the relevant disease that there was necessarily negligence on someone's part. It follows that the assessment of whether there was negligence in any particular case will involve findings of fact by the trial judge based on evidence. That process may well be both difficult and complex and each case will, necessarily, depend to a significant extent on its own facts." (Page 6)

9.12 The occurrence of an interval cancer in a previously screened individual is a fully anticipated event and a statistical certainty and, as such, cannot be automatically attributable to the negligence or failure on the part of the relevant screening programme. Despite this, Ireland has seen a growth both in the extent of litigation bought by participants in cancer screening programmes and in the level of compensation awarded to affected individuals. As described in Supplement 3, Irish personal injuries compensation levels are high when compared with most other jurisdictions and it is acknowledged that Ireland is now an outlier in this regard when compared to other programmes internationally.

9.13 In addition, and unique to Ireland, litigation is growing in relation to screen detected cervical cancer cases based on a belief that the cancer detected should have been detected at an earlier stage. This is a fundamental contradiction to the very purpose of a cervical cancer screening programme and what it can achieve. There is now a need to have a discussion with Irish society to decide whether we are willing to accept the limits of performance of cancer screening programmes or not. Under the current medico-legal environment, there is a risk that new cancer screening programmes in Ireland will be considered too high risk for clinicians and too costly for the state irrespective of any independent evidence-based recommendation to do so.

9.14 In *Dunne v National Maternity Hospital*[25], the Supreme Court set out a series of prerequisites for the establishment of clinical negligence that have become known as the six "Dunne principles". In essence, these state that a medical practitioner cannot be considered negligent unless they take a course of action that no reasonable practitioner of equal status would have taken in those circumstances. The Supreme Court[24] has confirmed that the "Dunne principles" remain the basis for identifying the legal standard of care by reference to which a claim in clinical negligence in respect of screening is to be assessed. It has also affirmed that this requires a court to determine [based on expert evidence] what standard of approach a reasonable screener must apply.

9.15 In order to ensure that the Dunne principles in claims arising from CervicalCheck are strictly adhered to, the Legal Framework Group's position, having taken advice (See Supplement 4) can be summarised as follows:

9.15.1 Recommend that the expert(s) engaged by a plaintiff to review an allegedly mis-read slide for the purpose of establishing that the course the defendant's screening technician took was "one which no medical practitioner of like specialisation and skill would have followed had he been taking the ordinary care required from a person of his qualifications" (see Dunne principle 2) must be another screening technician, and not an expert in a different area of specialisation such as a consultant cytopathologist who may never have worked as a screening technician.

9.15.2 Recommend that any review of the allegedly mis-read slide carried out on the part of a plaintiff is conducted as far as practicable under the same laboratory conditions as it was originally reviewed by the defendant's technician – i.e., being one of perhaps 30 slides being read by a typical screening technician during the course of his/her day's normal work, rather than a review of a single slide in isolation.

9.15.3 Recommend the need to avoid 'hindsight bias', and hear evidence from an expert in the effects of 'hindsight bias'.

9.15.4 Recommend that where a plaintiff's expert is other than a screening technician, and who examines the suspicious slide under different working conditions, make appropriate submissions to the Court that lesser weight should be attached to that evidence than the evidence of any blind review that is conducted by the defendant.

9.15.5 Recommend that any third-party review be "blind" – in other words the slide should be unmarked, and anonymised – again, to reduce and ideally avoid any risk of 'hindsight bias'

9.16 It is impossible to ignore that in addition to reducing public trust in the screening programme, legal claims arising from false negative results can be very costly for the screening programme in question [26]. There are significant ethical ramifications insofar as high legal costs may undermine the cost-effectiveness of screening, lead to professional demoralisation and lack of retention, divert resources from other areas of healthcare and, ultimately, threaten the continued survival of population screening programmes. There are significant opportunity costs arising from legal claims involving national screening programmes in Ireland that cannot be ignored. It is a well-established and required criterium that not only should population screening programmes be ethically sound, but that the resources they command "would not be better spent elsewhere in the health and healthcare sector"[27].

9.17 The National Screening Advisory Committee (NSAC), established in 2019, is an independent advisory committee and advises the Minister and Department of Health on all new proposals for population-based screening programmes and revisions to existing programmes. The NSAC has published criteria for appraising the viability, effectiveness, and appropriateness of a screening programme[28].

9.18 In this context, the Legal Framework Group has noted criterion no. 14 within the National Screening Advisory Committee (NSAC) published criteria for appraising the viability, effectiveness, and appropriateness of a screening programme publication, namely *"The opportunity cost of the screening programme (including testing, diagnosis and treatment, administration, training, and quality assurance) should be economically balanced in relation to expenditure on medical care as a whole (value for money). Assessment against these criteria should have regard to evidence from cost benefit and/or cost effectiveness analyses and have regard to the effective use of available resources."*

9.19 Economic evaluations, including cost benefit and cost-effectiveness analyses, are some of the tools which can enable decision-makers to identify the most efficient way of deploying healthcare resources, Determining whether cancer screening as a public health intervention is "reasonably efficient, of questionable efficiency, or inefficient" is now further complicated by the need to incorporate legal costs into the analysis in jurisdictions such as Ireland in which litigation is increasingly common[29].

9.20 Regardless of whether a legal claim is settled through mediation, the process involved in following a legal route is adversarial, lengthy, expensive and traumatic for plaintiffs and defendants. It is also known to have long term negative consequences for all parties[30]. Previous attempts to examine alternative non-adversarial dispute resolution process for interval cancers has not been successful. However, an alternative system offers the opportunity for those harmed by the system for screening to claim compensation without the need to pursue litigation through the Court. It is important that this does not preclude the right to justice, but it may provide for a more appropriate system for screening as a public health measure

9.21 The Citizens' Assembly is an exercise in deliberative democracy, giving voice to people living in Ireland and placing them at the heart of important legal and policy issues facing Irish society. Over the last decade, citizens' assemblies have become an important part of the Irish democratic process, playing a meaningful role in informing wider public debate on important issues. The contradiction in screening can be stark. Screening programmes bring significant benefits to the public but will cause harm to a small number. Constantly monitoring sensitivity and specificity to achieve the right balance and to minimise these harms is the best that any screening programmes can do i.e., harm is not wholly avoidable. Therefore, whilst most patients will benefit from screening, some will be harmed or at least will not benefit from a screening programme at all (See Figure 2). However, the current cost of these harms – in recruitment and retention of staff, in traumatic and expensive legal cases and the cost of the programmes to mitigate the harms - may outweigh the benefits of screening programmes for the majority, both now and in the future. Screening programmes are deliberate public health interventions for the otherwise well population. Decisions are needed on the future viability of population screening programmes. A Citizens' Assembly or an independent commissioned citizens' jury which allows the consideration of a range of views, examination of reports and studies, consideration of experiences in other countries, hearing from experts in their fields, as well as hearing the lived experiences of ordinary people affected by the subject matter would give the opportunity to make an informed assessment of all perspectives on the topic. The discussions amongst the members of the assembly or jury could result in recommendations for the Government and the Oireachtas to consider.

The Legal Framework Group urges the Government to commence new Part 2A of the Civil Liability and Courts Act, 2004 immediately. This will enable pre-action protocols to be introduced in relation to clinical negligence claims, and will enable case management rules to be introduced, so that such claims can be progressed more expeditiously and at far less cost to the parties involved in a dispute.[2]

The Legal Framework Group has noted the long-established position that the "Dunne principles" are the appropriate legal test for medical negligence in Ireland. In order to ensure that the Dunne principles in claims arising from CervicalCheck are strictly adhered to, the Legal Framework Group's position, having taken advice is as follows:

- Recommend that the expert(s) engaged by a plaintiff to review a slide for the purpose of establishing that the course the defendant's screening technician took was "one which no medical practitioner of like specialisation and skill would have followed had he been taking the ordinary care required from a person of his qualifications" (see Dunne principle 2) must be another screening technician, and not an expert in a different area of specialisation such as a consultant cytopathologist who may never have worked as a screening technician.
- Recommend that any review of the slide carried out on the part of a plaintiff is conducted as far as practicable under the same conditions as it was originally reviewed by the defendant's technician – i.e., being one of perhaps 30 slides being read by a typical screening technician during the course of his/her day's normal work, rather than a review of a single slide in isolation.
- Recommend the need to avoid 'hindsight bias', and lead evidence from an expert on the effects of 'hindsight bias'.
- Recommend that where a plaintiff's expert is someone other than a screening technician, and who examines the suspicious slide under different working conditions, make appropriate submissions to the Court that lesser weight should be attached to that evidence than that attached to the evidence of any blind review that is undertaken.
- Recommend that any third-party review be "blind" – in other words the slide should be unmarked, and anonymised – again, to reduce and ideally avoid any risk of 'hindsight bias'.

The Legal Framework Group recommends that a further examination, with appropriate expert advice, of the feasibility of a non-adversarial alternative dispute resolution process for interval cancers diagnosed as part of participation in population cancer screening programmes.

The Legal Framework Group recommends that an assessment, with appropriate expert advice, of the most appropriate economic evaluation of population cancer screening programmes in Ireland should be completed in 2023 with a view to completing an economic evaluation in 2024.

The Legal Framework Group recommends the involvement of a Citizens' Assembly (or a viable independently commissioned alternative, such as a citizens' jury) to engage debate within society on all aspects of cancer screening.

2. The Legal Framework Group has noted (a) the establishment of an Interdepartmental Working Group that will examine the rising cost of health-related claims and consider mechanisms to reduce costs and (2) the Interdepartmental Working Group's recently announced (6 June 2023) Public Consultation on Health Claim Costs. Available at Department of Health - Consultation on Health Claim Costs (accessed 7 June 2023).

10. Addendum – International Agency for Research on Cancer Report 2023

Recommendations on best practices in cervical screening programmes: audit of cancers, legal and ethical frameworks, communication, and workforce competencie [31]

A collaborative initiative between The International Agency for Research on Cancer Lyon, France and The Department of Health and the Health Service Executive of Ireland, Dublin, Ireland

Executive Summary

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Well-organized cervical screening programmes have been shown to reduce the incidence of and mortality from cervical cancer at the population level. This document describes current best practices in the following aspects of a cervical screening programme:

- conducting an audit of cervical cancers;
- establishing legal and ethical frameworks to safeguard the interests of screening participants, health professionals, and programme managers associated with cervical screening;
- developing a strategy for effective and transparent communication with target populations and other stakeholders about the benefits, risks, and limitations of cervical screening; and
- establishing a framework for developing workforce competencies in communication.

This document is based on a review of the scientific literature and on the opinions of technical experts who were convened through three Technical Working Groups. A summary of the current best practices as noted by the members of the Technical Working Groups is given below.

Audit of cervical cancers in a screening programme

- The purpose of programmatic audit of cancers in a cervical screening programme is to discover discrepancies between actual practice and recommended standards in order to identify any changes needed in the process or the system to improve the quality of care. Audit findings are expected to direct further investigations of screening practice that target improvement rather than blaming an individual professional or an organizational entity for perceived lapses.
- There is variation between countries with regard to the need for, the implementation of, and the communication of audit of cervical cancers. No legal or ethical consensus prevails internationally.
- It is not possible to achieve zero-error screening in standard practice, no matter how high the quality of cancer screening is.
- Audit planning and the engagement of stakeholders are key to the success of the entire audit process.
- An individual case review should be distinguished from a programmatic audit and should be planned and implemented differently, because the two processes have different objectives.
- The public good and the responsibility to provide a high-quality screening programme outweigh the possible risks to an individual from participating in the audit. Thus, not obtaining individual informed consent at the time of a programmatic audit is justified.

However, this means that the women who undergo screening must be informed at the time of the screening of the possibility of an audit.

- The European guidelines recommend that all cervical cancers should be investigated, whether detected in screened women or in unscreened women.
- An interval cervical cancer is defined as any cancer (including microinvasive cancer [stage IA]) diagnosed in a woman between her most recent screening episode and her next screening round, at an interval stipulated by the programme, who had either (i) no abnormal screening test result or (ii) an abnormal screening test result but a negative triage test result or a negative diagnostic test result. It is important to distinguish between these two different types of interval cancers.

Legal and ethical frameworks associated with cervical screening programmes

- A screening-eligible woman who is invited to participate in cervical cancer screening should be informed about the nature and purpose of cervical screening and of the tests, the possible results, and the benefits, risks, and limitations. The woman's right to decline to undergo a test and the possible consequences of opting out should also be explained.
- Operators of cervical cancer screening programmes have an ethical obligation to carry out programmatic audits that seek to improve patient care and outcomes through systematic review of care against explicit criteria and to take action to improve care when standards are not met.
- Confidentiality and the protection of privacy are essential in cervical screening. Information about a cervical screening test is highly sensitive, given that it may include the results of the test and information about the participant's cancer or precancer status.
- Programmatic audit should preferably be conducted using anonymized or deidentified data, whereby consent from each screening participant is not necessary and disclosure of findings is not possible.
- Consent to undergo a cervical screening test as a health-care intervention is not the same as consent for the processing of data related to that screening test for audit. Even where consent is not relied upon as the basis for data processing, the data controller should ensure that privacy notices are prominently displayed that inform the screening participants about how their data will be processed.
- Screening programmes may offer an individual case review to participants after obtaining informed consent. When consent is obtained for an individual case review, participants should be asked whether they wish to be informed of a discrepancy if one is detected in the future.
- Regarding legal liability for errors in screening, it should be possible to make a claim for negligence with respect to cervical screening, but the standards applied by courts in assessing such claims should accommodate and reflect the reality of cervical screening, including hindsight bias in an audit of cancers. The determination of whether the particular screening error was serious enough to be categorized as negligent and/or serious enough to entitle the participant to compensation needs to consider the inherent limitations of cervical screening.

Effective and transparent communication about cervical screening

- Because of the heterogeneity of the target population for screening, the approaches to screening and downstream management are variable across settings, and so are the access barriers encountered. These differences need to be considered when developing messages and designing communication strategies to promote uptake of cervical screening.

- The screening information conveyed should highlight that screening is a personal choice and should include clear statements on the benefits, risks, and limitations of screening. The information needs to provide a clear statement on the estimates of probabilities of the condition and potential positive and negative outcomes from screening. It also needs to highlight that the programme provides screening because of the significant burden of disease and because the benefits of undergoing the tests outweigh their risks and limitations.
- Acknowledging that screening has risks and describing the benefit-to-risk balance through a pragmatic communication strategy is likely to build longlasting trust in the programme and ensure autonomy in decision-making by every potential screening participant.
- When developing screening information materials, the information should be provided using a tiered approach, starting from basic concepts and building up to more complex information, supported by visual aids and using behavioural science support.
- A multipronged delivery strategy and obtaining feedback from all relevant stakeholders on the appropriateness of the content and the acceptability of the delivery modes are important.
- Communication with all other stakeholders is essential to build relationships of trust that will facilitate the implementation and operation of the screening programme. Stakeholder analysis helps to define various audiences, their level of sophistication, and their willingness to hear the messages that are communicated. The content and delivery mode of the messages must be tailored to the intended audience and must consider cultural norms and sensitivities.
- Once the stakeholder analysis is complete, a documented stakeholder engagement strategy needs to be developed. Such a strategy improves trust in the screening policies, increases buy-in, and may help to mitigate any short and long-term issues with the programme.
- Screening programmes should be prepared by having a communication strategy in place for events that may evolve into a crisis. Such incidents may be related to risks of screening, a change in the screening criteria or the interval of screening, or any occurrences after screening, which may not be directly related to the screening programme itself.

Workforce competencies in communication about cervical screening

- Health professionals involved in the screening pathways need to acquire appropriate knowledge and should be able to demonstrate skills that include:
  - being able to foster a relationship of mutual trust, understanding, and commitment;
  - being able to exchange information that recognizes the individual's information needs and overcomes any barriers related to low health literacy and poor understanding of statistical information and considers cultural contexts;
  - being able to manage uncertainty by acknowledging it and providing further information, support, and cognitive strategies;
  - supporting shared decision-making through active involvement of the potential participants and their family members in the information-exchange and deliberation stages of the decision-making process; and
  - enabling people to navigate the health system by providing appropriate guidance on seeking appropriate care and finding further information.

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Note: Weblinks are accurate as of 1 June 2023

Appendix 1
List of Supplementary Reports

1) The benefits and limitations of population screening with respect to mortality and morbidity
2) Ethical considerations in relation to population screening with specific attention to the balance between the benefits and harms of screening and the limitations of participation
3) Comparative Analysis of Legal Liability/Compensation in respect of Interval Cancers
4) Advices on the Legal Framework Group Interim Report

Appendix 2
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