CHAPTER 2.

Legal and ethical frameworks to safeguard the interests of cervical screening participants, health professionals, and programme managers associated with cervical screening and related services

2.1 Law and ethics in the context of cervical cancer screening

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.

Furthermore, although patients will often understand and accept complications that occur in the investigation or treatment of a disease process, they are perhaps less forgiving of a complication that arises from an intervention when they are apparently healthy, especially because the interaction is initiated by a screening programme or a health professional.

Although cervical screening is not treatment or diagnosis, it is a medical intervention and an intervention that involves an interference with bodily integrity. Accordingly, core principles in health-care law and ethics must be upheld in screening, albeit in a different context. The fundamental rights of the individual screening participant must be protected, while ensuring the efficacy of the screening system as a whole.

Cancer screening is directed at achieving an aggregate benefit within a population, but it achieves that benefit by accepting that most of the population will benefit at the cost of harm to a small proportion. This presents an ethical challenge. Some people will undergo investigations and treatments for precancers that would never progress to cancer, or even for cancers that would not have become symptomatic in their lifetime, and thus the intervention turns out to have been unnecessary. The experience of undergoing the intervention may also have caused the person unnecessary psychological

trauma and inconvenience. Routine medical interventions usually occur in the presence of symptoms or signs of possible disease, which the patient–clinician team seek to understand, thus increasing the threshold for tolerance of any adverse impacts of what are seen as necessary investigations or treatments. Non-maleficence – the requirement not to do harm – is a fundamental principle of medical ethics. Cancer screening poses a challenge because the potential for harm is an anticipated outcome of the intervention in an apparently healthy person.

A separate challenge arises from the fact that 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. Even the highly objective laboratory-based HPV detection tests are not 100% sensitive [39]. Again, this distinguishes cervical cancer screening from routine medical interventions. Such errors that are inherent in all subjective tests pose ethical and legal questions in the context of screening, especially with regard to informed consent and legal redress. As discussed below, a major challenge is ensuring that those few cases where negligence has occurred are distinguished from the inevitable cases of non-negligence where an abnormality is not found but actually exists. The difference between clinical negligence and errors in screening is shown in Box 5.

Box 5. Clinical negligence versus errors in screening

In a clinical negligence claim, the true test for establishing negligence in diagnosis or treatment on the part of a medical practitioner is either:

- whether he or she has been proved to be guilty of such failure as no medical practitioner of equal specialist or general status and skill would be guilty of if acting with ordinary care

or

- whether, if he or she deviated from a general and approved practice, it is proved that the course he or she did take was one which no medical practitioner of like specialization and skill would have followed, had he or she been taking the ordinary care required from a person of his or her qualifications.

However, the clinical circumstances in which a slide is being read by a screening technician as part of a national screening programme are very different from the above-mentioned principles of negligence and causation, considering the different circumstances under which the initial examination of the slide is performed, compared with any later examination of the same slide under very different conditions and by people with a different and higher qualification and level of experience, especially when the reviewer knows that an abnormality has been missed.

This document is intended to be applicable globally and does not have a particular jurisdictional focus. Rather, it attempts to set out some general principles that may be of use across a range of legal systems. However, in some instances this document refers to pieces of legislation or legal rules that originate in a particular jurisdiction (e.g. the General Data Protection Regulation [**GDPR**] in the European Union) where these are of special relevance. It is important to recognize that the legal context and framework for cancer screening varies widely across jurisdictions, and it has been observed that the lack of a legal framework for screening causes problems in many regions or jurisdictions. Variation across legal systems will affect the implementation of some of the best practice principles discussed in this document. Best practice should be implemented to the extent possible within the domestic legal system.

The legal issues addressed in this document are primarily ones that arise between the individual screening participant and the screening system. The focus is not on broader regulatory issues with respect to cervical screening or oversight and quality assurance in the screening system. These issues engage various complex legal concerns that span a multiplicity of legal fields, such as regulatory law, administrative law, public procurement law, and constitutional law. However, the members of the TWGs consider that the best approach is to establish a bespoke legal framework for cervical screening through legislation. Such a framework would help countries to address the legal and ethical issues that arise, because it would enable effective standardization of practice across the system. In the absence of a specific legal framework for screening, it is difficult for countries to put in place legal mechanisms to achieve the aims discussed in this document.

2.2 Consent and information

The requirement that the participant provides informed consent (written or verbal, depending on the local regulations) is a fundamental principle in cervical screening. Although issues about consent also arise in the context of data protection or privacy, it must be recognized that informed consent is a stand-alone ethical principle in medical practice [40] and in clinical research [41]. In most jurisdictions, the principle of informed consent is also a legal requirement [42]. Informed consent in the healthcare context requires that the participant should be fully informed about the nature of the intervention, and the projected benefits and risks of that intervention, compared with alternative interventions, and with the benefits and risks of taking no action. A proper informed consent considers the particular characteristics of the person undergoing the intervention and their particular needs and preferences. Typically, the requirement to disclose information is more onerous in the context of elective medical interventions.

The general principles that govern informed consent must be adapted for implementation in the context of cervical screening, which, as discussed above, differs from routine medical treatment in several important respects. Participation in a screening programme is always voluntary. Screening is directed at population-wide outcomes, and a screening programme with poor uptake cannot deliver population-wide results. A well-organized screening programme requires a built-in mechanism to improve coverage (e.g. sending invitations to all screening-eligible women). Nonetheless, every individual participant has an absolute right to decline to participate in screening, whatever the reason. Thus, screening will always fall into the category of elective medical intervention. Where a woman is advised to undergo a cervical screening test on the basis of a specific clinical indication, this is properly considered a diagnostic test and is not technically part of the screening system. Accordingly, asymptomatic people have a right to decline to undergo a cervical screening test and should also be afforded the right to withdraw entirely from the screening programme into the future.

The members of the TWGs noted that it may not be advisable to allow people to opt out of the screening programme on a permanent basis. A person may in time wish to reconsider their decision, but if they are entirely outside the programme then they will never receive a reminder about future cervical screening tests and therefore may be denied the chance to opt back in, even if they have changed their mind. The members of the TWGs recommend that the managers of individual screening programmes should consider whether to allow people to opt out on a permanent basis. This issue is not applicable in a programme that does not have a system for inviting individual women.

Taking these factors into account, a screening-eligible woman who is invited to participate in cervical cancer screening should be informed about the following:

- The nature and purpose of cervical screening overall.
- The nature and purpose of an individual cervical screening test. This should expressly describe what the experience of undergoing a cervical screening test is like.
- The various possible results of the cervical screening test and the likely recommendations for further management.
- The benefits, risks, and limitations of undergoing the cervical screening test for the individual participant.
- Explanation of the fact that a cervical screening test is not a diagnostic test.
- Explanation of the limitations of cervical cancer screening, including:
  - the subjective nature of cytology and its inevitable inherent error rate;
  - the relative rate of false-positive and false-negative test results in cytology, oncogenic HPV tests, or any other screening test in use in the programme;
  - the fact that the cervical screening system cannot achieve a zero error rate; and
  - information on interval cancers and the fact that screening cannot prevent every cancer.
- The right of the person to decline to undergo a cervical screening test.
- The right of the person to opt out of the cervical cancer screening programme on a long-term or permanent basis.
- Information on the consequences of opting out of the programme, such as not being re-contacted for screening and an increased risk of developing cervical cancer.
- Information about methods of withdrawing consent for participation in the screening programme, and information on how to re-enter the screening programme if the person changes their mind.

These basic information requirements should be supplemented as appropriate with information about data protection or privacy and audit, as discussed below.

Receiving comprehensive information about the benefits, risks, and limitations of screening will enable prospective participants to make an informed decision about whether to participate in the programme (see Chapter 3). Without good and timely information, they cannot make an informed and autonomous decision. A person who is offered screening should also be offered the opportunity to ask questions about undergoing a cervical screening test. This opportunity might be provided by

the individual health-care provider who will administer the test, who needs to be appropriately trained. The above-mentioned information should also be made available to the participant immediately before they undergo the screening test, for example via a leaflet provided by the health-care provider or, more properly, by the screening programme.

2.3 Legal liability for errors in cervical screening

There have been examples of people receiving compensation for errors in cervical cancer screening across many jurisdictions [43–45]. The nature of cervical screening presents challenges for legal liability for negligence or malpractice. Unlike routine medical interventions, cervical screening tests, especially cytology, have a well-recognized false-positive and false-negative rate. Both false-positive and false-negative results may cause risk, for which participants may seek redress. As noted in Section 1.4, one systematic review found the false-negative rate of cytology to be between 20% and 55% [18]. Clearly, if every participant with such a result were to be entitled to compensation, screening programmes would quickly become unsustainable. Uncontrolled and unjustified litigation poses a serious threat to current screening programmes and to the establishment of new screening programmes.

Reviews of individual interval cancer cases (which are known to trigger a claim for compensation) are associated with hindsight bias, which is known to play a significant role in the evaluation of an antecedent event and has been demonstrated in both medical and judicial settings. The knowledge that the participant went on to develop cancer can bias the reviewer's ability to pass judgement and heighten the reviewer's perception that the cancer was preventable. This might lead to an unjustified evaluation based disproportionately on a poor outcome, and not because care was poor. No matter how closely any review panel tries to reproduce the original screening conditions, the conditions of the review are different, and the fact that a review includes the records of a patient who is known to have a serious condition, such as cancer, will inevitably heighten a reviewer's vigilance and will increase reports of abnormality. 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.

Of course, if negligence occurs at any of the screening or management stages, complete immunity cannot be afforded. This would conflict with the fundamental principles of most national legal systems. It would also fail to appreciate that claims for negligence are often a mechanism for vindication of the human rights of the person injured through medical error [46]. Instead, the members of the TWGs recommend that it should be possible to make a claim for negligence with respect to cervical screening, but that the standards applied by courts in assessing such claims should accommodate and reflect the reality of cervical cancer screening, including hindsight bias in an audit of cancers. Successful claims for negligence should concern errors that are not merely inevitable consequences of the limitations of the screening process.

The particular mechanism for achieving this end will vary depending on the type of legal system in question and the precise form of negligence proceedings. Some systems will require people to go to court to secure compensation, and some will not. All systems will involve some 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. The members of the TWGs consider that the processes in place to make this determination should be designed to reflect the inherent limitations of cervical cancer screening. These include the following:

- Tests involved in cervical screening (cytology, visual inspection with acetic acid [VIA], colposcopy, histopathology, and immunohistochemistry) are subjective. There is necessarily some variation in how properly qualified and trained health-care providers would read a particular slide on cytology or histopathology or interpret changes seen on colposcopy. There is also some variation in how a specific person would read a particular cytology or histopathology slide on different occasions (e.g. during routine practice versus during an audit) [47]. Legal determinations of negligence in cytology, histology, or colposcopy must allow valid objective and contextual determination of the performance of the test. A test result is not necessarily negligent just because a different screener would have formed a different opinion.
- The standard should be tailored to the qualification level of the person performing the original screening within the particular screening programme. If the slide was originally reported by a cytologist, the report should be judged by reference to the skill of the reasonably competent cytologist. The report should not be judged by reference to the skill of a differently skilled professional, such as a cytopathologist or histopathologist. If the expert witness works at a different qualification level than the original screener, this should be declared as part of the evidence.

- The reporting of the slide should be judged by reference to the information available to the screener at that time. The original screener would not have been aware that the participant would go on to develop cancer. The expert witness should also comment on the influence of hindsight bias on the preparation of their report.
- The reporting of the slide should be judged with reference to the conditions of the original screening. For example, if the original screener had to review the slide briefly alongside many other slides, this should be reflected in the standard to which the screener is held.
- Judging the cytology or histology slide for the purposes of assessing legal liability is a very different exercise to reviewing the reporting of a slide or performance in the context of audit. In an audit, hindsight is an actively helpful and important factor because it enables the audit to assess the original report in the context of what actually occurred for the participant. Legal processes for assessing negligence in slide reporting must be differentiated from audit review processes.

In audits of cytology slides from patients with interval cancers, abnormalities have been seen on up to 40% of the slides originally reported to be normal. Although most of these missed abnormalities will be a result of pitfalls of cytology, there are likely to be about 5% of cases where the screening is considered unsatisfactory because there are abnormalities present that most screeners would be expected to detect. This is scientifically unavoidable, because the proficiency test for screeners is that they are expected to detect 95% of high-grade changes when presented with a slide pack where the outcomes are known. Because of the complexities of negligence assessment, the judge may request a specific adviser to the court who can help to adjudicate over clinical evidence by the plaintiff and defence expert witnesses.

Concerns may arise with regard to the personal liability of individuals within a screening programme for errors. This should be governed in line with general rules of liability in a legal system. Operators of cervical screening programmes should take steps to ensure that individual health-care providers involved in screening are not at risk of individual legal liability unless special circumstances arise where personal liability is justified. This may be achieved by the provision of an indemnity by the operator of the screening programme in favour of individuals. Similarly, where screening activities are allocated between different organizations, legal liability may be governed by indemnities with regard to negligence claims.

2.4 Data protection and privacy in cervical cancer screening

Confidentiality is a founding principle of medical ethics [48]. In many jurisdictions, it has long been supplemented by legal protection of the patient's right to confidentiality. In the 20th century, the duty of medical confidentiality came to be characterized as a fundamental right of the patient [49]. Protection of confidentiality or privacy is essential in cervical screening. Information about a cervical screening test is highly sensitive. It may include the results of the test and information about the participant's cancer or precancer status. It may also contain other relevant information either provided by the patient while undergoing the test or observed by the health-care professional performing the test. Therefore, there is a strong ethical imperative to ensure the confidentiality of this information. Notably, the ethical principle of medical confidentiality persists after the death of the patient. This is an important distinction from the position under data protection law.

2.4.1 Data protection law

In recent decades, many jurisdictions have enacted data protection law regimes, which usually supplement older forms of privacy or confidentiality law [50]. These regimes have important implications in the health-care context [51]. One of the most significant and far-reaching data protection regimes is contained in the European Union GDPR [52]. Because of the extensive influence of the GDPR in countries with organized cervical screening programmes, this document specifically considers some key issues in the application of the GDPR in the context of cervical cancer screening. However, it should be noted that this document does not provide formal legal advice. Individuals and organizations that are subject to the GDPR should seek specific legal advice tailored to their domestic context and, if necessary, should seek guidance from the national supervisory authority.

2.4.2 The GDPR and cervical screening programmes: general principles

The GDPR applies only to personal data, which is defined as "any information relating to an identified or identifiable natural person" (Article 4(1)). Information that is anonymous is not personal data. However, information is only anonymous if it is irreversibly anonymized. If it is possible – albeit difficult – to trace the data back to an identifiable person, the data will be considered pseudonymized data and will be subject to the GDPR. The definition of natural persons does not include deceased persons. Operators of screening programmes should be very clear

about whether the various categories of data that they are dealing with are anonymous or not.

The GDPR regulates all "processing" of personal data (Article 4(2)). This is defined as "any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction". In effect, all actions that may be taken with regard to data – including storage of that data – are governed by the GDPR.

The GDPR attaches an enhanced level of protection to "special categories of personal data", and one of those is health data. Accordingly, almost all data processed in the context of screening will constitute special category data.

The GDPR establishes fundamental principles relating to the processing of data (Article 5). The first of those is that data must be processed lawfully, fairly, and in a transparent manner. This means that there must be a clear legal basis for all processing of personal data. Thus, operators of screening programmes must clearly identify the legal basis for the processing of data. The GDPR provides for several different legal bases for processing (Article 6(1)), and the processing of health data must also satisfy one of the exceptional bases provided for in Article 9(2).

The provision of consent is one of the potential legal bases for processing of data [53]. However, it must be noted that Article 9(2) states that for the processing of special category data, only explicit consent (as opposed to implied or assumed consent) constitutes an adequate legal basis. Furthermore, the nature and quality of consent are strictly controlled by the GDPR. For consent to be valid under the GDPR, it must adhere to the following requirements (Article 7):

- Consent must be specific and granular.
- If the consent is provided alongside consent for other matters or purposes, the consent for processing of data must be clearly delineated.
- The request for consent must be presented in an intelligible and easily accessible form.
- The data subject must have a genuinely free choice with respect to giving consent. Where consent is sought for the provision of a service, it is not permissible to make that service conditional on the provision of consent to something that is not necessary for the provision of that service.

These principles raise some issues of particular note in the context of cervical screening and audit:

- The request for consent must specifically describe how the participant's data will be processed in the context of cervical screening, including an audit of cancers, if applicable.
- Consent for the processing of data related to undergoing cervical screening must be distinguished from consent for the processing of data for other purposes, such as audit.
- It is not necessary to include a woman's personal data in an audit. Therefore, a woman who denies consent to include her data in an audit process must have all her personal data removed irreversibly before her slide is included in the audit.
- It would not be permissible to make participation in screening conditional on the participant consenting to the processing of data for other purposes, such as audit.

It is essential to appreciate that 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. It may be permissible to request consent for both purposes in one document. The members of the TWGs recommend that, whether or not separate documents are used, consent for each purpose should be specifically delineated. The participant should understand the distinction between consent to undergo the cervical screening test and consent for the processing of data about that screening test. The data subject has a right to withdraw consent at any time (Article 7(3)).

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.

Other potential legal bases under Article 6(1) for processing data in cervical screening are the following:

- Article 6(1)(c) – processing is necessary for compliance with a legal obligation to which the controller is subject; and
- Article 6(1)(e) – processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller.

Article 6 (1)(c) will apply only if there is a legal obligation to process the data within the domestic legal system. Article 9(2) contains several legal bases that may apply as an alternative to relying on consent. These include where processing is necessary for substantial reasons of public interest in the area of public health (Article 9(1)(2)(i)). However, many of these alternative bases require that the processing should be carried out on the basis of European Union or domestic law, or pursuant to a contact with a health-care professional, and therefore they cannot be relied upon in the absence of that. Furthermore, some of these legal bases operate only if there are "suitable and specific safeguards" in

place to safeguard the fundamental rights and interests of data subjects.

The GDPR also provides for several ongoing rights on the part of the data subject that are relevant to the context of cervical screening. Data subjects have a right of access to their data (Article 15), a right to rectification (Article 16), a right to erasure (Article 17, often known as the "right to be forgotten"), a right to restriction of processing (Article 18), and a right to data portability (Article 20). Mechanisms to facilitate the exercise of these rights, where applicable, should be built into the screening programme.

2.5 Audit of cervical cancers – ethics and data protection issues

2.5.1 Ethical obligations and audit

As discussed in Section 1.1, audit of any health-care service is considered by WHO to be a critical function of an organization and to provide objective assurance on its integrity and credibility. 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. Retrospective audit of invasive cancer is part of this quality improvement process and includes audits in many other programmatic aspects, such as the detection rates of low-grade and high-grade precancers, positive predictive values of screening tests and colposcopy, laboratory turnaround times, and waiting times to receive test results and colposcopy appointments.

Interval cancers – cancers that are diagnosed in between routine screening episodes – are an unfortunate but inevitable part of any population screening programme. Although interval cancers are rare in the context of the number of individuals screened and the numbers of lives saved through screening, they are nonetheless a painful and upsetting reality and a potential risk for any individual participating in any cancer screening programme. Measuring the interval cancer rate gives a good indication of whether the screening programme in question is performing within standards and in line with its peers internationally, although the information that their screening test missed a probable or imminent cancer may be painful to an individual woman.

Participants in cervical screening should be informed when they consent to undergo screening that their test results will be subject to a programmatic audit. The slides and data from a participant may be included in an audit even if the participant denies consent to be included in an audit, but only after careful removal of all personal data. This is because 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 in an anonymized manner. However, in this situation it is essential that the audit process makes exceptionally determined efforts to ensure that data are kept safe and confidential.

2.5.2 The GDPR and audit

Undertaking a clinical audit raises a range of additional issues under the GDPR. Overall, all the general principles discussed earlier will apply. Operators of a screening programme must first consider whether the data involved in the audit are identifiable. If so, the data are subject to the GDPR. Audit of clinical data is by definition the processing of data. It must therefore be justified by a legal basis. It is possible to rely on consent as a legal basis for the processing of data for clinical audit. However, the right to consent can be withdrawn at any time. This can constitute a logistic challenge. Furthermore, participants are entitled to provide consent to undergo the screening test but to refuse consent for the audit. If consent is the only available legal basis, then the audit would not include the data of these participants and would therefore not be able to provide a full clinical picture of the screening programme. For this reason, it is sometimes recommended that consent is not used as the legal basis for clinical audit [54].

Furthermore, screening programmes that are currently operational may hold data for the purposes of audit but may not have obtained consent for the use of that data for audit. Thus, they are precluded from relying on consent unless they contact each individual data subject and obtain fresh consent.

A potential alternative legal basis for audit is found in Article 9(2)(i), which governs processing in the public interest for reasons of public health, including to ensure "high standards of quality and safety of health care". Article 9(2)(h) is potentially also applicable, because it addresses "the provision of health or social care or treatment or the management of health or social care systems". Both bases require suitable and specific safeguards. Article 9(2)(i) requires a basis in Member State or European Union law, whereas Article 9(2)(h) requires either a basis in Member State or European Union law or a contract with a health-care professional.

It is also of relevance to note that regardless of which legal basis applies, data subjects have a right to object to processing of their data, subject to certain limited exceptions (Article 21).

Those designing audit systems may wonder whether pseudonymization of data within an audit might relieve the data controller of the obligation to ensure the rights of data subjects under Articles 15–20, particularly the right of data subjects to access their data. As a general principle, pseudonymization does not mean

that the rights of the data subject are compromised. Rather, the GDPR conceives of pseudonymization primarily as a mechanism to safeguard data from third-party risks [55]. Therefore, it has to be assumed that even pseudonymized data will be subject to the ongoing rights of the data subject, including the right of access. Article 11 provides for a limited exception to this principle. The rights of data subjects under Articles 15–20 will not apply where the controller can demonstrate that it cannot identify the data subject by reference to the data that it holds. However, if the data subject can provide additional information that enables the subject to be identified, then the rights under Article 15–20 will apply as normal.

2.6 Disclosure of audit results

It is important to distinguish between population-based programmatic audit, which is performed as a quality assurance exercise, and an individual case review, which is performed to help a single individual understand their particular case history.

A question that has arisen in many screening programmes is whether a participant should be informed if an audit detects a discrepancy between an original test result and a test result on review. Typically, this situation will arise where the original result was negative but the review detected an abnormality. As discussed earlier, the review result is usually arrived at with the benefit of hindsight – the knowledge that the participant went on to develop cancer. It is important to prepare women in advance about the likely results of an individual case review and to explain that a finding of discordance is not proof of poor performance of the programme.

There is a wide divergence in practice across screening programmes with respect to the disclosure of audit results [56]. The members of the TWGs also noted that the inconsistent approach to disclosure of audit discrepancies proved very problematic in Ireland and generated a great deal of public criticism of the cervical screening programme, with some people characterizing the non-disclosure as a "cover-up" [57]. The independent report into the CervicalCheck Screening Programme was also extremely critical of failures to inform women of the outcome of audits and was adamant in recommending that open disclosure and a duty of candour must be enshrined within the system in the future [58]. Despite this diversity of practices, the members of the TWGs believe that programmatic audit should preferably be conducted using anonymized or de-identified data, whereby consent from each screening participant is not necessary and disclosure of findings is not possible.

The benefits of anonymization of a programmatic audit (hence, not being able to disclose results) are that:

- it protects individual privacy;
- it enables health information to be shared when it is not mandated or practical to obtain consent from each participant;
- operators do not need to rely on consent as the primary mechanism, which may lead to bias in audit findings; and
- it will gain support from health-care providers, who will be keen to get involved in programmatic audit.

The members of the TWGs acknowledge that some screening participants who were diagnosed with an interval cancer will wish to know whether a discrepancy has been detected upon audit. Because of this, screening programmes may offer an **individual case review** to such participants after obtaining informed consent. At the time 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. If they say they do not wish to be informed, they should not be contacted in the future for this purpose. If they say they do wish to be informed, they should be contacted if a discrepancy is detected. If a discrepancy is detected, the participant should be informed of the simple fact of a discrepancy and asked whether they wish to have more information about it. If they indicate that they do wish to be further informed, further information should be provided. This information should be delivered by a trained senior clinician who can answer questions about all aspects of the screening process. Support should be made available to patients before, during, and after meetings where discordant results are discussed, because this situation can be traumatic for patients.

In addition to the ethical justifications for open disclosure of findings of an individual case review, it should be noted that many participants will have a legal right of access to audit and review results pursuant to the GDPR or analogous legislation. It is preferable to actively disclose this information in a sensitive and constructive manner, rather than for participants to access it via a data subject access request.

2.7 Research and the GDPR

Many screening programmes will generate data that can be a useful resource for further research. Research is entirely distinct from audit and raises different issues under the GDPR. For example, it is more likely that data used for research will be entirely anonymized. If so, they are outside the scope of the GDPR. If not, the GDPR applies. Importantly, the GDPR provides a specific legal basis for the processing of data for research purposes (Article 9(2)(j)). This applies only where processing is based on Member State or European Union law and there are suitable and specific safeguards in place.