

# Introduction

Well-organized cervical screening programmes have been shown to reduce the incidence of and mortality from cervical cancer at the population level. In such screening programmes, important quality assurance measures need to be ensured. These include:

- high coverage of the target population with minimal inequalities;
- a strong linkage between screening and management of screen-positive women, to ensure timely and appropriate treatment of precancers and cancers; and
- high quality of services across the screening continuum.

On the basis of expert consensus, the International Agency for Research on Cancer/World Health Organization (IARC/WHO), France, identified 16 essential criteria that a screening programme needs to fulfil in order to be considered an organized programme (Fig. 1). Audit of cancers, as an inte-

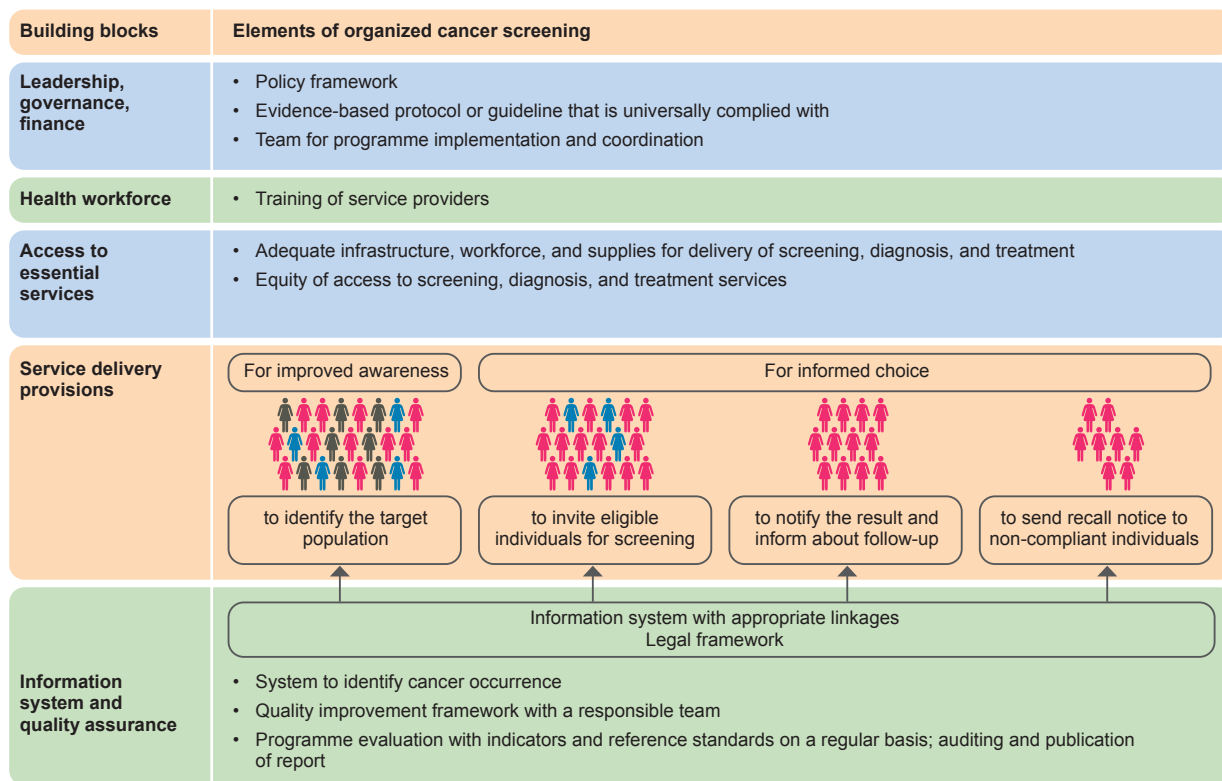
gral part of a quality improvement exercise, is included in these essential criteria. Despite the pivotal role of an audit of cancers in the quality improvement process, there is a lack of consensus on its definition, role, and methodology. Interpretation of the audit outcomes in the context of individuals whose records or specimens were audited in relation to the larger programmatic context has sometimes been a source of contention.

Recent incidents in Ireland have demonstrated that gaps in communicating audit outcomes in a timely, efficient, and transparent manner may lead to confusion, psychological trauma, litigation, and loss of trust in the programme (Box 1). In Ireland, this was to some extent due to the lack of a clear legal framework on how to conduct such audits of cancer, and to lapses in communicating the outcomes in a transparent manner to the women whose review test results

have been found to be discrepant. In fact, effective communication at all levels of the screening process through a workforce that is adequately competent in health communication may be a key determinant of the success of an audit.

**In the context of health care, a best practice is defined by WHO as “a technique or methodology that, through experience and research, has proven to reliably lead to a desired outcome” [1].** Best practice is not about perfection or setting the gold standard. It is about learning from others and avoiding similar mistakes in order to develop and implement solutions adapted to similar health problems in different situations. Best practices are time-sensitive because they may change with new evidence and experience. For this reason, this document uses the term “current best practices”, which are described in subsequent sections.

**Fig. 1.** Elements of organized cancer screening, categorized across the five building blocks of health systems. Source: [2]. From Zhang et al. (2022). Published under <https://creativecommons.org/licenses/by/4.0/>.



**Box 1.** Experience with audit of cancers in the cervical screening programme in Ireland

As part of a quality assurance exercise in the cervical screening programme in Ireland, an audit of all cervical cancers detected in a cohort of 1.1 million eligible women screened in 2008–2014 was undertaken in 2018 by the national screening service (CervicalCheck). On average, the programme screens about 300 000 women per year. The audit identified 221 cancer cases where, on review, the screening cytology result was upgraded to one that would usually lead to referral for colposcopy or repeat testing.

Although the programme management aimed to communicate the audit outcomes to patients with cancer, there was hesitancy and delay in communicating the results, and this led to a public outcry. The perception grew that the non-disclosure of the audit result had led to delayed treatment for women. Many people were convinced that finding discordant cytology results on review meant that the cervical screening programme in Ireland had performed poorly and had tried to cover up inadequacies.

An independent review by the Royal College of Obstetricians and Gynaecologists, United Kingdom, found discordance between a retrospective expert smear review and the original CervicalCheck result in 30% (308 of 1034) of cancer cases, which included microinvasive cancers. In nearly half of these discordant cases, the expert panel considered that the original CervicalCheck result had an adverse effect on the woman’s outcome because it led to a delay in diagnosis. Crucially, the report also found that the discordance rate was similar to that observed in the cervical screening programme in England. Despite this, the view that the Irish cervical screening programme had not served women well or honestly prevailed in Ireland.

A scoping inquiry was also conducted, and the recommendations of this have been implemented by the Irish cervical screening service. Although the Irish cervical screening service has consistently met the highest international performance standards, since the audit incidents there has been an exponential increase in the number of legal cases in Ireland arising from participation in screening programmes. As of August 2022, the estimated potential liability of legal claims is up to €300 million against a 2019 operating budget of €34 million; this could render screening financially unsustainable.

### **Key learnings from the incidents in Ireland**

- Screening tests for cervical cancer and precancer are very different from diagnostic tests, and they will both miss and overcall abnormalities routinely, even in a programme that is performing well.
- Screening services and the professionals involved need to take responsibility for comprehensive, timely, and transparent communication to women who opt for screening.
- Audit of cancers is crucial to improving the quality of screening programmes, and an appropriate legal framework is needed to conduct such audits.
- Screening staff and clinicians need to have indemnity from non-negligent inadequacies of screening.