

RESEARCH OUTPUTS / RÉSULTATS DE RECHERCHE

The new privacy law in Belgium : a legal Basis for organised cancer screening

Dhont, Jan; Arbyn, M.; Wallyn, S.; Van Oyen, S.; Nys, H.

Published in:

European Journal of Health Law

Publication date:

1999

Document Version

Publisher's PDF, also known as Version of record

[Link to publication](#)

Citation for pulished version (HARVARD):

Dhont, J, Arbyn, M, Wallyn, S, Van Oyen, S & Nys, H 1999, 'The new privacy law in Belgium : a legal Basis for organised cancer screening', *European Journal of Health Law*, no. 6, pp. 401-407.

General rights

Copyright and moral rights for the publications made accessible in the public portal are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

- Users may download and print one copy of any publication from the public portal for the purpose of private study or research.
- You may not further distribute the material or use it for any profit-making activity or commercial gain
- You may freely distribute the URL identifying the publication in the public portal ?

Take down policy

If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

SELECTED LEGISLATION AND JURISPRUDENCE

BELGIUM

**The New Privacy Law In Belgium:
A Legal Basis For organised Cancer Screening**

M. ARBYN¹, S. WALLYN¹, H. VAN OYEN¹, H. NYS², J. DHONT^{3,4},
B. SEUTIN⁵

1. Scientific Institute of Public Health, Brussels.

2. Centre for Bio-ethics and Law, Catholic University of Leuven, Leuven.

3. Faculty of Law, Catholic University of Brussels, Brussels.

4. Facultés Universitaires Notre-Dame de la Paix, Namur.

5. Council of State, Brussels.

Screening is a type of secondary prevention, which implies the detection of lesions that have the potential to develop to serious disease in people who do not yet manifest clinical symptoms.¹ The precise pathological diagnosis, follow-up and management of confirmed lesions can anticipate severe morbidity or death. Sufficient scientific evidence has been accumulated that indicates the potential effectiveness of screening for cancer of the breast^{2,3,4} and the uterine cervix.^{5,6}

Cytological precursors of cervical cancer can be detected easily with the classical Papanicolaou smear many years before invasion of surrounding tissues occurs. The multi-country study, performed by the International Agency for Research on Cancer (IARC), provided quantified evidence that the cumulative incidence of cervical cancer can be reduced to a small residual fraction by screening at an interval of 3 to 5 years.⁷ Cervical cancer is therefore the malignancy for which screening is most effective. The protective value of screening can hardly be improved by increasing the frequency of Pap testing.^{7,8}

Malignant breast tumours can be detected by mammography when they are still limited in size and minor or no lymph node involvement has taken place. A tumour, detected at the occasion of a radiological screening examination, has a considerably higher cure rate, than if discovered as a

consequence of distinct complaints. Two-yearly mammographic screening of women between 50 and 75 years significantly reduces mortality due to breast cancer.³ The protective effect among younger women is still the object of vivid debate and extensive research.²

Organised screening on a population level is considered to be more efficient and usually more effective than screening on the individual initiative of the woman or her doctor.^{9,10} The general purpose of the organisation consists of the maximisation of the participation of the target population at adequate intervals and assuring the best available quality. The central cornerstone of an organised screening programme is the registration of the participation of the target population and the recording of the test results (quality of the screen test and occurrence of suspect lesions). Such a screening register can, after linkage with population databases, be used for the direct invitation (call-recall) of women who are eligible for their next smear or mammography. Moreover, the register guarantees correct follow-up of screen positives and offers opportunities for policy evaluation.

Since the Belgian state reform of 1980, the Communities are empowered in health policy, i.e. policy on health care dispensed in or out hospitals, notwithstanding several exceptions, as well as health education and preventive medicine activities and services, with the exception of prophylactic measures at the national level.¹¹ This means practically that preventive health care in Belgium is mainly confined to the Communities, while curative care remains essentially a national matter. In 1993, the Government of the Flemish Community, decided to reorientate the organisation of cervical cancer screening according to European recommendations.^{10,12} The five Flemish provinces were instructed to create awareness among women between 25 and 64 years concerning the utility of a 3-yearly cervical smear. Special attention was given to women, who do not yet attend to regular screening, and who usually are older than 40 years or belong to lower socio-economic categories.¹³ A co-ordination centre was set up at the Scientific Institute of Public Health. Technical working parties developed guidelines on important quality issues such as: the sampling and preparation of an adequate Pap smear, the uniform reporting of cervical cytology¹⁴ and the management of cytological lesions.¹⁵ Meanwhile a multi-centre study was started in order to define the optimal strategy for assuring the highest possible participation in two-yearly mammographic screening among women of 50 to 69 years old in the Flemish Community.¹⁶ There was ample evidence from past experiences in both programmes that the creation of a population-based register was a necessary condition for rational organisation and accurate monitoring of activities and their impact.

No formal cancer screening programme is executed at the level of the

French Community despite a broad scientific consensus accepted by the francophonic universities and professional societies concerned.¹⁷ Only local initiatives are implemented at provincial or city level.

Since the enactment of the law on the protection of privacy concerning the treatment of personal data of 8 December 1992, it has become exceedingly difficult to establish an exhaustive registration system of medical personal data in Belgium.¹⁸ The inclusion of data concerning attendance for cancer screening in a structured database was conditioned by the prior written consent of the woman concerned. Application of this principle led to low response rates.¹⁹ The privacy law contained no particular regulations about the collection and treatment of encoded personal data. Despite the use of important administrative and technical protective measures (for example, separate transmission of medical and name data, encryption of the identifying variables by an independent population bank and limitation of access to the databases) no explicit permission could be obtained from the Commission for Privacy Protection. The National Board of the Order of Medical Doctors had, however, adopted the point of view that in this way the basic principle of the professional secret was not violated.²⁰

In 1995, the European Community launched a new directive in order to regulate the right to privacy of all citizens in the Member states.²¹ The national laws needed, therefore, to be adapted within three years. In the course of 1998, a Government bill was introduced in the Belgian House of Representatives.²² Amendments for the creation of a legal basis for cancer screening registration were presented as a result of successful lobbying by the Scientific Institute of Public Health.²³ The Chamber approved the new law, including the concerned amendments, on 11 December 1998 in plenary session. On 3 February 1999, it was published in the *Moniteur belge*/Staatsblad under the title of Law on conversion of the directive 95/46/EC of 24 October 1995 of the European Parliament and of the Council on the protection of natural persons with regard to the processing of personal data and on free movement of such data. Article 10 contains the fundamental prohibition for processing personal data concerning health, but also specifies, in paragraph 2, a number of exceptions. In this case, exception d) mentions that the prohibition does not apply when treatment is necessary for the improvement and the protection of public health, including population screening. Article 13 deals with the obligations to inform the individual person whose personal data are processed. However, an exemption is envisaged, if notably for statistical aims or for historical or scientific research or for population screening considering the protection or the improvement of public health the notification of the concerned person proves to be impossible or disproportionately difficult.

This new law opens up a clear perspective to finally establish organised

screening for breast and cervical cancer in Belgium^{12, 16, 24, 25} within a legal framework. As a consequence of this new law, organised screening for breast and cervical cancer at population level will finally be legalised.

No definition of population screening is provided in the new law. In the Dutch version of the *Moniteur belge/Staatsblad* 'bevolkings-onderzoek' (research, examination or screening of the population) is used. In the French edition, it is translated as 'dépistage' (screening, examination), which is even more imprecise. Several jurists are therefore in favour of a strict interpretation of the term population screening. It should be applied to organised activities, aimed at a large part of the population and at the improvement of health, and carried out on commission of the competent authorities. The effect (the improvement of the quality of life, the reduction of the risk of illness and premature death) has to be based on scientific evidence and has to be monitored by way of pertinent epidemiological indicators. Recommendations, formulated by the Council of Europe concerning the epidemiological, socio-economical and juridical criteria for widespread screening as a tool for preventive medicine, are inspiring in this matter.²⁶ A Royal Decree, including directives concerning the registration of personal data for historical, statistical and scientific aims, is currently being prepared under the authority of the Belgian Minister of Justice and will probably be published in the course of 1999. Statistical analysis and epidemiological interpretation are only a part of population screening. By lack of specific regulations regarding population screening, it seems indicated to apply the directives concerning scientific research.

In consultation with the Flemish authorities and while waiting for executive decrees to the new law, scenarios are now being developed concerning the practical organisation of screening in the field. Particular measures are being considered to guarantee the maximum integrity of the individual woman, concerning both the right to health and protection against life-threatening disease as well as the right to information, confidentiality and respect of personal liberties.²⁷ The following safeguards are examined: definition of a performant and unique identification and coding system; supervision of the medical databases by a medical officer subject to the obligation of professional secrecy; use of coded identifiers at the level of the medical data files; inclusion of an intermediate and independent population bank, having access to administrative information of the target population and equipped with keys for encryption/decryption (conversion of identifying variables (identity codes) but separated from any medical data; impossibility of disclosure of medical information concerning an identified individual by unqualified individuals; information of the women via pamphlets, posters, invitation letters or her doctor; the right to refuse inclusion in the call-recall

system; limitation of access to data banks to authorised personal subject to contractual regulations; physical and electronic protection of data files against voluntary, accidental or erroneous modification or deletion; publication of only aggregated data not allowing identification of individuals; individualised feedback to data-providers (laboratories, radiological centres, clinicians) only concerning patients for whom they have or had responsibilities in order to improve the quality of the screening process. The whole procedure will consecutively be presented to the competent ethical, deontological and juridical institutions. Hence, it can be hoped that the juridical way will soon be paved for more efficient cancer screening based on a secure, feasible and economically acceptable population register.

Acknowledgments

We acknowledge the redactions of *Tijdschrift of Geneeskunde* and *Acta Clinica Belgica* and for the authorisation for the publication of this paper in the *European Journal of Health Law*. Earlier shorter announcements concerning the covered material were already published in these journals respectively in Dutch and English under the following references: "Arbyn M, Wallyn S, Van Oyen H, Seutin S, Dhont J. Registratie bij bevolkingsonderzoek naar kanker ... eindelijk legaal! *Tijdschr Geneesk* 1999; 55: 555-558" and "Arbyn M, Wallyn S, Van Oyen H. The new law on privacy protection: perspectives for organised cancer screening. *Acta Clin Belg* 1999; 54: 147-149".

References

1. Morrison A.S. The natural history of disease in relation to measures of disease frequency. In: *Screening in chronic disease*, 2nd edition., Oxford University Press, New York, 1992, 21-428.
2. Clarke R.A. Breast Cancer. In: D S Reintgen, R A Clarke: *Cancer Screening*. Mosby, St.-Louis, 1996, 23-40.
3. Kerlikowske K, Grady D, Rubin S.M, Sandrock C, Ernster V.L. Efficacy of screening mammography. A meta-analysis. *JAMA* 1995; 273: 149-154.
4. Tabar L, Fagerberg G, Chen H H, Duffy S W, Smart C R, Gad A, Smith R.A. Efficacy of breast cancer screening by age. New results from the Swedish Two-County Trial. *Cancer*. 1995; 75: 2507-2517.
5. Miller A.B. 1991. The natural history of cancer of the cervix and the implications for screening policy. In: Miller A.B. *et al.*: *Cancer screening*. Cambridge University Press: 141-152.
6. Day N E. Screening for cancer of the cervix (review article). *J Epid Comm Health*. 1989; 43: 103-106.
7. IARC Working Group on Cervical Cancer Screening. In: *Screening for Cervical Cancer* (ed. by ...)

- uterine Cervix. Editors M. Hakama, A.B. Miller, N.E. Day. World Health Organisation, International Agency for Research on Cancer, International Union Against Cancer. IARC Scientific Publications N_ 76, Lyon, 1986: 133-142.
8. Eddy M.. Screening for cervical cancer. *Annals of Internal Medicine* 1990, 113: 214-226.
 9. Coleman D, Day N, Douglas G et al. European Guidelines for Quality Assurance in Cervical Cancer Screening. *Eu J Cancer*. 1993; 29A, suppl. 4: 1-38.
 10. European Commission. European Guidelines for Quality Assurance in Mammographic Screening, 2nd edition. Europe Against Cancer, Radiation Protection Actions, Editors: C J M de Wolf & N M Perry, 1996.
 11. Alen A. Treatise on Belgian Constitutional Law. Kluwer Law and Taxation Publishers. Deventer, 1992, 276.
 12. Detiège L. Policy paper of the Flemish Minister of Employment and Social Affairs: Cancer Prevention in Flanders (in Dutch), Brussels, 1993.
 13. Arbyn M, Quataert P, Van Hal G, Van Oyen H. Cervical cancer screening in the Flemish region (Belgium): measurement of the attendance rate by telephone interview. *Eu J Cancer Prev*. 1997; 6: 389-398.
 14. Cuvelier C, Arbyn M, Bourgain C, De Roy G, Drijkoningen R, et al. The organisation of cervical cancer screening in Flanders: uniform cytology reporting. *Acta Cytol*. 1998; 42: 468.
 15. Arbyn M, Albertyn G, De Groof V. Consensus omtrent follow-up adviezen bij cytologische screening naar baarmoederhalskanker. *Tijdschr voor Geneeskunde*. 1996; 52: 709-715.
 16. Weyler J, Schrijvers J, Vandermeeren I, Vuylsteke de Laps L. Multi-center study breast cancer screening in Flanders (in Dutch). Subcommission for Breast Cancer Prevention/Flemish Advisory Board for Cancer Prevention. Ministry of the Flemish Community & Administration for Health Care, Brussels 1997.
 17. Anonymous. Screening for cancer of the uterine cervix (in French). *Santé et Communauté* 1992, 20: 5-8.
 18. Arbyn M, Van Oyen H, Wallyn S, Dhont J. Cancer Screening Registration at Population Level and Privacy Protection: How to manage the paradox? 2nd World Conference for Cancer Organisations, American Cancer Society, Atlanta, 19-23 May, 1999.
 19. Arbyn M, Peeters A, Vyslouzilova S, Van Oyen H. Screening for cervical cancer in the Flemish Community (in Dutch). In: L Denis, ed. *Cancer Prevention in Flanders, Study day of the Flemish Advisory Board for Cancer Prevention, Flemish Cancer League*. Leuven, 27th of April 1996: 13-49.
 20. National Board of the Order of Medical Doctors. Advice: cervical smears (in Dutch). *Tijdschrift van de Nationale Raad*. 1996; V 74: 19-20.
 21. European Communities. Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data. *Official Journal of the European Communities*. 1995; L 281 (23 November), 31-50.
 22. Parl. Doc., House of Representatives, 1997-98, nr. 1566/1. Bill on the conversion of the directive 95/46/EC of 24 October 1995 of the European Parliament and of the Council on the protection of natural persons with regard to the processing of personal data and on free movement of such data..
 23. Parl. Doc., House of Representatives, 1997-98, nr 1566/61 and 1566/62. Amendments no 61 and 62 submitted by Y. Leterme, the 7th of October 1998.
 24. Arbyn M, Wallyn S, Van Oyen H, Cannoodt L, Mulkers A, Calcoen P. Nationwide registration of cervical cytology, a practical approach. International Symposium on Cervical Cancer Screening. Belgian Society of Clinical Cytology, Flemish Community, Europe Against Cancer, Gent, 22 March 1997.
 25. Demeester W. Policy paper of the Flemish Minister of Finances, Budget and Health

- Policy: Quality as a lever for a Flemish health policy (in Dutch), Brussels 1995.
26. Council of Europe, Committee of Ministers, 1994, Recommendation No R (94) 11 of the Committee of Ministers to member states on screening as a tool of preventive medicine (adopted by the Committee of Ministers on 10 October 1994 at the 518th meeting of the Ministers' Deputies).
 27. Muir C S, Démaret E. Cancer registration: legal aspects and confidentiality. In: *Cancer Registration: Principles and Methods*. IARC Scientific Publications No 95, Lyon, 1991: 185-198.