348 P. Alberto et al.

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# A Model-based Prediction of the Impact on Reduction in Mortality by a Breast Cancer Screening Programme in the City of Florence, Italy

E. Paci, R. Boer, M. Zappa, H.J. de Koning, G.J. van Oortmarssen, E. Crocetti, D. Giorgi, M. Rosselli Del Turco and J.D.F. Habbema

The efficacy of breast cancer screening for women older than 50 years has been shown in several studies. Service screening is now ongoing or planned in several countries in Europe. MISCAN, a computer simulation programme, has been used to analyse data from the Florence District Programme (FDP) breast cancer experience. First, the model was fitted to the screening results for the period 1975–1986. A good correspondence between the model outcomes and the FDP results was achieved. It was then used to predict the impact on mortality of the new starting programme of the city of Florence (63 000 women, 50–69 years old). Assuming a 70% attendance rate, then for the city of Florence, 2563 screen-detected breast cancers are predicted for the period 1991–2020 out of the total number of 9095 breast cancers for all ages (28%). A total of 3720 deaths for breast cancer are expected without screening. An absolute reduction of 472 deaths (13%) is predicted for the whole population. The estimated number of years of life gained by screening until 2020 is 4354. Simulation by MISCAN has previously been a useful support tool for decision-making about screening. The present paper is the first based on a southern European experience. The possibility of applying MISCAN to predict the impact of a national programme in Italy is discussed.

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## INTRODUCTION

EVIDENCE OF the efficacy of breast cancer screening for women older than 50 years has been provided by several randomised trials and case-control studies [1], and service screening is now ongoing or is planned in several countries in Europe. The

question remains as to what the consequences of such programmes are in a population as a whole, in terms of the effectiveness of the programme in reducing mortality for breast cancer. This can be investigated by using simulation models.

In the Netherlands, the MISCAN model was used to make a

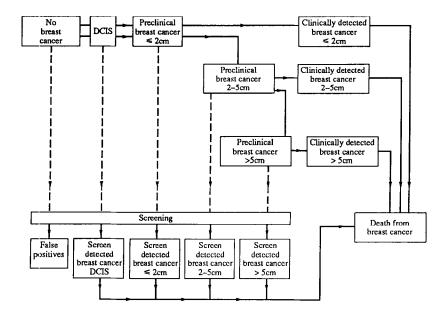


Figure 1. Structure of the disease model for breast cancer and the stages used in the model (the possible courses of the disease are indicated).

DCIS, ductal carcinoma in situ.

detailed analysis of breast cancer (and cervical cancer) screening. MISCAN has been developed for the analysis of screening projects and has already been applied to Health Insurance Plan of Greater New York (HIP) and Dutch programmes [2, 3]. It has also been used for predicting results of "service screening" in the Netherlands and for calculating the expected effects of alternative screening policies [4, 5].

A breast cancer screening programme, the Florence District Programme (FDP), has been carried out in a district near Florence since 1970. Women between the ages of 40 and 70 were invited for screening every 30 months, on average. The protective effect of mammography was estimated by means of a case—control study showing a significant reduction of mortality for 50–69-year-old women (odds ratio (OR) 0.51; 95% confidence interval (CI) 0.29–0.89). The estimated efficacy for 40–49-year-old women showed a statistically non-significant effect (OR = 0.63; 95% CI 0.24–1.64) [6]. When the compliance rate was taken into account, this finding for women older than 50 years was comparable with results in Swedish trials.

The aim of the present analysis is to evaluate a MISCAN breast cancer screening model against the available data of the FDP, and to predict the impact on mortality of the Breast Cancer Screening Programme of the city of Florence, which started at the end of 1990. Firstly, MISCAN was used for modelling the FDP programme by testing the model assumptions against the observed results. Then, the estimated parameters were applied to the city of Florence female target population to predict the impact of screening on breast cancer mortality until the year 2020.

Correspondence to E. Paci.

E. Paci, M. Zappa and E. Crocetti are at the Unit of Epidemiology; M. Rosselli Del Turco is at the Breast Unit, Center for the Study and Prevention of Cancer, Viale A. Volta 171, 50131 Florence, Italy; R. Boer, H.J. de Koning, G.J. van Oortmarssen and J.D.F. Habbema are at the Department of Public Health and Social Medicine, Medical Faculty, Erasmus University, Rotterdam, The Netherlands; and D. Giorgi is at the Istituto Nazionale per la Ricerca sul Cancro, Genova, Epidemiology Unit, c/o C.S.P.O. Florence, Italy. Revised 2 Jul. 1993; accepted 4 Aug. 1993.

## **MATERIALS AND METHODS**

**MISCAN** 

The MISCAN computer programme has been developed at the Department of Public Health and Social Medicine at Erasmus University in Rotterdam, The Netherlands. A detailed description of the MISCAN programme has been previously documented [3]. Parameters to be specified for the model are: demographic structure of the population, life tables, age- and stage-specific breast cancer incidence, stage- and age-specific survival, sensitivity of mammography, attendance rate to the programme and assumptions about the breast cancer disease progression. A list of the main assumptions for the FDP and the Florence City Programme (FCP) is presented in the Appendix. The model produces simulated results which can be compared with the observed ones in the FDP, such as detection rates and proportion of interval cancers. The model will also produce output concerning the effects of screening, by predicting incidence, stage distribution and mortality in the absence and in the presence of a screening programme.

#### The FDP model

The FDP was based on a high quality, two-view mammography offered to all resident women aged 40–70 years. Until 1986, nine screening rounds were organised in several municipalities involved in the programme, the last municipality being enrolled in 1981. A detailed description of the programme has been presented previously [6].

The natural history of breast cancer was modelled as a progression through a number of states. These states are different from those used in previous MISCAN models [3]. In this model, the preclinical and clinical states were considered as Tis or T1, T2, or T2+, according to TNM-UICC [7], which means that size categories are  $\leq 20$ ,  $> 20 \leq 50$  and > 50 mm. The assumed disease progression is shown in Figure 1. Nodal status was not considered in the natural history of the disease because it is not considered a diagnostic determinant for mammographic detection.

The age distribution of the population of the FDP was obtained from the 1981 Italian Census, and a life table for deaths

350 E. Paci et al.

from causes other than breast cancer was derived from the 1982 mortality figures of the Province of Florence for breast cancer and other causes. The breast cancer incidence by 5-year age groups was estimated from a pathological registry existing in the Province of Florence between 1977 and 1982 [8].

The relative cumulative survival for clinically detected cancers (CD) was estimated from the Varese Tumour Registry data, regarding 10-year survival based on breast cancer cases in the years 1976–1981 [9]. The survival was extrapolated up to 50 years by a lognormal assumption of the survival distribution [10].

The stage distribution in the absence of screening was based directly on the clinically detected cancers in the screened FDP case series: Tis = 3.7%, T1 = 35.7%, T2 = 49.3%, T2+ = 11.3%.

Population-based stage-specific survival was not available for the whole period. We used the 5-year survival of the 1985/1986 breast cancer cases of the Florence area by state, i.e. 100, 84.6, 68.6 and 45.4% for Tis, T1, T2 and T2+, respectively.

Reference data of the FDP screening programme, which have been used in modelling, have already been published [6, 11]. The attendance after a first invitation to the screening programme was 55% on average, with an age dependency ranging from 65% at age 40 to 45% at age 70. The screening interval was set at the average value of the FDP, which is assumed to be 30 months [6]. The attendance rate of those who attended the previous screening was 80% and for those who did not attend after the previous invitation 17%.

The estimation of duration of the preclinical detectable phase (PCDP) and sensitivity of the mammography are interdependent. The ratio between the prevalence rate at the first screening, observed in the FDP, and the expected incidence rate, in the absence of screening (P/I ratio), is an estimate of the product of the mean sojourn time in the preclinical phase and the sensitivity. For all ages a constant sensitivity of the screening test was assumed: 40% for Tis, 90% for T1 and 95% for T2 and T2+. The 5-year age group-specific P/I ratios observed in FDP, corrected by sensitivity, were used for the estimation of the duration of the PCDP [11].

Interval cancers were assessed since the last negative test, as the proportion of the incident number of cases expected, in the absence of screening. The proportion observed was age dependent and estimated as 24, 45 and 98% in each of the first 3 years after the test for 40–49-year-old women. The same figures were 17, 45 and 51%, and 9, 35 and 51% for 50–59- and 60–69-year-old women, respectively.

In summary, the model assumptions were checked by comparing model outcomes with the following main results of the FDP:
(a) detection rates by age and screening rank (first versus repeated); (b) proportion of interval cancers by age and time since the last negative test; (c) stage distribution of screen-detected cancers by age and screening rank.

The reduction of the risk of dying from breast cancer, achieved through screen detection, has been assumed on the basis of results in women older than 50 years in the Swedish trials, and the estimate by case—control study in the FDP. The improvement of prognosis was not entirely explained by the shift in tumour size category that results from early detection [3]. There is a within-size improvement, due to the differences in lymph node status, between clinically and screen-detected cases.

## The city of Florence programme

The MISCAN programme was used to simulate results of the new starting programme in the city of Florence. The female population is about 216 000, and the target population at the start of the programme was 63 000 50-69-year-old women resident in the city of Florence on 31 December 1990. They received a personal invitation for a double-view mammography, and all women will be enrolled in the first 3 years after the start of the programme. The attendance after a first invitation to the screening programme was assumed to be 70%, on average, ranging from 80% at age 50, to 60% at age 70. A second simulation assumed a 55% attendance, on average, with an age dependency ranging from 65% at age 50, to 45% at age 70. The screening interval is planned to be 2 years. It was assumed that the programme will stop in 2019. The attendance rate of those who attended the previous screening was assumed to be 80%, and for those who did not attend after the previous invitation 17%. The population size and age distribution was obtained from the computerised and continuously updated Municipality Registry. The breast cancer age-specific incidence rates were obtained from the Tuscan Tumour Registry (1985-1987) [12], and mortality from the mortality rates of the city of Florence in the period 1985-1988. The pathological stage distribution at diagnosis was estimated from a histological revision of all incident cases, which occurred in 40-74-year-old women resident in the city in 1985–1986 [13] (Tis = 2.6%, T1 = 46.9%, T2 = 36.1%, T2+ = 5.7% and 8.7% of unknown data). The stage distribution was modelled by age. The relative cumulative survival rate by state was as in the FDP model.

Because of the more favourable clinical stage distribution in the city of Florence, it seems reasonable to expect a shorter preclinical duration than in the FDP. Therefore, the dwelling times were adapted by assuming constant transition rates between preclinical stages, and higher clinical detection rates that reproduce the clinical stage distribution.

## Statistical analysis

The FDP observed number of cases was compared to the number simulated by the model by calculating the observed/simulated (O/S) ratio, and a Poisson 95% CI. The difference was considered non-significant if the value 1 was within the upper and the lower boundary of the 95% CI.

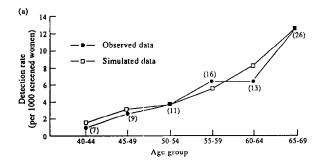
## RESULTS

Simulation of the FDP results

Observed FDP and MISCAN model-simulated detection rates (DR) at the prevalence and repeated screening test are shown in Figure 2. The observed DR was 5.0 and 3.0 per thousand (40-69-year-old women) at the prevalence and repeated screening test, respectively. The simulated results were 5.3 at the first and 3.4 at the repeated test. In general, the model fits quite well through age groups. The simulated stage distribution at the first screening test (Table 1) also fits the observed quite well, but simulated results at the repeated screening test show a better stage distribution than the observed ones. Specifically, a higher proportion of T1 cancers was expected. The incidence of interval cancers (IC) after a negative screening test was compared with the expected incidence in the absence of screening. The rates and the ratios (Table 2) of IC simulated by the model were comparable with those observed in the FDP, in particular at 3 years since the last negative test.

The mortality reduction was assumed in modelling on the basis of the Swedish trials and the Florence case-control study, and estimated as 17% for all ages, which means 30% of the 50-70-year-old screened population.

In general, the model seems to give a good reflection of the screening outcome regarding detection rates, stages and interval



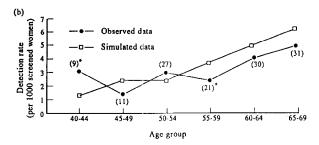


Figure 2. FDP observed and simulated detection rates (per 1000) by rank and age. (a) First screening; (b) repeated screening. Values in parentheses are numbers of observed cases. \*O/S ratio: 2.3; 95% CI 1.1-4.4. †O/S ratio: 0.6; 95% CI 0.4-0.9.

Table 1. Observed (OBS) and MISCAN-simulated (SIM) proportion of breast cancer by tumour size and screening rank in the Florence District Programme (1975–1986)

	First s	creening	Repeated	screening
Tumour size	OBS (%)	SIM (%)	OBS (%)	SIM (%)
Tis				
<b>T</b> 1	9.1	5.4	6.3	7.0
T2	50.6	57.8	50.1	72.8
T3	31.2	30.0	39.7	17.6
T2+	9.1	6.8	3.9	2.6
Total	100.0	100.0	100.0	100.0

Note: For the stage distribution in the absence of screening see the text.

Table 2. FDP-observed (OBS) and MISCAN-simulated (SIM) interval cancer rates (×1000) by age and year since the last test

Age group	Time since last negative test					
	l year		2 years		3 years	
	OBS	SIM	OBS	SIM	OBS	SIM
40–49	0.29	0.35	0.50	0.80	1.18	1.17
	(24%)	(28%)	(41%)	(66%)	(98%)	(97%)
50–59	0.25	0.23	0.65	0.70	0.92	1.18
	(17%	(16%)	(45%)	(49%)	(63%)	(75%)
60-69	0.16	0.22	0.31	0.47	0.70	0.66
	(9%)	(12%)	(17%)	(27%)	(39%)	(37%)

Note: The observed/predicted ratio was never statistically different from 1. The percentages of interval cancers of the total numbers expected without screening ( $\times 100$ ) are in parentheses.

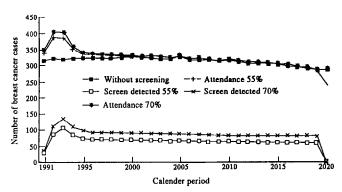


Figure 3. MISCAN-predicted number of breast cancer cases with and without screening programme.

cancers. Therefore, it was justified to use the model to predict outcomes of the FCP.

#### Predictions for the FCP

The model presented has been used to simulate the FCP, by adapting the parameters to the situation at the start of the programme. In Figures 3 and 4, the prediction of the numbers of breast cancer cases and breast cancer deaths, respectively, in the absence and presence of the screening programme, are shown for all ages considering two different attendance rates. In the first 7 years since the start of the programme, a higher occurrence of cancer is expected in the city of Florence, with a maximum of 406 cancer cases predicted in 1993 (+26.7%). This excess should be reduced after the seventh year, when an average number of 311 cases are expected versus the 317 cases predicted in the presence of screening (+2.0%). The last screening round of the simulated programme will be in 2019, and the end of screen detection of breast cancer cases explains the sudden decrease of the number in 2020.

In total, the cumulative number of screen-detected cancers until 2020 should be 2563, out of the total number of expected cases for all ages of 9095. On average, 28% of the cases would be screen-detected. The comparison of the stage distribution for all ages in the absence and presence of screening is shown in Table 3. 49% of breast cancer cases would have a tumour size below 20 mm in the absence of screening, while this percentage would be 64% with the screening programme.

A total of 3720 deaths from breast cancer were expected during the study period. Figure 4 shows the yearly number of

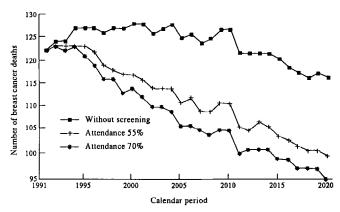


Figure 4. MISCAN-predicted number of breast cancer deaths with and without screening programme.

352 E. Paci et al.

Table 3. Distribution by tumour size with or without a screening programme as predicted by MISCAN for the city of Florence programme

Tumour size	Without screening (%)	With screening (%)	
Tis	1.6	4.6	
T1	47.3	59.7	
T2	41.7	30.7	
T2+	9.4	5.0	
Total	100.0	100.0	

Age group 50-69 years, attendance rate 70%.

breast cancer cases and deaths until 2020 predicted for the women of Florence.

With an attendance rate of 70%, on average, the screening programme should determine an absolute reduction of 472 (13%) deaths from breast cancer for all ages (Fig. 5) up to 2020. At 2020 the estimated total number of years of life gained by screening was 4354 for all ages. A second prediction, using an attendance rate of the 55% on average, predicted 357 (10%) fewer deaths than in the absence of screening and 3329 years of life gained.

#### **DISCUSSION**

The MISCAN simulation has two main steps. Firstly, the simulation of the observed results in a screening programme is obtained to check the basic assumptions used in the model; secondly, the model is used to predict the programme impact on mortality reduction in a target population over time. The application of MISCAN using the FDP basic parameters is important because, until now, MISCAN modelling of screening impact has been carried out using assumptions derived from Dutch and Swedish experiences, and this is the first application using a southern European experience.

The model seems to give a good reflection of the FDP screening outcomes, i.e. detection rates, stage distribution at the prevalence test and proportion of interval cancers, except for the stage distribution of screen-detected cancers at repeated screening.

In general, the model fits the prevalence screening observed data better than the ones at the repeated screening test. This discrepancy could be attributable to the different interscreening

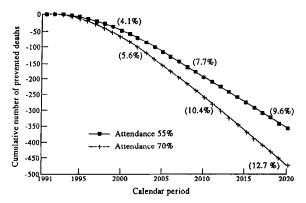


Figure 5. Cumulative number of prevented breast cancer deaths until 2020 with screening. Numbers in parentheses indicate the cumulative percentages of breast cancer mortality reduction, respectively, in the years 2000, 2010 and 2020.

interval since the previous test owing to the irregular FDP round schedule and to the 'irregular user' women. A longer interval than the scheduled one would reproduce the prevalence screening situation as time since the last test elapses [11]. For this reason we think that the prediction of the model assuming a regularity of the scheduled screening programme is correct.

In our model, the natural history of the disease is less detailed than in the previous modellings on Dutch data. Nevertheless, we consider in this context, the MISCAN simulation useful and more typical of a southern Europe experience. The mortality reduction achieved by screening in the FDP model was based on the Swedish trial and the Florence case—control study, and modelling was able to reproduce the expected result.

The proportional benefit expected for the city of Florence will be lower than in the FDP programme, mainly because of the improvement of the clinical stage distribution. The sensitivity analysis with the attendance rates of 55 and 70%, on average, confirms the relevant importance of compliance for the programme's success.

The simulation by MISCAN of the expected number of cases in the city of Florence in the absence of screening was obtained from the 1985–1987 incidence rates assumed as constant for the future. The predicted decreasing number of incident cases is only related to the lower number of women in younger cohorts. The assumption of constancy of the basic parameters over time might be biased because of cohort effects and/or diagnostic and therapeutic improvements. For this reason, MISCAN modelling should be primarily considered as a support in decision-making and to compare screening effectiveness with other health policies.

In conclusion, the MISCAN model simulated the FDP results quite well and allowed us to predict the impact of screening in the city of Florence, using assumptions based on the experience of the FDP screening programme. This scenario of the breast cancer screening impact on the city of Florence will be linked to the diagnostic and treatment procedures and costs expected in the absence and presence of screening.

Our model could be useful in the future to predict the impact of other new screening programmes in southern Europe and specifically to predict the impact of a public health programme at a regional or national level in Italy, using assumptions about parameters derived from an Italian screening experience.

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#### **APPENDIX**

Main assumptions for MISCAN modelling (sources are in the text). FDP = Florence District Programme. FCP = Florence City Programme

Age group	FDP	FCP
0-4	2.9	2.4
5_9	3.7	4.0
10–14	4.9	3.4
15–19	5.9	5.6
20–24	5.1	6.3
25–29	6.0	5.6
30–34	5.9	5.3
35-39	6.7	6.2
40 <del>-44</del>	6.6	6.2
45 <del>4</del> 9	7.1	7.2
50-54	6.7	6.8
55-59	7.1	7.4
60-64	7.5	8.1
65–69	5.8	6.2
70–74	5.9	6.6
75+	11.2	12.8

Cumulative probability of death from causes other than breast cancer for specified ages

Age (years)	FDP	FCP
5	0.0076	0.0076
10	0.0079	0.0080
15	0.0089	0.0090
20	0.0106	0.0107
25	0.0122	0.0123
30	0.0137	0.0138
35	0.0151	0.0154
40	0.0181	0.0185
45	0.0223	0.0227
50	0.0291	0.0296
55	0.0392	0.0406
60	0.0567	0.0586
65	0.0879	0.0920
70	0.1384	0.1434
75	0.2205	0.2297
80	0.4678	0.4545
85	0.6500	0.6700
90	0.8600	0.8600
95	0.9750	0.9750
100	1.0000	1.0000

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Stage-specific parameters

	Tis	T1	T2	T2+
Stage dist	ribution			
FDP	3.7%	35.7%	49.3%	11.3%
FCP	2.8%	50.9%	39.2%	6.2%
5-year sui	vival for sta	ge-specific br	east cancer	
	100%	86.5%	68.6%	45.4%
Sensitivit	y of the test			
	40%	90%	95%	95%
Prognosti cancers [3		ent for stage-	specific scree	n-detected
		52%	33%	39%