

EUROCHIP-II
FINAL SCIENTIFIC REPORT
ANNEX 13

**REPORT OF
EUROCHIP-2 ACTION IN
MALTA**

Screening coverage

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Introduction

The Maltese Action group selected and obtained approval from the EUROCHIP 2 Steering Committee to conduct a study to try to answer the following 2 questions as the ACTION for which Malta will receive funding from this project.

These 2 indicators were extracted from the Screening domain.

- 1. Percentage of women that have undergone a mammography (breast cancer)*
- 2. Percentage of women that have undergone a cervical cytology examination (cervical cancer)*

The aims of the Maltese study included investigations:

- To determine the amount of cancer screening activity happening on the Islands for breast and cervical cancers in the absence of national organised screening programmes.
- To determine the number of persons screened (by gender, age and other relevant criteria)
- To describe the type and format of output from these tests
- To describe the methods and types of tests used for screening

This research has obtained the approval of the Human Subject Research Ethics Committee of the University of Malta.

1. Percentage of women that have undergone a cervical cytology examination (cervical cancer)

1.1 Methodology

During 2006, the Maltese Action group has worked towards collecting information to evaluate the cervical cancer screening activity on the Maltese Islands. It contacted the 7 laboratories (1 public and 6 private) that perform cervical cytology examinations and requested permission to collect information on all the cervical cytological examinations performed by each laboratory from 2003-2005 (3 years).

All laboratories were approached and requested to allow the researchers to collect the following data items on each cervical cytology screen performed during the above-mentioned time frame. Permission to allow the use of the extracted necessary information from the laboratories' data sources was given to the researchers by all the laboratories that perform these examinations on the Islands.

The data requested were:

1. **Identification:** this information was aimed at collapsing all smears to single women so as to obtain an estimate of the women screened versus smears performed. Extraction of the ID numbers of cases was made available from 4 laboratories. The remaining 3 laboratories either do not collect this data item or this information was withheld from inclusion for analysis in this study.
2. **Age at smear:** age was available and collected from 5 laboratories. The remaining 2 laboratories do not retain this information in their databases.
3. **Locality of residence:** information on locality was available and collected from 5 laboratories. The remaining 2 laboratories do not retain this information in their databases.
4. **Result of smear test:** this information was available and collected from 6 laboratories. The remaining laboratory does not retain this information in a retrievable manner.

The fieldwork (collection, validation and coding) of data items for each cervical smear from the laboratories was all performed by the under-signed members of the Maltese Action group. These painstaking operations took up an inordinate time because the formats of the information stored by each laboratory differed significantly from the rest. For one of the laboratories the necessary information was only available in a paper-based register and the members of the action group had to complete the database from scratch by typing in all the information from this register.

1.2 Results

From 2003 to 2005, 90278 cervical cytological examinations were performed in the Maltese Islands. Table 1 shows the number of smears performed per year and the annual average number of smears for this time frame.

Table 1

Year	No. of smears
2003	24850
2004	25545
2005	26272
Total no. of smear for which test result is known	76667
Total no. of smears for which test result is not known	13611
Total no. of smears performed from 2003-2005	90278
Annual average number of smears	30093

Table 2 shows the proportion of the cases (smears) for which the data items documented above could be recorded.

Table 2

Data Item	No. of cases with data item	% of the total no. of cases
Identification (ID number)	35291	39.1
Age at smear	38334	42.5
Locality of residence	40487	45.9
Result of smear test	76667	84.8

1.2.1 Results on identification number

Maltese residents have a unique identification number that is given to them on registration either at birth (in the vast majority of cases) or on acceptance as a Maltese resident and/or citizen. In our subset the identification number was recorded for almost two fifths of the whole group. Aggregation of repeated identification numbers in this group yielded the results shown in Table 3 about the frequency of smear taking by the women who were examined within this 3-year time period.

Table 3

No. of smears performed from 2003-2005	No. of women	% of all women with known ID no.
Once	16719	68.2
Twice	5492	22.4
3 times	1827	7.5
4 times	315	1.3
5 times	107	0.4
6 times	45	0.2
7 times	6	0.02
8 times	1	0.004
Total no. of women with known ID no.	24512	100

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It is acknowledged that this subset is not representative of the whole group. However, it can be assumed that the group of cases with recorded ID numbers is not markedly different from the group for which the identification number could not be obtained. This information can be used to indicate that about 70% of women performing a smear from 2003-2005 had only one smear taken during this 3-year time period.

1.2.2 Result on age

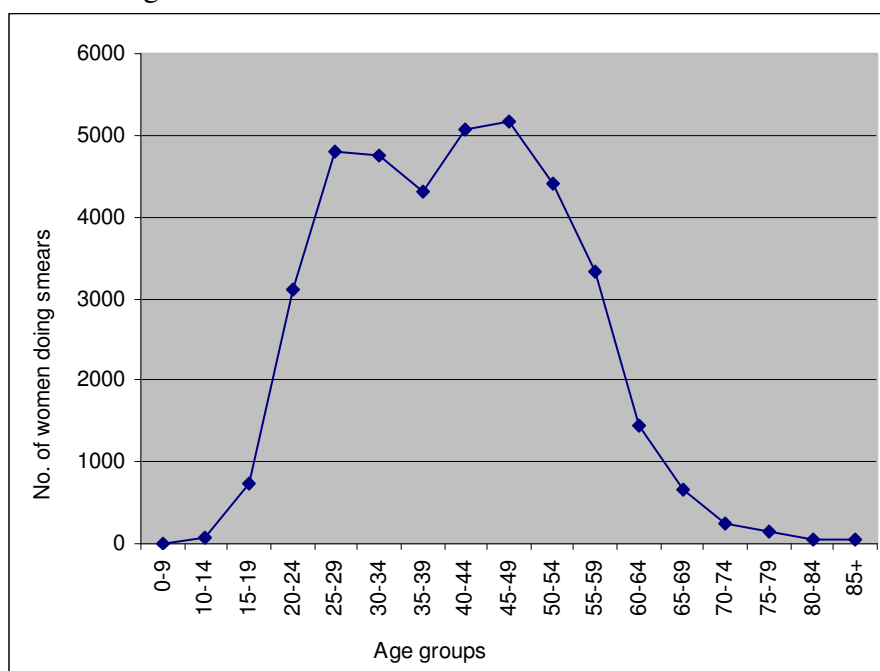
The reported age of the cases at the time of the smear was retrieved for 38334 (42.5%) cases. Table 4 shows the age groups of the cases with known recorded age.

Table 4

Age group	No. of cases	% of all women with known Age
0-9	0	0
10-19	805	2.1
20-29	7905	20.6
30-39	9056	23.6
40-49	10241	26.7
50-59	7755	20.2
60-69	2094	5.5
70-79	380	1.0
80+	98	0.3
Total no. with known age	38334	100
No. with unknown age	51944	
Total no. of smears	90278	

Figure 1 shows the distribution of cytological examinations by age groups. Smear taking peaked between the ages of 25 and 49 years. The activity started to drop from age 50 years and dropped sharply during the 6th and 7th decades of life. This distribution contrasts with what would be expected in an organised screening programme, since in most countries where such a programme is operating invitation to women is sustained until around 70 years of age.

Figure 1



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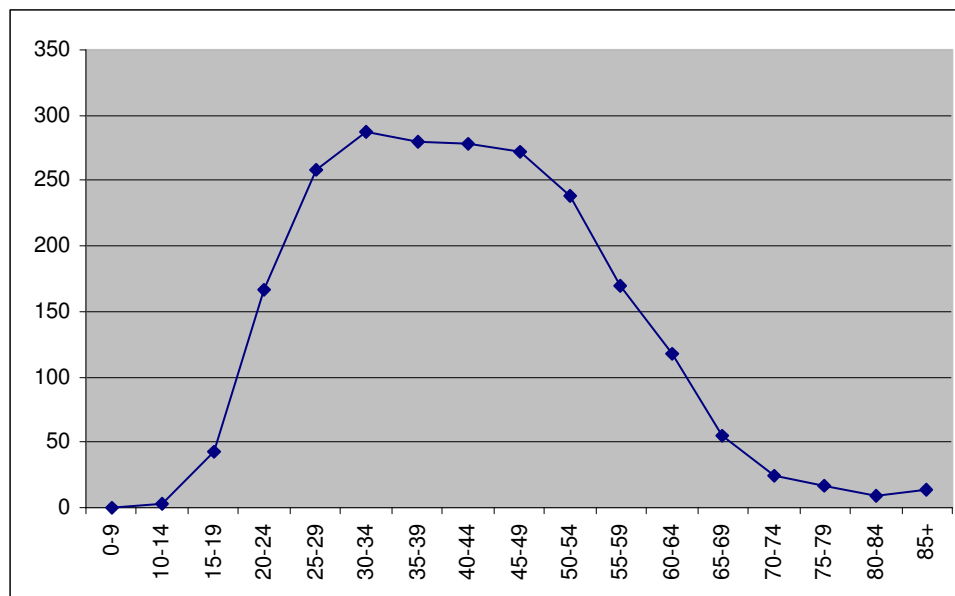
It was assumed that the age structure of the whole group of smears performed from 2003-2005 was not markedly different from the subset of cases for which the information on Age was retrieved. Using this assumption, the data was extrapolated to the whole group and the number of smears per age group per 1000 women in that age group of the population was calculated using the mid-2004 population for the Maltese Islands^{1,2}. The results of these calculations are shown in Table 5.

The rates showed in Table 2 and illustrated in Figure 2 compliment the distribution of the number of smears done by age groups. The highest rates were between the ages of 30 and 49 years, with correspondingly lower rates for the 20-29 age groups and for women at or older than 50 years. Presumably, the practice of having regular cervical cytological examinations is fairly recent for Maltese women, and since this is done only on self-initiative (there is no formalised invitation system on a national scale) one may expect that younger women will continue in this new practice as they get older and thence the rates will continue at a higher level for older age groups in the future.

Table 5

Age groups	Cases with known age	Extrapolation of age to all smears	Annual no. of cases [Observation/3]	Mid-year population 2004 females	Annual smears /1000 population
0-9	0	0.0	0.000	21593	0
10-14	65	153.1	51.026	13389	3.811
15-19	740	1742.7	580.909	13774	42.174
20-24	3110	7324.2	2441.389	14683	166.273
25-29	4795	11292.4	3764.135	14542	258.846
30-34	4750	11186.4	3728.809	12956	287.806
35-39	4306	10140.8	3380.266	12116	278.992
40-44	5074	11949.5	3983.153	14346	277.649
45-49	5167	12168.5	4056.159	14921	271.851
50-54	4420	10409.3	3469.755	14507	239.186
55-59	3335	7854.0	2618.016	15443	169.528
60-64	1435	3379.5	1126.493	9582	117.563
65-69	659	1552.0	517.323	9378	55.163
70-74	245	577.0	192.328	8090	23.775
75-79	135	317.9	105.977	6103	17.365
80-84	47	110.7	36.896	4198	8.789
85+	51	120.1	40.036	2809	14.253
Total	38334	90278.0	30092.667	202429	148.658

Figure 2



1.2.3. Results on locality

Information on the locality of residence was obtained for 40487 (45.9%) of the smears performed between 2003 and 2005. However, unlike Age we cannot assume that the group of cases with known locality is not markedly different from the group for which we could not retrieve this information. This is because people living within the geographic proximity of any of the private laboratories tend to gravitate more towards this laboratory for their needs than those living further away. Therefore, due to considerable number of cases for which this information is absent, it was felt that further analysis of this information was not possible and worthwhile.

1.2.4. Result of smear test

This data item was obtained for 76660 (84.8%) of all the cytological examinations. Table 6 demonstrates the categories in which these results were classified, the number of smear results in each category and the percentage of each of these groups to the total number of smears. Assuming that the distribution of results of smears in the whole group is not markedly dissimilar to the group for which this information was acquired, the number of smears resulting in an ‘Abnormal’ or ‘Malignant’ outcome would be 1007 and 29 respectively, for the whole group of smears performed from 2003 and 2005. Therefore, for one positive outcome in these last two categories there were 87 smears with results that were classified in the ‘Normal’ or ‘HPV/ Viral changes’ categories.

Table 6

Category	Number of smears	% to the total number of smears
1. Normal/ Inflammatory/ Infections/ Borderline	74752	82.80
2. HPV/ Viral changes	1028	1.14
3. Abnormal (Dyskaryosis/ CIN/ LGSIL/ HGSIL/ ACSUS/ Atypical/ Suspicious cells)	855	0.95
4. Malignant (Squamous/ Endocervical/ Endometrial/ Recurrence in vault smears)	25	0.03
9. Unknown	13618	15.08
Total no. of smears	90278	100.00

2. Methods of cervical cytological examinations employed in Malta

All laboratories receive cervical smears on glass slides that have already been fixed with an alcohol spray fixative / 95% ethyl alcohol. They are registered and given a laboratory identification number and then stained using the Papanicolau staining routine. Stained slides are examined by a cytoscreener (qualified medical laboratory scientist), and in some laboratories a percentage or all slides are re-examined by another cytoscreener for quality assurance purposes. Abnormal slides are referred for final diagnosis and reporting by a pathologist.

Unlike in many other countries in Europe the liquid-based technique has not been yet introduced by any of the laboratories in Malta. Smears are still being taken using the conventional spatula/brush methods.

3. Conclusions

This study managed for the first time to quantify the amount of cervical cytological examinations that were performed on the Maltese Islands. On average about 30,000 smears are performed annually. Organised cervical cytology screening programmes usually cater for women aged between 20 and 69 years of age. The number of women in this age group in the mid-2004 population estimates amounted to 132,473. Invitations for cytological screening are often delivered to entitled women every 3 years. Therefore, the volume of annual smears that would be expected to be performed if an organised cervical screening programme is implemented, assuming a 100% response rate, would amount to about 44,000 smears for women in the 20-69 year age group. Currently, with the opportunistic screening scenario prevalent in Malta about 29,000 of the women in this age group are being screened annually.

The major problem encountered during the fieldwork for this research was the inconsistencies between the laboratories' internal data storage facilities for these tests. Six laboratories had an electronic database while one of the laboratories only kept a paper-based register. In addition, the six existing databases were all of a different format, collected different data items on their cases and most of them are rather unsuitable for audit purposes and analysis of outcomes. Consequently, the collation of the necessary information for this study was rendered very laborious and time-consuming.

4. Recommendations

A consensus building exercise should be initiated to promote a more uniform and appropriate collection of information on laboratory procedures both in respect of cervical cytology examinations and also for other activities. Laboratories will benefit from the assistance provided during this initiative to develop database capabilities that will primarily facilitate their own internal audit of their operations and outcomes of their activities. Subsequently, a more consistent national approach of data collection will benefit the whole population of the Islands because it will enable the collection of more complete, timely and reliable information that needs to be utilised for qualitative and qualitative assessments of the capacity to perform these procedures, to evaluate the effectiveness of the services offered and identify the priority areas for services development.

Acknowledgments

The researchers wish to acknowledge and show their appreciation for the valuable cooperation received from all the laboratories that perform cervical cytological examinations on the Maltese Islands during the implementation of this study.

References

1. Demographic Review of the Maltese Islands, 2003: National Statistics Office, Malta (2004)
2. Demographic Review of the Maltese Islands, 2004: National Statistics Office, Malta (2005)

2. Percentage of women that have undergone a mammography (breast cancer)

During 2007, the Maltese Action group has worked towards collecting information to evaluate the breast cancer screening activity on the Maltese Islands. Currently, in Malta there are 14 operating mammography units (two in the public sector and the rest in the private sector).

Permission was requested from the Chairman of Radiology to collect information on the mammography examinations performed at St. Luke's Hospital (SLH), which at that time was our public hospital (since November 2007 the acute general public hospital services have all been transferred to the new Mater Dei Hospital). The permission was granted and we were given information on all mammographies done with the only unit in the public sector from 2003-2005, which amounted to a total of 10938 mammographies. However, on evaluation of this data, it resulted that the only information that could be extracted was the number of screens. This data did not have any information on patient characteristics (such as age and location). Up to now there is no organised breast cancer screening in Malta. Women referred for mammographic examination at the public unit include both symptomatic patients and women referred for screening due to increased risk (mostly strong family history). Opportunistic screening activity is also known to occur. However, from the database available it was not possible to quantify the number of cases in the 3 referral groups identified above. Also, to date the results of the mammography examinations were not being recorded electronically and hence were not available from the information examined.

Following extensive consultation and evaluation, the Maltese Government pledged its intention to implement an organised breast cancer screening programme for women aged 50-59 years in accordance with European guidelines on quality assurance in mammography, late in 2007. The programme infrastructure is currently being set up (the biggest limiting factor being the lack of specialised human resources) and should roll out in 2008. All females aged between 50 and 59 (30,000) will be invited for breast screening over a three-year period. Once the programme is well established, it is envisaged that the next step will be extend screening to women aged 60 to 69.

Under these circumstances, the researchers (who are both public officials) and who are involved in the administration of the public health care sector, felt that it would be not wise to further continue with their data collection by contacting the private sector. Researchers believe that trying to collect information on the mammography screening activity from the private facilities at this stage may be interpreted as an attempt to interfere with their commercial business activity. This information will now need to be collected through official channels.

Results

From 2003 to 2005, 10938 mammograms were performed in our public hospital.

Table 1 shows the number of mammograms performed per year and the annual average number of smears for this time frame.

Table 1

Year	No. of mammograms
2003	3508
2004	3536
2005	3894
Total no. of mammograms performed from 2003-2005 at SLH	10938
Annual average number of mammograms	3646

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During 2003 and 2005 there were 2458 patients referred for mammography by the Breast Clinic.

Most of these patients were symptomatic patients, but some of them were referred for screening due to high risk from a strong family history of breast cancer. Unfortunately from the data given we cannot quantify which were the screening patients and the symptomatic patients. Table 2 shows the number of mammograms that were referred by the Breast Clinic.

Table 2

Year	Total no. of mammograms performed at SLH	No. of mammograms referred by the Breast Clinic
2003	3508	735
2004	3536	731
2005	3894	992
Total no. of mammograms performed from 2003-2005 at SLH	10938	2458

Conclusion

In 2007, the declaration of the Government of Malta commitment to roll out the initial phase of an organised population-based screening programme during 2008 will be addressing the need that has been felt for a long time for such a service. Presently, a steering committee is working towards solving the significant logistic issues that need to be rectified before implementation is realised. The most important problem involves the securing of the expert human resources needed to operate the programme. These include radiologists, surgeons, pathologists, cytoscreeners and other professionals specialised in the techniques specific to breast cancer screening methodologies. This problem is compounded by the smallness of the country and also by the increased mobility of health care professionals to other countries (especially to other EU Member States) that can offer more competitive and attractive employment packages and opportunities than their home country.

The opportunistic mammographic screening activity currently prevalent in Malta is currently a major income generator to private healthcare facilities and the proposed organised screening programme may be viewed as a threat by these business concerns. Because of this, the under-signed researches strongly believe that if they continued with their plans to contact private imaging centres with the planned requests on their past activity, they could have jeopardised government's efforts to successfully organise and launch the organised programme*. Both researchers have however, through their other professional activities (especially the Malta National Cancer Registry) helped significantly towards creating and promoting the case for population-based organised breast cancer screening in Malta. These efforts culminated by the declared government commitment in 2007.

* both researchers are known government employees