

STATISTICAL REPORT

October 2000 - December 2003

REVIEW



PHASE I

Mid-Western Health Board

DECEMBER 2004

summary



Phase I of the Irish Cervical Screening Programme commenced in October 2000 in the Mid-Western Health Board with the purpose of testing the operational elements of implementing a national organised call / recall cervical screening programme.

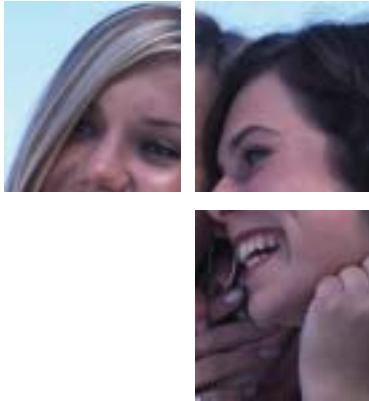


This statistical review, which looks at the outcomes of this new cervical screening service up to December 2003, found that coverage of the target population of women aged 25-60 in the Board's region progressed well reaching a level of 70.1% in 2003 and is within reach of international cervical screening targets of 80%. For the majority of women access to the service was initiated at the discretion of their doctor compared to only around 20% of women having a smear test taken in response to an Irish Cervical Screening Programme invitation letter.

Altogether, 38,150 women were smear tested with 5% requiring referral to colposcopy services. Just under 57,000 smears were taken over the three year review period of which 21,033 generated a follow up recommendation of a one year repeat smear following a first time normal smear result.

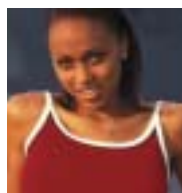


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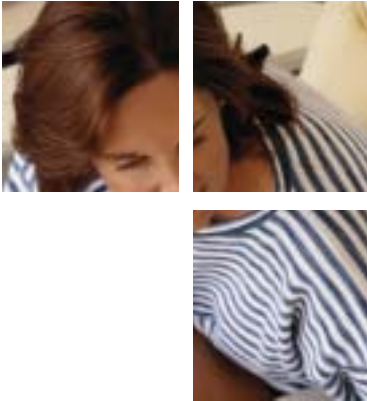
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1.1 Background

The aim of the Irish Cervical Screening Programme (ICSP) is to decrease the incidence of, and mortality from, cervical cancer in Ireland. The screening tool is the smear test and screens for asymptomatic pre-cancerous cell changes in the neck of the womb (cervix) providing the opportunity for early clinical intervention to preclude invasive cancer.

The first phase of the ICSP was launched in the Mid-Western Health Board in October 2000. The Phase I programme has a dual purpose, firstly, to offer free cervical screening to all women aged between 25 and 60 residing in the Mid-Western Health Board's regions defining the eligibility criteria for Phase I, and secondly, to test the operational elements of implementing a national organised cervical screening programme for the population of Irish women.

An electronic Cervical Screening Register (CSR) of eligible women has been created and is the basis for the ICSP call/ recall screening programme. The CSR is populated primarily from the Department of Social and Family Affairs database of women. Provision is made in the Health (Provision of Information) Act 1997 for the ICSP to have this information for the purpose of inviting women for screening.

1.2 Phase I screening policy

The ICSP is committed to a quality assured cervical screening pathway for women from smear taking, screening and diagnostics through to treatment. The screening policy framework for Phase I ICSP to date is delineated from the 1996 *Report of the Department of Health Cervical Screening Committee*. In general, a routine five yearly screening cycle is offered to eligible women with no abnormalities detected on smear testing. In this initial phase of the programme, women experiencing first time screening are recommended to have a one year repeat, and women over 60 are accepted for screening where no previous smear history exists. Table 1 details the standardised ICSP cytology reporting codes and recommended follow up for the full range of possible smear test results.

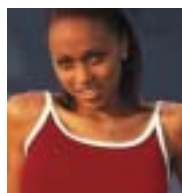
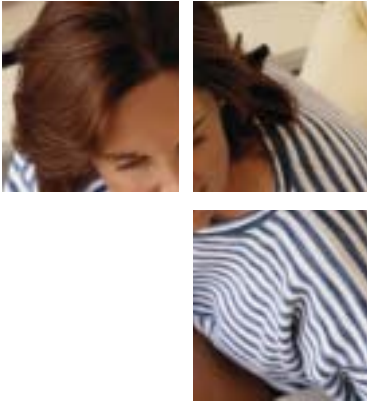


Table 1. ICSP cytology result codes and management recommendations

Cytology pattern		Management recommendations	
P1	Unsatisfactory / inadequate	R6 R7 R7	Repeat smear in 1 – 3 months time Refer for colposcopy after 3 consecutive unsatisfactory / inadequate results Refer for colposcopy – single unsatisfactory / inadequate after treatment
P2	Negative	R1 R2 R3 R4 R7	No further screening required Normal recall Repeat in 12 months (either previous history available or first smear) Repeat smear in 6 months if first negative after colposcopy treatment Refer for colposcopy opinion if suspicious cervix
P3	Borderline nuclear abnormalities (BNA) (squamous) or HPV	R4 R7	Repeat smear in 6 months Refer for colposcopy after 3 consecutive BNA (sq)
P4	Mild dyskaryosis	R4 R7 R7 R7	Repeat smear in 6 months Refer for colposcopy after 2 consecutive mild dyskaryosis Refer for colposcopy - single mild dyskaryosis after colposcopy treatment Refer for colposcopy - if 3 untreated mild dyskaryosis in 10 years
P5	Moderate dyskaryosis	R7	Refer for colposcopy
P6	Severe dyskaryosis	R7	Refer for colposcopy
P7	Query invasive squamous carcinoma	R7 R8	Refer for colposcopy Refer for specialist gynaecology opinion
P8	Borderline nuclear abnormalities (glandular)	R5 R7	Repeat smear in 3 months Refer for colposcopy after 2 consecutive BNA (gl)
P9	Query glandular neoplasia	R7 R8	Refer for colposcopy Refer for specialist gynaecology opinion
P10	Slide damaged	R6	Repeat smear in 1-3 months



1.3 ICSP working structures

The ICSP central office provides strategic direction and planning for cervical screening at regional and national levels. The operational components of the central organisation are management of the CSR, quality assurance, promotion, smear-taker co-ordination and training, laboratory co-ordination, and information technology and administration supports. The key designated partner services working with Phase I ICSP along the screening continuum are:

Smear-takers	General Practitioners (GPs)	(n =219)
	Practice Nurses	(n =128)
	Family Planning Clinic medical / nursing staff	(n=10)
	Women’s Health Centre medical / nursing staff	(n=2)
	Colposcopists / colposcopist nurses	(n=9)
Screening	Cytology Laboratory	St. Luke’s Hospital, Dublin
	Cytology Laboratory	University College Hospital Galway (UCHG)
	Cytology Laboratory	Royal College of Surgeons Ireland (RCSI) –an operational trial in 2002-2003
Diagnostics	Histology Laboratory	Mid-Western Regional Hospital, Limerick
Treatment	Colposcopy Clinic	Mid-Western Regional Maternity Hospital, Limerick

1.4 Scope of statistical report

This statistical report sets out to retrospectively review ICSP Phase I activity relating to the woman for the period October 2000 to December 2003 with the purpose of analysing the short term outcomes of the early stages of a population screening programme for women in the Irish setting. Medium to long term outcomes will be reviewed in time to include the impact of the screening programme on cervical mortality and morbidity, and sensitivity and specificity validity testing of the screening tool.

The objectives of this analysis focus on the levels of screening, and on smear generated cytology and clinical activity. In particular:

1. To ascertain the annual uptake, and overall coverage, of smear testing by women in the Phase I Mid-Western Health Board region.
2. To outline the method of entry for women into the screening programme.
3. To determine the frequency of smears and to provide a measure of the level of adherence to ICSP screening policy.
4. To report ICSP generated laboratory and colposcopy activity describing cytology and histology findings amongst women screened.



2.1 Data collation

The prime source of data for this presentation is taken from the CSR and based on data up to 31st December 2003. Reporting on screening activity at population level in the Phase I Mid-Western Health Board region is made possible by the demographic details and screening data stored centrally in the CSR for each woman.



2.2 The CSR information system

The CSR has a number of functions and is programmed to action the following key service requirements of the ICSP:

- systematic call/recall of women in the ICSP target age group for routine screening
- central collection and retention of screening generated clinical data on the women
- activation of timely failsafe mechanisms for prompt follow up of results that are not normal.



2.2.1 Call / recall of women for routine screening

Women are systematically targeted from the CSR by invitation letter to attend a registered smear-taker for a routine smear. In the start up phase of the programme, women do not have to wait for an invite from the ICSP and can enter the programme directly at the discretion of their GP. Each woman at the time of her smear is requested to give signed informed consent on the cytology request form to have her information retained on the CSR and be part of the ICSP screening service. Cytology laboratories only report consented smears to the ICSP office.

2.2.2 Collection and retention of clinical screening data

The CSR is the central electronic repository and conduit for cytology, histology and colposcopy activity on the woman. Electronic linkages are established at the CSR interface with the cytology laboratories at St. Luke's Hospital and UCHG, with the histology laboratory at the Mid-Western Regional Hospital, and with the colposcopy clinic at the Mid-Western Regional Maternity Hospital.

By way of these electronic linkages, cytology notification of smear sample receipt and result (Table 1) is sent to the CSR. Only notifications of smears fulfilling ICSP policy requirements trigger payments to GPs. Similarly, receipt and result information relating to biopsies is transferred to the CSR from the histology laboratory. Data received on the woman from colposcopy include attendance frequency and a list of procedures undertaken.

2.2.3 Failsafe

Non events, within defined periods, against expected cytology management recommendations (Table 1) set in motion the CSR's failsafe mechanism. Current failsafe procedures are applied to all repeat smears and failsafe letters are issued to both the woman and her GP.



2.2.4 Validation of the CSR's population of women

A minimum data set is established for the CSR and interface electronic linkages to facilitate unique identification of a woman across inputs and outputs. The Personal Public Service (PPS) number is the unique identifier recommended. An extensive de-duplication process of women's files has been undertaken and matching software is active on the CSR. Information retained on the women for ICSP purposes is subject to the Data Protection Act.



3.1 Profile of the CSR

The CSR contained the files of 84,731 women for Phase I of the screening programme as of December 2003. These women are grouped into one of three categories: active, inactive or permanently inactive (Table 2).



The active category essentially represents the live register for the programme. Women in this category are those who are known to meet the ICSP eligibility criteria and are available for ICSP initiated call/recall/repeat smear testing.

The inactive category identifies those women who are, for an interim, exempt from the programmed call/recall/repeat smear testing cycle embedded in the CSR for reasons such as self-deferral of routine smear, the woman is under the care of colposcopy services or undergoing other medical treatment, is reported to be pregnant, is under age or has temporarily moved out of the ICSP region.



The permanently inactive file is an archive of women who are not, or no longer, eligible for the screening programme due to death, reaching the age of 61, having a history of a total hysterectomy, lost to follow up, having moved out of the country or having requested not to be part of the programme.

Table 2. Number of women on the CSR by age group and category

Age group	Active	Inactive	Permanently inactive	Total
<25	0	1,613	12	1,625
25-29	5,977	780	171	6,928
30-34	13,715	1,305	820	15,840
35-39	12,267	1,110	551	13,928
40-44	10,941	839	463	12,243
45-49	9,352	572	457	10,381
50-54	8,345	521	452	9,318
55-59	7,024	472	681	8,177
60 only	1,140	84	124	1,348
61+	401	159	4,383	4,943
All Total	69,162	7,455	8,114	84,731



Figure 1 profiles the CSR population demographics against the 2002 census data for the Mid-Western Health Board region. The under 25 and over 60 age groups, and women in the permanently inactive CSR category have been excluded to better reflect the ICSP target population.

On the whole the correlation is good between the CSR and census 2002 counts of women. The number of women aged 35 years and over in the CSR is aligned well with the census while less congruence is evident in the lower age groupings especially for those women under 30. This younger cohort is more mobile in residential terms than older age groups and could explain the disparity.

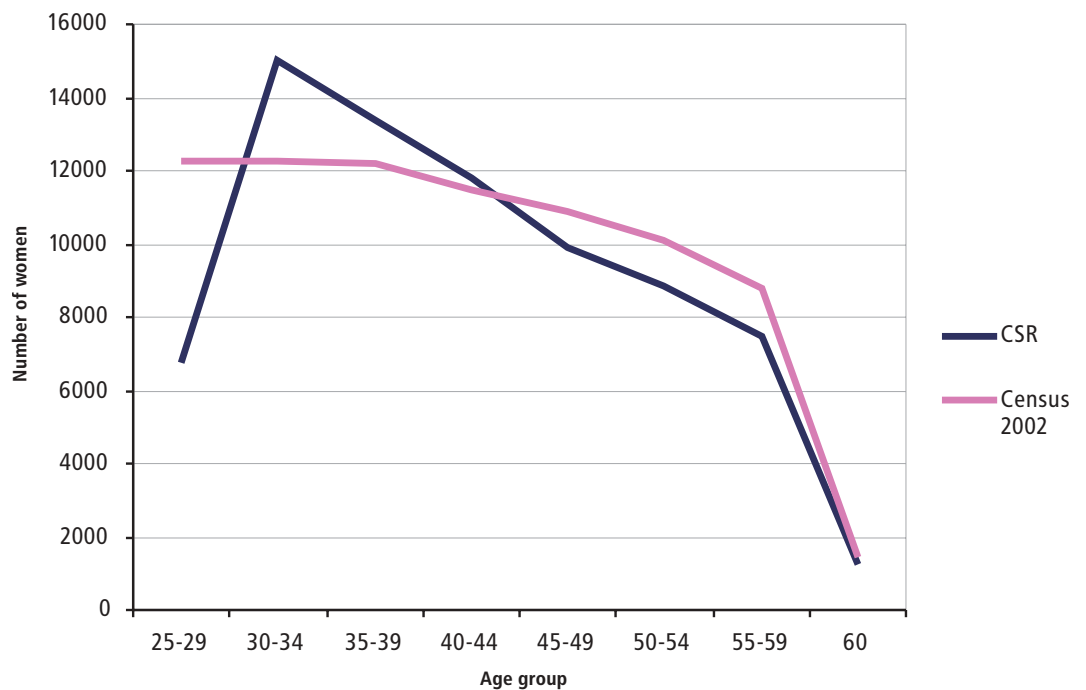


Figure 1. Correlation between the number of eligible women on the CSR database and the census 2002 for the Mid-Western Health Board region

3.2 Level of screening

3.2.1 Number of women screened

Between 2000 and 2003, 38,150 women attended for cervical screening in the Phase I region of which 8.2% (3,127/38,150) were below the age threshold for ICSP screening (Table 3). The number of new women screened each year for the complete years of 2001-2003 remained steady and 1,114 women over 60 had a smear test for the first time by way of the programme.



Table 3. Annual number of new women screened by age at first ICSP smear

Age group	2000*	2001	2002	2003	Total
<25	221	1,040	965	901	3,127
25-29	289	1,819	1,749	1,540	5,397
30-34	277	1,837	1,818	1,881	5,813
35-39	265	1,826	1,832	1,847	5,770
40-44	251	1,601	1,565	1,641	5,058
45-49	245	1,304	1,292	1,438	4,279
50-54	183	1,072	1,030	1,181	3,466
55-59	118	670	1,530	1,267	3,585
60 only	14	78	293	156	541
61+	41	280	466	327	1,114
Total	1,904	11,527	12,540	12,179	38,150

* From October

3.2.2 Coverage

Coverage is a cumulative measure of the number of eligible women (25-60 years) who have undergone smear testing over the screening interval and provides information on the relative extent to which the ICSP is reaching its target population. Coverage of women in the Mid-Western Health Board region over the 39 months period from October 2000 – December 2003 is defined as the number of women screened expressed as a percentage of the number in the active and inactive CSR database expected to be screened up to that period into the five year screening interval (39/60 months).

Coverage to the end of 2003 was 70.1% (33,909/48,388) and was highest in the 25-34 and 55-59 age groupings (Figure 2). This latter group has been targeted more frequently with invitation letters to attend for screening before reaching the age of 61.

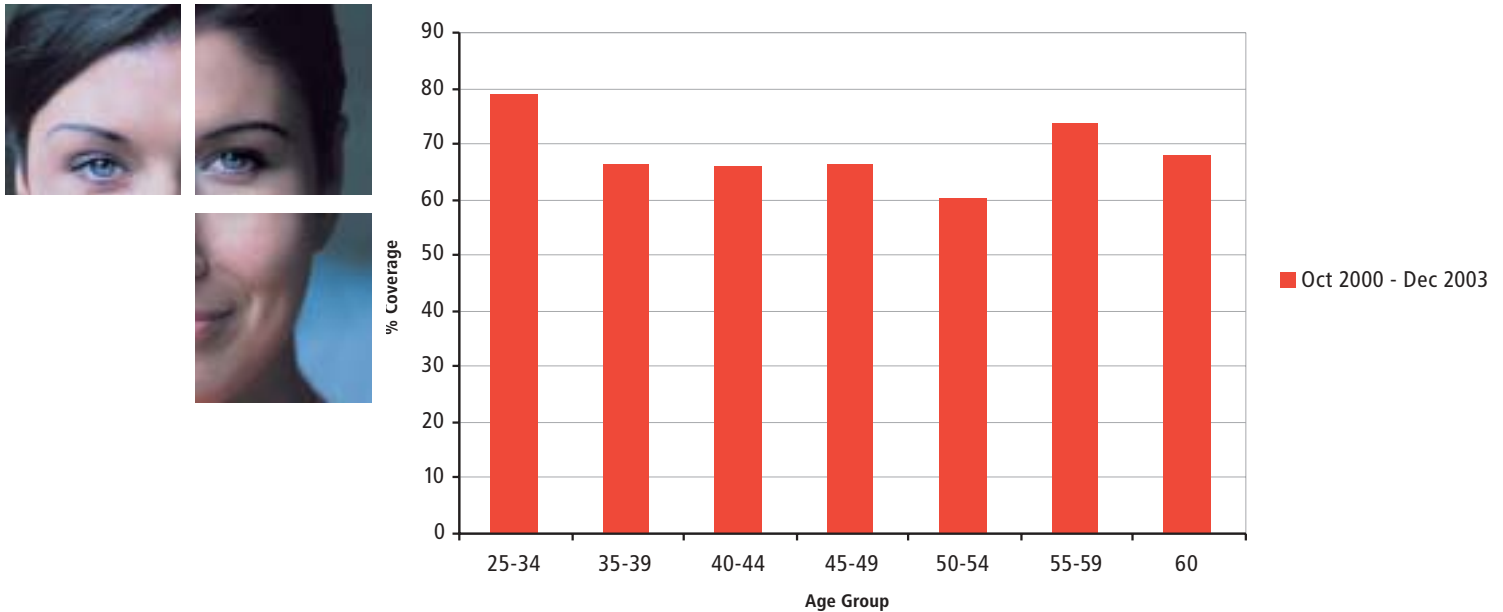


Figure 2. ICSP coverage for the period October 2000 –December 2003

3.3. Entry for women into the cervical screening programme

During Phase I of the ICSP, first programme smear can be as a result of an ICSP invitation letter issued to the women or can be directly initiated at the discretion of her doctor. The ICSP did not begin to issue invitation letters until 2001. A direct smear pre-empts an invitation letter being sent to the woman in the first five year screening interval.

3.3.1 Method of entry

The majority, 81.1% (30,929/38,150), of women screened entered the programme directly and included almost all women under 30 years of age (Figure 3) taking into account that no invitation letters are issued to women under 25. Those most likely to attend for smear testing as a result of an invite from the ICSP were women over 55 years of age. Some 61 year old women received invitation letters prior to 2004.

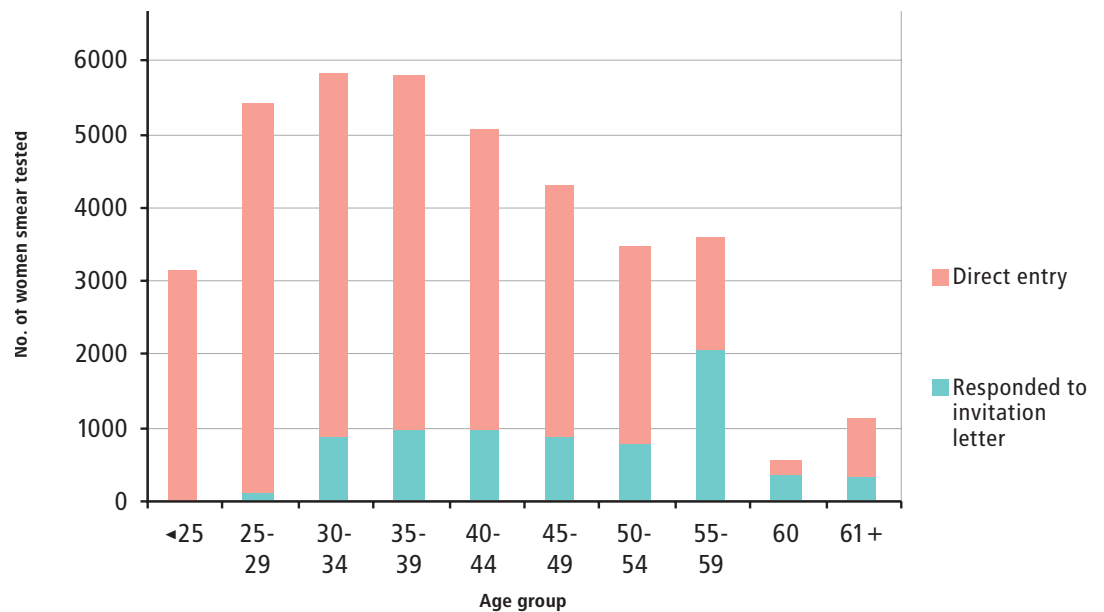


Figure 3. Method of programme entry for women by age group

3.3.2 Response of women to invitation letters

The CSR initiates a 'call' for individual women in an organised manner and invitation letters ensue calling these women to attend an ICSP registered smear-taker for free smear testing. The length of time the call currently remains open is six months and reminders are sent to the woman if no smears are forthcoming within the call cycle.

Over the review period, 74,797 invitation letters including reminders were sent to 27,652 women offering free screening as part of the ICSP systematic call / recall programme. Table 4 gives an indication of the level of response of these women to the invite letters with response benchmarked against the call open cycle of six months. Twenty eight percent (7,832/27,652) of women had a smear taken sometime during the six months following the issuing of the invitation letter. A further 13.1% (3,613/27,652) did not have a smear taken for a number of reported reasons as listed in Table 4. There were a large number of non-responders, 58.6% (16,207/27,652), which cannot fully be explained by the possibility of the CSR holding an incorrect address on the woman. Further exploration is required of the reasons why some women do not respond to an ICSP written invitation.



Table 4. Response of women to an invitation letter to attend for an ICSP smear

Responses	No. of women	% of total no. of women issued an invitation letter
Smear taken within the call open period	7,832	28.3
Recent smear taken prior to receiving letter	177	0.6
Woman requested not to be part of the ICSP	297	1.1
Woman reported to have died	84	0.3
Reported history of total hysterectomy	1,216	4.4
Living outside the ICSP region	1,267	4.6
Non responders	16,207	58.6
Other	572	2.1
Total	27,652	

3.4 Smear activity

3.4.1 Number of smears

The 38,150 women screened generated almost 57,000 smears (Table 5) arising out of routine smears, routine one year repeat smears, repeats in follow up of results that were not normal and some inappropriate smear-taking. The number of women over the review period having a smear for the first time for which the cytology result recommended a routine repeat smear in one year was 21,033.



Table 5. Number of annual smears taken by woman's age group

Age group	2000*	2001	2002	2003	Total
<25	221	1,181	1,338	1,371	4,111
25-29	289	2,155	2,779	3,091	8,314
30-34	278	2,108	2,918	3,609	8,913
35-39	265	2,096	2,849	3,395	8,605
40-44	251	1,837	2,492	3,124	7,704
45-49	245	1,503	2,047	2,670	6,465
50-54	184	1,210	1,647	2,151	5,192
55-59	118	758	2,001	2,286	5,163
60	14	86	359	326	785
61+	41	316	631	678	1,666
Total	1,906	13,250	19,061	22,701	56,918

* From October

3.4.2 Adherence to ICSP screening policy

Smears are deemed to adhere to ICSP policy if the woman has given consent; meets the eligibility criteria for the ICSP, and repeat smears are as a result of one of the cytology management recommendations outlined in Table 1.

Overall, policy smears represented 82.1% (46,721/56,918) of all smears received by the ICSP and accounted for €1,939,063 worth of payments issued to GPs to the end of 2003 (fee per smear ranged from €40.19 in 2000 – €44.98 in 2003). Almost one fifth (10,197/56,918) were inappropriate smears for which no payment was made and included all non policy smears on women under 25 years of age. The level of inappropriate smear-taking was generally low within the ICSP eligible (25-60 years) population (Figure 4).

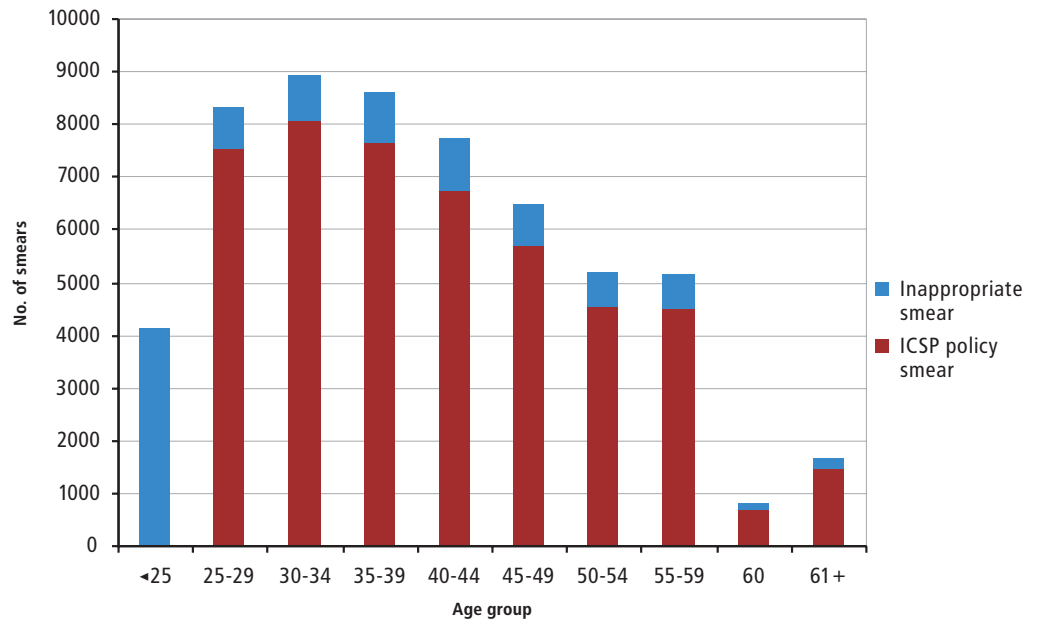
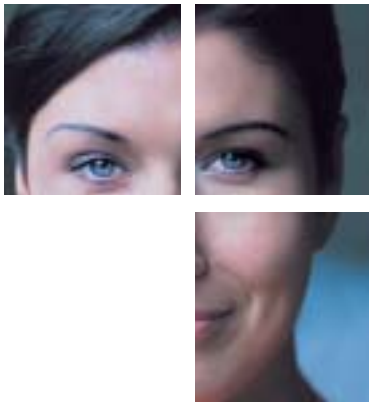


Figure 4. Distribution of ICSP policy and inappropriate smears by woman's age

3.5 Cytology

Of the 56,918 smears taken, the slides of 320 smears were either damaged or broken and a further 3,231 were pending results at the end of 2003 and are not included in this analysis. The remaining 53,367 smear samples are reported here.

3.5.1 Cytology findings

Eighty three percent of smears were found to be normal while around 10% were inadequate for cyto-screening and required repeating (Table 6). Smear samples where moderate and severe dyskaryosis was found and where invasive squamous carcinoma and glandular neoplasia were suggested represented almost 2% of all smears tested.

Laboratories at UCHG and St. Luke's Hospital process the ICSP's conventional PAP smears. The RCSI laboratory undertook a trial of liquid based cytology (LBC) smears in 2002-2003 to report on logistics and transport issues with that type of smear preparation.

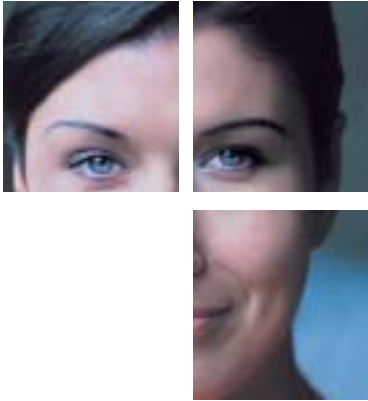
University College Hospital Galway was the largest processor of ICSP smears up to the end of 2003 accounting for 67.3% (35,935/53,367) of all smears reported with another quarter (12,810/53,367) being processed by St. Luke's Hospital. The level of inadequate or unsatisfactory reporting at UCHG and St. Luke's Hospital on PAP smears ranged from 9.2% (3,311/35,935) - 12.5% (1,598/12,810) respectively compared to 2.1% (97/4,622) at RCSI using LBC.

analysis

Year	Smear		Cytology findings												
	NAD		Unsatisfactory/ Inadequate	BNA (sq) or HPV	BNA (gl)	Mild dyskaryosis	Moderate dyskaryosis	Severe dyskaryosis	Query invasive Sq Ca	Query Glandular Neoplasia					
	No. % of n		No. % of n	No. % of n	No. % of n	No. % of n	No. % of n	No. % of n	No. % of n	No. % of n	No. % of n	No. % of n	No. % of n		
2000*	17 8 47.1	4 23.5	1 5.9	0 0	3 17.6	0 0	0 0	0 0	0 0	1 5.9					
2001	8,642 7,162 82.9	842 9.7	260 3.0	19 0.2	174 2.0	80 0.9	102 1.2	1 0.0	2 0.0						
2002	20,324 16,825 82.8	2,046 10.1	636 3.1	25 0.1	375 1.8	207 1.0	193 0.9	13 0.1	4 0.0						
2003	24,384 20,365 83.5	2,114 8.7	767 3.1	22 0.1	590 2.4	263 1.1	237 1.0	14 0.1	12 0.0						
Total	53,367 44,360 83.1	5,006 9.4	1664 3.1	66 0.1	1142 2.1	550 1.0	532 1.0	28 0.1	19 0.0						



Table 6. Cytology findings



3.6 Histology

Histology findings relating to the cervix were reported for 752 women screened. The highest ranking SNOMED coding (British Society of Clinical Colposcopy and Cervical Pathology) is reported here for each woman.

3.6.1 Histology findings by age

For almost half of women the severest SNOMED result was low grade CIN 1 with a high distribution among women under 25 years of age (Table 7, Figure 5). Over a quarter of women were found with pre-invasive CIN 3. Carcinoma was diagnosed in 5 women.

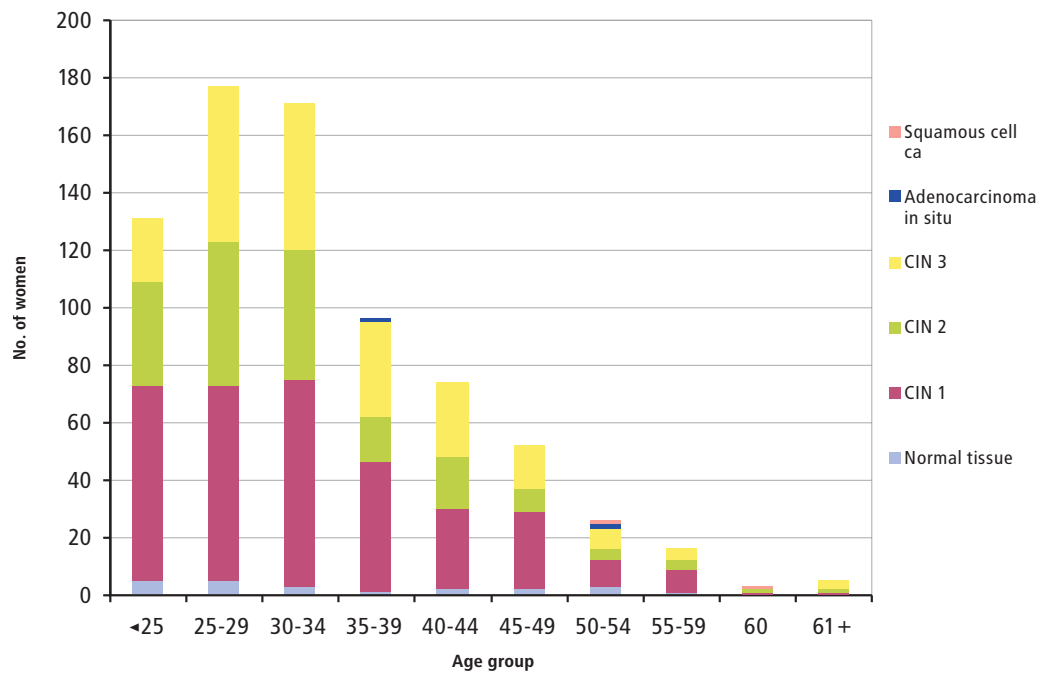


Figure 5. Age distribution of histology findings by highest ranking SNOMED grade

analysis

Age group	n	Histology findings* Women											
		Normal tissue			CIN 1		CIN 2		CIN 3		Adeno-carcinoma in situ		Squamous cell ca
		No.	%of n	No.	%of n	No.	%of n	No.	%of n	No.	%of n	No.	%of n
<25	131	5	3.8	68	51.9	36	27.5	22	16.8				
25-29	177	5	2.8	68	38.4	50	28.2	54	30.5				
30-34	171	3	1.8	72	42.1	45	26.3	51	29.8				
35-39	96	1	1.0	45	46.9	16	16.7	33	34.4	1	1.0		
40-44	74	2	2.7	28	37.8	18	24.3	26	35.1				
45-49	52	2	3.8	27	51.9	8	15.4	15	28.8				
50-54	26	3	11.5	9	34.6	4	15.4	7	26.9	2	7.7	1	3.8
55-59	16	1	6.3	8	50.0	3	18.8	4	25				
60	3			1	33.3	1	33.3					1	33.3
61+	6			2	33.3	1	16.7	3	50.0				
Total	752	22	2.9	328	43.6	182	24.2	215	28.6	3	0.4	2	0.3



Table 7. Age distribution of histology findings by highest ranking SNOMED grade



3.7 Colposcopy

The following provides information on the level of activity in colposcopy on screened women – (Table 8,9) (Figure 6,7). There were a total of 1,966 women seen in colposcopy over the three year period representing 5.2% (1,966/38,150) of the total number screened.

Table 8. Number of new women who attended colposcopy under the ICSP by age group, year of first attendance and total number of attendances

Age group	No. of women				Total	No. of attendances 2000-2003
	2000*	2001	2002	2003		
<25	1	141	85	97	324	559
25-29	5	162	108	135	410	773
30-34	2	145	81	145	373	717
35-39	2	99	67	110	278	485
40-44	1	77	45	62	185	354
45-49	2	67	39	73	181	318
50-54	0	31	26	31	88	157
55-59	0	28	24	29	81	128
60	0	2	5	5	12	22
61+	0	9	7	18	34	51
Total	13	761	487	705	1,966	3,564

* From October

Table 9. Number of ICSP related colposcopy procedures undertaken by year

Year	Total number n	Lletz		Punch biopsy		Smear	
		No.	% of n	No.	% of n	No.	% of n
2000*	17	0	0.0	6	35.3	11	64.7
2001	1,410	100	7.1	391	27.7	919	65.2
2002	1,305	104	8.0	343	26.3	858	65.7
2003	2,041	185	9.1	510	25.0	1,346	65.9
Total	4,773	389	8.2	1,250	26.2	3,134	65.7

* From October

analysis

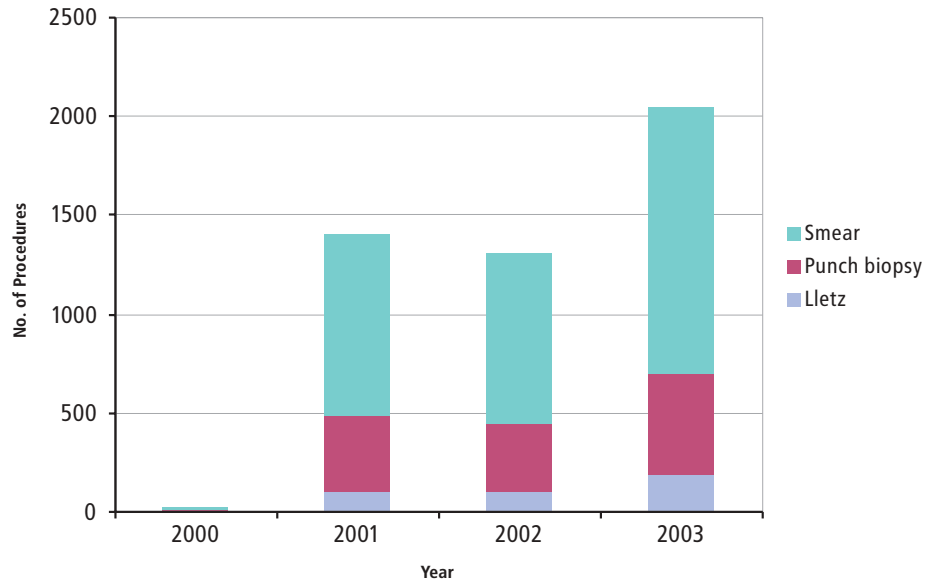


Figure 6. ICSP related colposcopy procedures undertaken by year

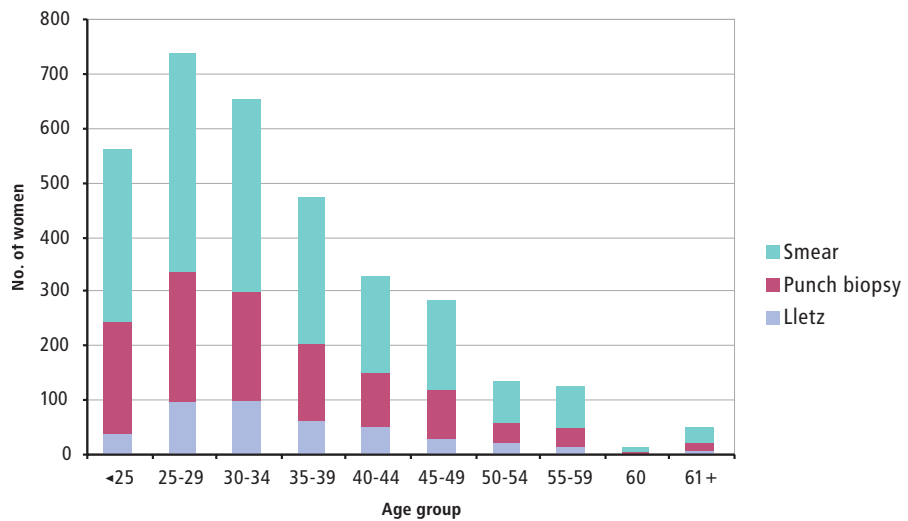


Figure 7. Colposcopy procedures undertaken by age group





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