Building a Better Health Service

Data validation project for the 221 women impacted by the cervical screening crisis

Final Report

01 February 2019

This report does not provide an individual report on each of the 221 women. This was not an audit or a clinical review. A clinical review is currently being undertaken by the Royal College of Obstetricians and Gynaecologists (known as the RCOG review). Finally, this report does not provide any opinion on the CervicalCheck audit as this was reported upon in the 'Scoping Inquiry into the CervicalCheck Screening Programme' by Dr. Gabriel Scally (September 2018).

Project Title	**Data Validation Project for the 221 Women impacted by the Cervical Screening Crisis**
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Service User Involvement	Two patient advocates representing the 221 women.
Date of Final Report	01 February 2019

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Abbreviations

BSO	Bilateral Salpingo-Oophorectomy
CIN	Cervical Intraepithelial Lesion
CSR	Cancer Screening Register
EBRT	External Beam Radiation Therapy
FIGO	Federation Internationale de Gynecologie et d'Obstetrique (International Federation of Obstetrics and Gynaecology)
GP	General Practitioner
HPV	Human Papillomavirus
HSIL	High-grade Squamous Intraepithelial Lesion
LEEP	Loop Electrosurgical Excision Procedure
LLETZ	Large Loop Excision of the Transformation Zone
LSIL	Low-grade Squamous Intraepithelial Lesion
NETZ	Needle Excision of the Transformation Zone
NSS	National Screening Service
NCRI	National Cancer Registry, Ireland
PLND	Pelvic Lymphadenectomy
RCOG	Royal College of Obstetricians and Gynaecologists
SCC	Squamous Cell Carcinoma
SIL	Squamous Intraepithelial Lesion
TZ	Transformation Zone

1. Background

The Strategy for Cancer Control was launched in Ireland in 2006, which advocated a comprehensive policy programme for prevention, screening, detection, treatment and the management of cancer. Following this, the National Screening Service (NSS) was established by the Minister for Health and Children in January 2007. The NSS encompasses BreastCheck - the National Breast Screening Programme, CervicalCheck - the National Cervical Screening Programme, BowelScreen – the National Bowel Screening Programme, and Diabetic RetinaScreen – the National Diabetic Retinal Screening Programme.

CervicalCheck came into operation in 2008 and offers a free cervical screening service that aims to reduce the incidence of and mortality from cervical cancer in women aged 25 to 60 years. CervicalCheck maintains a Cervical Screening Register (CSR), incorporating a population register which contains demographic data of eligible women for the purposes of screening. This register facilitates CervicalCheck to call and re-call women for screening and colposcopy treatment.

Over 3 million cervical screening tests have been performed in Ireland since 2008 and over 50,000 cases of pre-cancer and cancer have been detected and treated following cervical screening. Approximately 3,000 women in Ireland have been diagnosed with cervical cancer since 2008, and approximately half of these cases were notified to CervicalCheck.

When CervicalCheck is notified of a woman with a diagnosis of cervical cancer from the treating colposcopy clinic, gynaecology/oncology clinic or their general practitioner (GP), the woman's previous screening history may be added to a review process. Between 2008 and 2018, 1,482 previous cervical screening tests on women who were diagnosed with cervical cancer were selected for a quality review.

Clinical audit is an on-going review process which forms part of the quality assurance framework of the CervicalCheck programme. The objective of audit and quality review at CervicalCheck is to facilitate continued improvement and ongoing learning within the programme. Of the 1,482 women included in this look-back audit, it was found that for 221 women the screening test could have provided a different result.

What is now known as the cervical screening crisis emerged into the public domain in 2018 because of a failure to disclose the results of the retrospective review of smear tests[1]. The NSS will establish an expert group to review clinical audit processes across all cancer screening programmes and recommendations will be implemented to improve practices.

This report is neither a part of, nor an endorsement of, the CervicalCheck audit. The methodology of the audit that led to the classification of the 221 women into this group is not addressed in this report. How, or why, an individual was assigned to this group was not considered. This validation project focused on the 221 women regardless of how they were classified for inclusion in the audit. It is noted that a small number of women (7) did not have cervical cancer. The explanation for these women being classified as cervical cancer is that they were classified as such on presentation with advanced pelvic disease and subsequent examination showed that they had other cancers – endometrial, ovarian, uterine and poorly differentiated tumours.

[1] A smear test is a screening procedure and not a diagnostic test. It detects abnormal cells in the cervix, which if left untreated could develop into cervical cancer. During the routine procedure, cells from the cervix are gently scrapped away and examined for abnormal growth. It is estimated that cervical screening can prevent 75% of cervical cancer cases.

This piece of work was commissioned by the HSE CervicalCheck Steering Group.

2. Purpose

The purpose of this validation project was to produce a summary report on the 221 women impacted by the cervical screening crisis and not to provide a detailed or individualised report into each of the women.

The intention of this report was to answer two questions that were frequently asked about the 221 women; what their current state of health is and what resources will be needed to address their on-going problems. The answer to the first question is presented in section 5.7 which demonstrates that whilst many of the 221 women have no evidence of active disease, the outcome for others has been less favourable.

Regarding the second question, in May 2018 the Government put together a package of supports for those women (and their families) affected by the cervical careening crisis, and for whom the review recommendations following the clinical audit differed from the original test. Current supports aim to assist those affected by concerns about access to and/or the affordability of health and social care supports, such as:

- Discretionary medical card without the need for the standard assessment process.
- Arrangements to enable all out-of-pocket healthcare expenses, prescription charges and or drug costs to be met, including the cost of medicines not officially approved for reimbursement, etc.
- Provision of primary care supports to meet individual care needs, including counselling and bereavement counselling for the immediate family members of those women affected.
- Provision of support including travel costs and childcare.
- Specially designated Liaison Officers to work with individuals around supports.

The findings from this project provide an insight into the answer to the second question; whilst some women may need little support, others have many and varied health and fertility issues.

This report summarises the source of notification of diagnosis, age profile of the 221 women, screening history, cancer diagnosis, cancer staging, treatment history and current health status. Furthermore, this piece of work will provide an accurate and validated dataset of the 221 women.

This report is presented in 'plain writing[2]' as far as possible to provide a greater understanding of the affect of the CervicalCheck crisis on the 221 women which has been a source of confusion to date. For example, the meaning of the various types of cervical cancer, the staging and the treatments received.

This report does not give a detailed individualised report into each of the women. This was not an objective and indeed would not be possible given that some data was not available. Please also note that this was not an audit or a clinical review, as a clinical review is currently being undertaken by RCOG (known as the RCOG review). In addition, this report does not provide any opinion on the CervicalCheck review as this was reported upon in detail in the 'Scoping Inquiry into the CervicalCheck Screening Programme' by Dr. Gabriel Scally (September 2018).

[2] Plain writing refers to language that is clear, direct, and straightforward. It is language that avoids obscurity, inflated vocabulary and convoluted sentence construction. It is language that allows the reader to concentrate on the message conveyed, not on the difficulty of the language used.

3. Objective

The objective for the project was set out by the HSE CervicalCheck Steering Group. Specifically, this was to update the following key pieces of information on each woman:

- Screening history,
- Cancer diagnosis and associated staging,
- Treatment history, and
- Current clinical condition (if known).

4. Methodology

Data for the 221 women was reviewed from the following sources:

- The National Cancer Registry of Ireland (NCRI)
- The National Cervical Screening Programme (CervicalCheck)
- The CervicalCheck CSR which contains cytology and histology data[3].

Data from the treating clinicians for the 221 women was also collated to verify and complete the women's information contained within the above datasets. In total, 54 clinicians were involved. Spreadsheets outlining the details of the women from all data sources were developed for each clinician. All data was password protected.

Communication to the clinicians was issued from the HSE Office of Acute Operations with a cover letter from the National Director Acute Operations. The letter outlined the purpose of the project, what was required of the clinicians and was sent to the relevant Chief Executive Officers of the Hospital Groups involved for distribution.

In addition, a guidance note was developed to accompany the spreadsheets to provide clarity on what was required from the clinicians. The guidance note contained a brief description of the fields (17 in total) within the spreadsheets and where input was required (6 fields) from the treating clinicians; as listed in the table 1. The guidance note was also provided to the two patient advocates involved in the project.

The treating clinicians retrieved the above data from the healthcare records of the 221 women at the treating hospital(s) and/or colposcopy clinic. The co-operation provided by the treating clinicians in carrying out this significant piece of work is appreciated. Without their support, this aspect of the project would not have been possible.

[3] Cytology is the examination of cells from the body under a microscope. More specifically, cytology is a branch of science that studies how cells work and grow and what they are made of. A smear test checks for infection, inflammatory disease, cancer, or precancerous conditions. If a cytologist observes abnormal cells, they provide a preliminary result indicating the possibility of disease. This result is relayed back to the woman's GP/smear taker. The GP will then refer the woman to a colposcopy clinic. At the colposcopy clinic, a biopsy may be taken. Histology is the examination of the biopsy tissue under a microscope. If a histologist observes abnormal cells within the tissue, they provide a detailed diagnosis of disease. This diagnosis is relayed back to the woman's colposcopy clinic. The woman will then receive the appropriate treatment.

Table 1: Content of Guidance Note and Required Input

Field	Input	Description
CSP_ID	Input not required	Cervical Screening Programme Identification[4]
Client_firstname	Input not required	Woman's first name
Client_surname	Input not required	Woman's surname
Client_DOB	Input not required	Woman's date of birth
Colposcopy reference	Input not required	Unique coloposcopy reference number
Clinic long identifier	Input not required	Coloposcopy clinic/other clinic attended
Provider_forename	Input not required	Treating clinician first name
Provider_surname	Input not required	Treating clinician surname
NCRI date of diagnosis	Input not required	Date of diagnosis taken from the NCRI database
NCRI final staging	Input not required	Final staging code taken from the NCRI database
NCRI invasive description	Input not required	Description of diagnosis taken from the NCRI database
Definitive diagnosis including histology	**Input required**	The treating clinician's details of the definitive diagnosis including details of histology
Initial staging	**Input required**	The treating clinician's details of the initial staging
Ultimate staging	**Input required**	The treating clinician's details of the ultimate/last staging
Treatment history	**Input required**	The treating clinician's details of the treatment history
Current state of health	**Input required**	The treating clinician's knowledge of the current state of health
Any other relevant information	**Input required**	Any other relevant information

5. Findings

The aim of this section is to provide a summary of the data which was validated from the various sources indicated previously.

Seven women did not have cervical cancer as their primary diagnosis but they did have a smear history with CervicalCheck. These women had various cancers of the female reproductive system, including uterine cancer (womb), endometrial cancer (endometrium) and ovarian cancer (ovary), and were included in the CervicalCheck review because they had changes detected in their smear tests. These seven women are therefore part of the 221 group and they have been included in the analysis and findings of this report. This validation project focused on the 221 women regardless of how they were classified for inclusion in the audit.

[4] Each woman on the CSR is assigned a CervicalCheck identification number known as the CSP-ID. A woman's record includes her demographic details and details of her screening history communicated to the programme, i.e., results of cervical smear tests, colposcopy procedures and biopsies taken in a colposcopy clinic, if any, and the results of histology examinations. The CSR provides a woman's screening history to contracted service providers, i.e., cytology and histology laboratories, and colposcopy clinics.

The aim of the following sections is to provide a summary of the data which was validated from the various datasets, i.e., NCRI, CervicalCheck and the CSR. Initially, this section will provide a summary overview of the source of notification of diagnosis and the age profile of the 221 women. It will also summarise the screening history, staging, cancer diagnosis, treatment history and current clinical status.

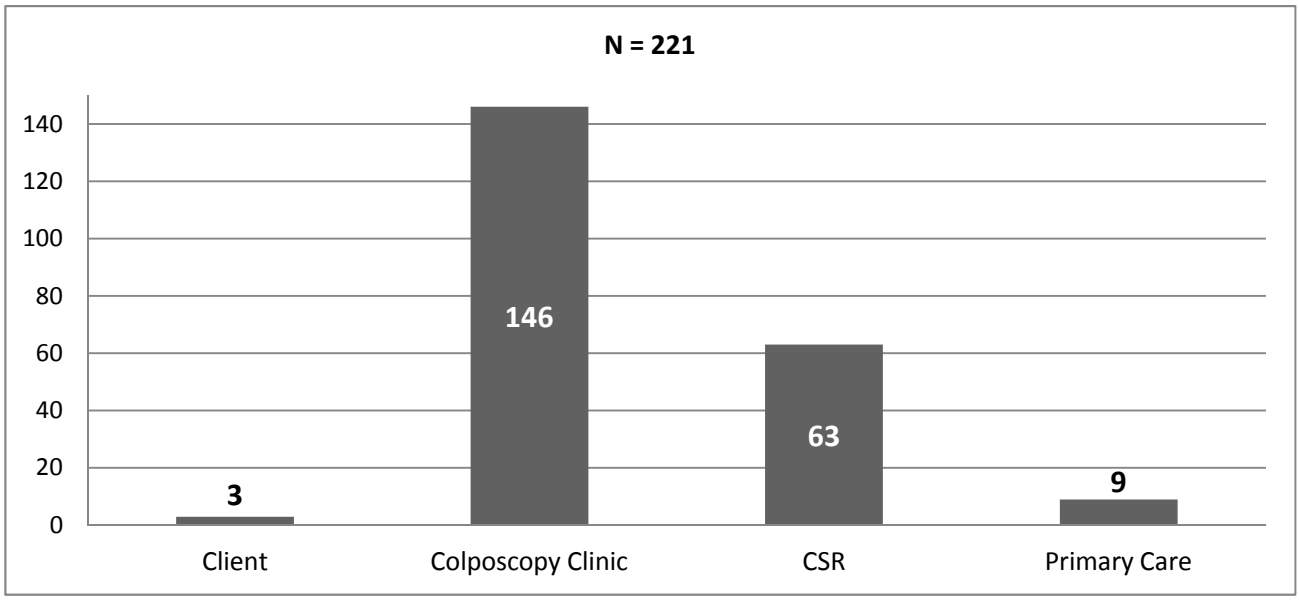
5.1 Source of notification

Abnormal clinical findings following a smear test require gynaecological investigation. In general, women will be referred for a colposcopy. Colposcopy services play a key role in the success of any screening programme by ensuring optimal management of women with detected smear test abnormalities. Many pre-cancerous and cancerous lesions[5] in these areas can be detected using this examination. Colposcopy determines the requirement and location for a biopsy following an abnormal smear.

A biopsy involves removing a sample of tissue from the cervix for examination. The biopsy allows for a sample of cells to be tested so they can be assessed more accurately. The diagnosis of pre-cancerous and cancerous disease is made based upon the result of the biopsy. Following a cervical cancer diagnosis, CervicalCheck is notified.

CervicalCheck receives notification of a diagnosis of cervical cancer from a variety of sources.

Figure 1: Source of Notification of Diagnosis



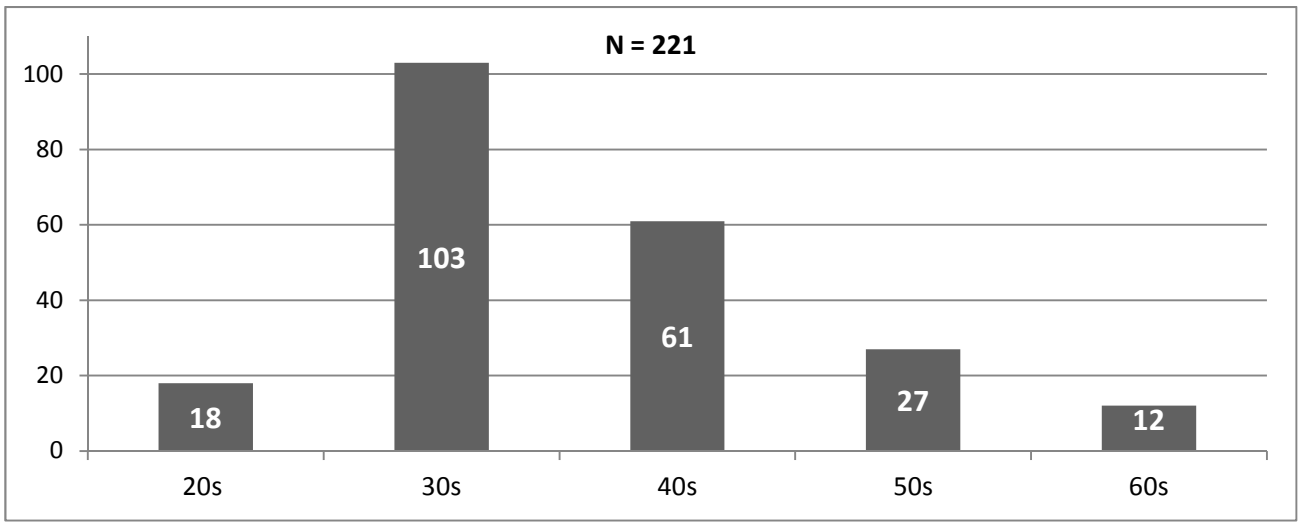
The majority of notifications came directly from colposcopy clinics (n=146/66%) followed by the CSR (n=63/28.5%). Nine notifications (4%) were stated as coming from primary care (GP services) with the remaining three (1.5%) noted as from the 'client', which would indicate a self-notification to CervicalCheck. It may appear unusual for a woman to 'self-notify', but occasionally a woman would contact CervicalCheck about a diagnosis (usually after receiving an invite letter) to let the programme know that she is in treatment.

[5] When used in the context of cancer, a lesion is an area of abnormal tissue that may lead to cancer. Lesions are categorised according to whether or not they are caused by cancer; i.e., a benign lesion is non-cancerous whereas a malignant lesion is cancerous.

5.2 Age profile

Figure 2 displayed in decades provides an overview of the age at diagnosis for the 221 women.

Figure 2: Age at Diagnosis



As demonstrated above, 18 women (8%) were in their 20s when diagnosed. Most women were diagnosed in their 30s (n=103/47%) and 40s (n=61/28%). Twenty-seven women were in their 50s (12%) and the remaining women were diagnosed in their 60s (n=12/5%).

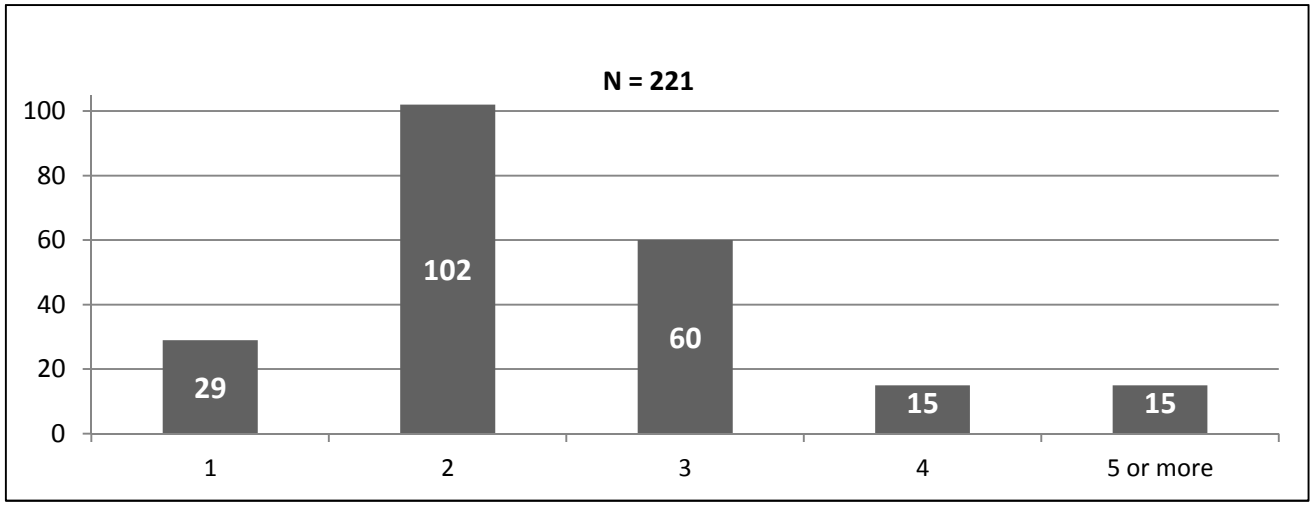
Studies indicate that cervical cancer is a cancer of young women and 50% of all cases are diagnosed in women aged less than or equal to 46 years. In the 221 women, this rate was higher with the number of women aged less than or equal to 46 (n=168) representing 76%. Those aged 47 or more (n=53) accounted for the remaining 24%. For the 221 women, the average age at diagnosis was 40.6 years. The youngest age at diagnosis was 26 and the oldest was 68 years.

5.3 Screening

Cervical screening detects abnormal cells in the cervix and if left untreated could develop into cervical cancer. It is estimated that cervical screening can prevent 75% of cervical cancer cases. But a cervical screening test is not a diagnostic test. Like all screening tests, it is carried out on women who appear healthy and without symptoms. Cervical screening will identify if a woman is at greater risk of developing cancer in the future. This is why screening can be so effective in reducing the incidence of cancer. But cervical screening, like all screening programmes, is not perfect. Some women will still develop cervical cancer despite regular screening. While the risk of cervical cancer can be reduced, it cannot be eliminated by screening alone.

CervicalCheck invites women between the ages of 25 and 60 to avail of a free cervical screening. Women aged 25 to 44 are invited for screening every three years and women aged 45 to 60 are invited every five years. If all smear tests were found to be normal, this would imply that a woman between the ages of 25 and 50 would be estimated to have had eight smear tests and between the ages of 50 and 60, she would be estimated to have a further two smear tests. Regardless of age, women must have two consecutive 'no abnormality detected' results at three yearly intervals before going on to a five yearly screening interval.

Figure 3: Number of Smears Performed Prior to Diagnosis



The figure above indicates the number of smears the 221 women had prior to receiving their diagnosis. The average number of smears pre-diagnosis was three per woman. An analysis of the average number of smears prior to diagnosis by age group is listed below.

Table 2: Average Number of Smears Prior to Diagnosis by Age Group

Age Group	20s	30s	40s	50s	60s	Total
Average no. of smears pre-diagnosis	2	2.5	2.9	2	2.5	3
Number	18	103	61	27	12	221

The above data indicates the average was relatively consistent and ranged from 2 to 2.9 across the age groups.

The requirement for a woman to attend for follow-up cervical screening post-treatment is considered on a case-by-case basis by the treating clinician and also determined by the treatment received. In 2018, 98 of the 221 women attended for a smear test and 77 women received a normal result (no abnormality detected). This indicates that 79% of the women who had attended for a smear test in 2018 received a normal result. Five women received a 'not normal' result and all of these related to low-grade abnormal changes. Nine women received an unsatisfactory result and this indicates that the cells were either of poor quality or insufficient in number and will require a repeat test. For seven women, the result is not yet known.

5.4 Staging

The stage of a cancer refers to its size and whether it has spread beyond the area of the body where it first started. Knowing the extent of the cancer will decide the most appropriate treatment. Cervical cancer is divided into four main stages with most stages having further sub-divisions.

For cervical cancer, the staging system developed by the International Federation of Obstetrics and Gynaecology (or FIGO) appears to be the most commonly applied by clinicians.

Three women attended treating clinicians privately, and therefore their staging details were not accessible from healthcare records; in these three cases the staging was retrieved from the NCRI dataset. Staging detail was unknown for one other woman, subsequently the following table provides a description of each FIGO stage and the ultimate staging for 220/221 women.

Table 3: Description of FIGO Staging

FIGO stage	Description	N = 220
Stage 0	Stage 0 means abnormal cells with the potential to become cancer have been detected. This is also called carcinoma in situ, non-invasive cancer, pre-invasive cancer, or precancerous.	9
Stage 1	The cancer has spread from the cervix lining into the deeper tissue but is still just found in the cervix. The subsets to this stage are described in more detail below.	2
Stage 1A	The cancer can only be diagnosed using a microscope to view the cervical tissue or cells. At this stage a biopsy is required. No lymph nodes are involved, and there is no distant spread.	3
Stage 1A1	There is a cancerous area of 3 millimetres (mm) or smaller in depth and 7mm or smaller in length. No lymph nodes are involved, and there is no distant spread.	60
Stage 1A2	There is a cancerous area larger than 3mm but not larger than 5mm in depth and 7mm or smaller in length. No lymph nodes are involved, and there is no distant spread.	8
Stage 1B	In this stage, the doctor can see the lesion, and the cancer is found only in the cervix. Or there is a lesion that can be seen using a microscope, and it is larger than a stage 1A2 cancerous area (see above). The cancer may have been found through a physical examination, laparoscopy, or other imaging method. The cancer may/may not have spread to lymph nodes.	24
Stage 1B1	The cancerous area is 4 centimetres (cm) or smaller. The cancer may/may not have spread to lymph nodes.	54
Stage 1B2	The cancerous area is larger than 4cm. The cancer may/may not have spread to lymph nodes.	8
Stage 2	The cancer has spread beyond the cervix to nearby areas, such as the vagina or tissue near the cervix, but it is still inside the pelvic area. The cancer may/may not have spread to lymph nodes. The subsets to this stage are described in more detail below.	3
Stage 2A	The cancer has not spread to the tissue next to the cervix, also called the parametrial area. The parametrial area is the fibrous and fatty connective tissue that surrounds the uterus. This tissue separates the back of the vagina and the cervix from the bladder. The cancer may/may not have spread to lymph nodes.	3
Stage 2A1	The cancerous area is 4cm or smaller. The cancer may/may not have spread to lymph nodes.	1
Stage 2A2	The cancerous area is larger than 4cm. The cancer may/may not have spread to lymph nodes.	0
Stage 2B	The cancer has spread to the parametrial area. The cancer may/may not have spread to lymph nodes.	28

Table 3 continued: Description of FIGO Staging

FIGO stage	Description	N = 220
Stage 3	The cancer has spread to the pelvic wall, and/or involves the lower third of the vagina, and/or causes swelling of the kidney, called hydronephrosis, or the cancer has stopped a kidney from functioning. The cancer may/may not have spread to lymph nodes.	1
Stage 3A	The cancer involves the lower third of the vagina, but it has not grown into the pelvic wall. The cancer may/may not have spread to lymph nodes.	1
Stage 3B	The cancer has grown into the pelvic wall and/or affects the kidneys. The cancer has spread to lymph nodes, but not distant sites and the cancer can be any size.	8
Stage 4A	The cancer has spread to the bladder or rectum, but it has not yet spread to other parts of the body.	4
Stage 4B	The cancer has spread to other parts of the body.	3

Treating clinicians may also use the following terms to describe the stage of the cancer:

- Precancerous stage – this refers to stage 0.
- Early-stage cervical cancer – this usually includes stages 1A to 1B1.
- Locally advanced cervical cancer – this usually includes stages 1B2 to 3B.
- Advanced-stage or metastatic cervical cancer – this usually includes stages 4A and 4B.

Treatment is dependent on many factors, including the stage of cancer. The treatment provided to the 221 women is set out in section 5.6 of this report and includes further detail on the various stages of cancer.

5.5 Type of cancer

The prerequisite causes of cervical cancer are many. However, cervical cancer nearly always involves the presence of the human papillomavirus (HPV) infection. HPV infection is extremely common; and most sexually active people will be infected with HPV at some point in life. Certain strains of HPV infection are noted to be more carcinogenic than others and four particular strains account for 81% of cervical cancer. Most of the time the infection does not last very long because the body's immune system will either clear or contain the infection.

The cervix is lined by two types of cells; these are known as squamous cells and glandular cells. The area of change from the squamous cells and the glandular cells is termed the squamo-glandular junction; also know as the transition zone (TZ). Most precancerous and cancerous changes occur in this TZ.

When cell changes occur this is called dysplasia or 'CIN', which stands for cervical intraepithelial neoplasia or in situ. Both CIN and in situ cell changes may become invasive if left untreated, however in some cases the dysplasia can resolve itself. Dysplasia can be quite a slow process and studies have shown that in women with an untreated in situ, 30% to 70% will develop invasive cancer over a period of 10 to 12 years. As mentioned, CIN is another way to describe abnormal changes and CIN1 is the least severe and compares to mild dysplasia; CIN2 is moderate/severe dysplasia; CIN3 is severe/most severe dysplasia.

Squamous intraepithelial lesion (SIL) is the newest way of describing abnormal changes to squamous cells. SIL is described as low-grade (LSIL) or high-grade (HSIL); LSIL affects the lower part of the cervical lining and is mild dysplasia and HSIL affects more of the cervical lining and is moderate to severe dysplasia.

Sometimes carcinomas are described as micro-invasive or invasive. Micro-invasive refers to early disease and is reserved for lesions with a depth of less than 3mm/5mm and a width of less than 7mm. The diagnosis of micro-invasive cancer is made during the histology test. Invasive carcinoma is a spread of the cancer from the surface to deeper tissue in the cervix or to other parts of the body. Carcinoma cells can be also described as well-differentiated, moderately differentiated or poorly differentiated cells. The level of differentiation describes how much or how little the cancer tissue looks like the normal tissue it originally came from. Well-differentiated cancer cells look more like normal cells and tend to grow and spread more slowly than moderately or poorly differentiated cancer cells.

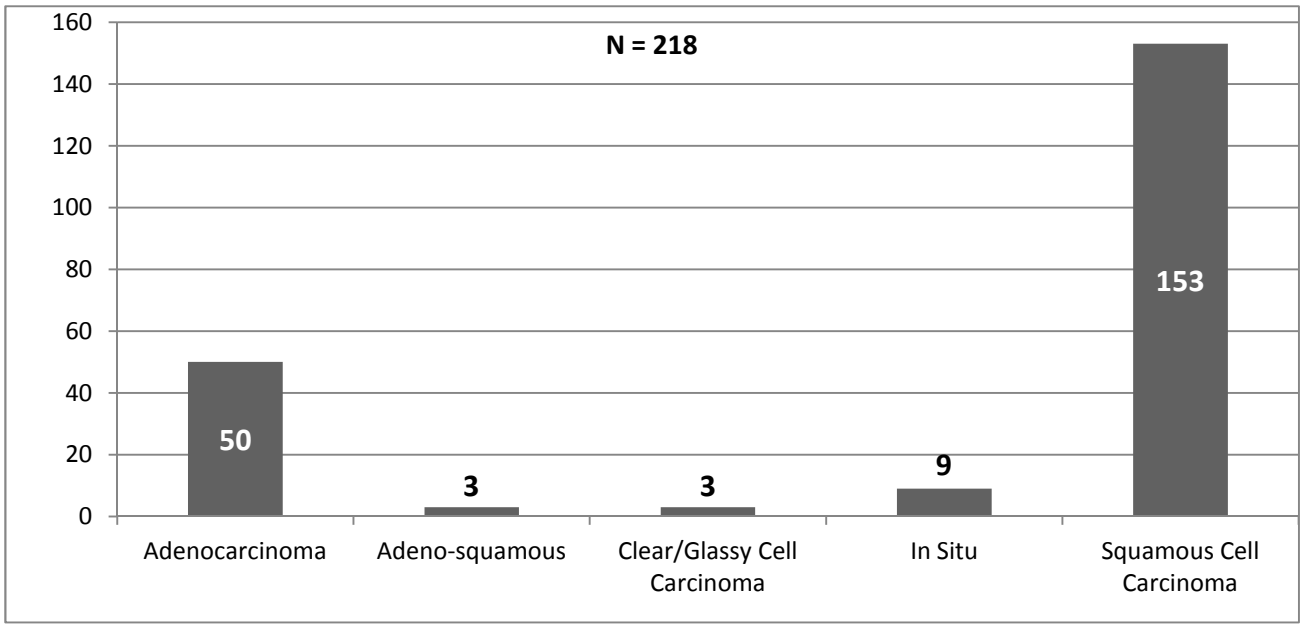
Table 4 presents a description of the types of cancer diagnosed for the 221 women.

Table 4: Description of the Types of Cancer

Type of cancer (A-Z)	Description
Adenocarcinoma	Adenocarcinoma is a cancer that starts in the glandular cells, which are found along the inner canal of the cervix and are columnar in shape. This type of cervical cancer is more difficult to diagnose because it occurs higher up in the cervix and the abnormal glandular cells are harder to recognise.
Adeno-Squamous Carcinoma	A small number of cervical cancers feature both squamous and glandular cells and are known as an adeno-squamous carcinoma. This is a rare type of cervical cancer accounting for 5-6% of all cervical cancers.
Clear Cell Carcinoma	Clear cell carcinoma is another rare cancer accounting for only 4% of all cervical adenocarcinomas.
Glassy Cell Carcinoma	Glassy cell carcinoma is a very rare form of poorly differentiated adeno-squamous carcinoma accounting for less than 1% of all cervical carcinomas.
In Situ	An in situ refers to abnormal cells that have not spread beyond from where they first formed. The words "in situ" translate to “in its original place”. The number of abnormal cells is too small to form a tumour. Some in situ will never develop into cancer, however others have the potential to become cancerous cells and spread to nearby locations. Other names for an in situ are stage 0 disease, non/pre-invasive cancer or CIN.
Squamous Cell Carcinoma	Squamous cell carcinoma is the most common type of cervical cancer. Squamous cells are found in tissue that lines the outer part of the cervix and these cells are thin and flat in shape.

Figure 4 presents the number of women diagnosed with the various types of cancer as described above. The seven women who did not have cervical cancer as their primary diagnosis are included as six had an adenocarcinoma and one had a squamous cell carcinoma (SCC). Data for three women was not available as they were treated privately; therefore the figure overleaf refers to 218/221.

Figure 4: Types of Cancer



The main type of cancer diagnosis related to SCC. Literature indicates that SCC is the most common type of cervical cancer accounting for about 70-80% of all cases and this was reflected in the 221 group (n=153/70%).

Of the 153 women, the treating clinicians reported that 92 women had a SCC. SCC can also be described as micro-invasive or invasive and an additional 14 women were reported to have a micro-invasive SCC, 12 had an invasive SCC, and 17 had a HSIL. In addition, the treating clinicians stated that one woman had a well-differentiated SCC, 12 had a moderately differentiated SCC, and five had a poorly differentiated SCC.

Literature indicates that adenocarcinoma is a less common type of cervical cancer accounting for about 20-30% of cases. Again, findings within the 221 group reflected the literature with 50 women (23%) diagnosed with an adenocarcinoma. The treating clinicians described 40 women as having an adenocarcinoma, two with a micro-invasive adenocarcinoma, three had an invasive adenocarcinoma, four had a moderately differentiated adenocarcinoma, and one woman had a poorly differentiated adenocarcinoma.

Six women (3%) had a rare type of cancer. Three of these women were diagnosed with adeno-squamous carcinoma and a further two had clear cell carcinoma. The remaining woman had glassy cell carcinoma.

Nine women (4%) were diagnosed with an in situ. An in situ refers to abnormal cells that have not spread beyond from where they first formed (see table 4 for full definition).

5.6 Treatment history

This section provides a description of the various treatments provided to the 221 women and the number of women that had those treatments or combinations of them.

Note: The retrieval of the treatment history was a complex process and the data presented is an as accurate account as possible. That is, many women received treatment at several different hospitals/clinics and this may not have been reflected in the hospital healthcare record accessed for this part of the validation exercise. In other cases, healthcare records were archived given the passage of time since some women received their treatment. In addition, many women received treatment at private locations and access to this information was not possible within the timeframe for this piece of work. Finally, entries into healthcare records are hand written and some entries in relation to the treatment provided to the women may have been missed during this process. Therefore, it is possible that some of the treatments provided to the women may not be listed.

Table 5 provides a description of the various treatments provided to 218/221 women as the details for the women treated privately were not available. The numbers shown are the number of women who received that treatment and in many cases the same woman received more than one treatment, therefore the numbers will not total 218.

Table 5: Description of Treatment(s) Provided

Treatment	Description of treatment received (A-Z)	No.
Bilateral Salpingectomy	Salpingectomy is the surgical removal of one (unilateral) or both (bilateral) fallopian tubes. Fallopian tubes allow eggs to travel from the ovaries to the womb. Salpingectomy can be done alone or combined with other procedures including an oophorectomy (see below) and hysterectomy (see below).	5
Bilateral Salpingectomy Oophorectomy (BSO)	A BSO is the surgical removal of both ovaries (oophorectomy) and either one or both fallopian tubes (salpingectomy – see above). A BSO can be done alone or combined with a hysterectomy.	21
Brachytherapy	Brachytherapy is a treatment in which radioactive material sealed in a device is implanted into the body using a needle or catheter. Brachytherapy is sometimes called internal radiation. For cervical cancer, this is often called intra-cavity brachytherapy where a device containing the radioactive material is placed in the vagina. The radiation given off by this source damages the DNA of nearby cancer cells. Brachytherapy allows higher doses of radiation to be delivered to a specific area of the body, compared with the conventional form of radiation therapy (external beam radiation therapy - EBRT) that projects radiation from a machine outside of the body.	9
Cone Biopsy	A cone biopsy is an extensive and more invasive form of a cervical biopsy. It is called a cone biopsy because a cone-shaped wedge of tissue is removed from the cervix and examined under a microscope for abnormal cells. The tissue high in the cervical canal is removed by a scalpel or a straight electric wire. It can also treat some early-stage cervical cancers and is usually performed under general anaesthetic and takes 4 to 6 weeks for the cervix to heal.	19

Table 5 continued: Description of Treatment Provided

Treatment	Description of treatment received (A-Z)	No.
Chemotherapy	Chemotherapy uses anti cancer (cytotoxic) drugs to destroy cancer cells. The drugs circulate throughout the body in the bloodstream. Chemotherapy may be given with a curative intent, or it may aim to prolong life or to reduce symptoms (palliative chemotherapy).	6
Chemoradiotherapy	Chemoradiotherapy (also called chemoradiation) is the combination of chemotherapy (see above) and radiotherapy (see below) to treat cancer. On the first day of chemotherapy the first radiotherapy treatment also occurs. It is continued in this way every for 5 to 6 weeks.	49
Hysterectomy	A hysterectomy is an operation to remove the womb (uterus). For a 'simple' hysterectomy, the womb is removed, but not surrounding tissue. A hysterectomy can be done in three ways: a vaginal hysterectomy (performed entirely through the vaginal canal); a laparotomy or abdominal hysterectomy (performed through an incision in the abdomen); or a laparoscopic hysterectomy (through several smaller incisions).	21
LLETZ/NETZ	LLETZ stands for large loop excision of the TZ and is the most common way of removing cervical tissue for examination and treating precancerous changes. NETZ stands for needle excision of the TZ. The TZ is a small area situated at the opening of the neck of the womb. When a smear reports abnormal changes in this area it is often advisable to remove the TZ in order to prevent cancer developing at some time in the future.	67
Loop Biopsy	A loop biopsy is the common name for the loop electrosurgical excision procedure (LEEP). The loop/LEEP uses a wire loop heated by an electric current to remove cells and tissue from the cervix or vagina. It is very similar to the LLETZ described above.	2
Omentectomy	An omentectomy is a surgical procedure designed to remove the omentum. The omentum is a thin fold of abdominal tissue which contains lymph nodes, lymph vessels, nerves and blood vessels and which encases the stomach, large intestine and other abdominal organs but is also close to the ovaries. This procedure is used if the cancer has spread to the ovaries and possibly the omentum.	1
Ovarian Conservation	Ovarian conservation means keeping the ovaries in place when having a hysterectomy. This is most commonly done for younger or pre-menopausal women in order to avoid sudden or early onset menopause. The average onset age of menopause after hysterectomy with ovarian conservation is 3.7 years earlier than normal.	7
Ovarian Transposition	Ovarian transposition is a surgical manoeuvre to protect ovarian function before delivery of high doses of radiation; it moves the ovaries out of the way of the radiation dose. Also called oophoropexy.	4

Table 5 continued: Description of Treatment Provided

Treatment	Description of treatment received (A-Z)	No.
Pelvic Lymphadenectomy (PLND)	A pelvic lymphadenectomy or pelvic lymph node dissection (PLND) is surgery to remove the lymph nodes from the pelvis for examination under a microscope to see if they contain cancer. The lymph nodes are part of the lymphatic system. If cancer cells break away from the cancer site, the first place they can travel to is the nearest lymph nodes. This is called lymph node or nodal metastasis (spread). Lymph node involvement or metastasis is a key diagnostic factor and a crucial step in deciding on the treatment required.	58
Radical/Wertheim's Hysterectomy	A radical hysterectomy involves the removal of the womb, the cervix, all the tissues holding the womb in place (the parametrium situated to the right and left of the womb), the top of the vagina and the lymph nodes around the womb. The ovaries and fallopian tubes are sometimes removed in a radical hysterectomy and this is usually associated with a Wertheim's hysterectomy. The ovaries are not always removed during a radical hysterectomy; this decision usually depends upon the age of the woman.	65
Radiotherapy	Radiotherapy refers to the use of high-energy x-rays to kill the cancer cells. There are two ways to deliver radiotherapy: brachytherapy (see above) or EBRT outside the body. In women with more advanced disease, EBRT is generally added to brachytherapy to decrease the chance of the cancer coming back.	13
Sigmoid Colectomy	This surgery is required to remove part of the bowel (called the sigmoid colon) affected by the cancer.	1
Total Hysterectomy	A total hysterectomy is the complete removal of the womb and cervix, with or without removal of the ovaries (oophorectomy – see above).	6
Trachelectomy	A trachelectomy is the removal of the cervix, the upper part of the vagina, the parametrium (see above), and certain pelvic lymph nodes may also be removed.	10
Uretric Stent Placement	The ureters are responsible for transporting urine from the renal pelvis to the bladder. Obstruction of the ureter in cervical cancer can be the result of disease progression and ureteral stricture (narrowing) can occur as an adverse effect of cancer treatment. Uretric stent placement involves the insertion of two J-shaped stents and is used to re-establish or maintain the openness of the ureter. For women requiring a long-term stent, these are changed every three months on average. A stent is a tiny tube inserted surgically into a blocked passageway to keep it open.	4

Table 6 lists the number of women that received a combination of the above treatments.

For two of the nine women classified at stage 0, their treating clinicians reported that they did not receive treatment; consequently these women are not included in the table. In addition, those women confirmed as being treated privately are not included. Therefore the valid number here is 216/221.

Table 6: Type of Treatment(s) Provided

Type of treatment received (A-Z)	N = 216
Chemoradiotherapy	31
Chemoradiotherapy & Brachytherapy	3
Chemoradiotherapy & Ovarian Transposition	1
Chemoradiotherapy & Palliative Chemotherapy	1
Chemoradiotherapy & PLND	1
Chemoradiotherapy & PLND & Palliative Chemotherapy	1
Chemoradiotherapy & Sigmoid Colectomy	1
Chemotherapy	3
Chemotherapy & Palliative Radiotherapy	1
Cone Biopsy (single &/or multiple)	8
Cone Biopsy & Hysterectomy	1
Cone Biopsy & PLND	1
Cone Biopsy & PLND & Trachelectomy	1
Declined Treatment	1
Hysterectomy	11
Hysterectomy & BSO	3
Hysterectomy & PLND	3
LLETZ/NETZ (single &/or multiple)	41
LLETZ & Chemoradiotherapy	1
LLETZ & Cone Biopsy	4
LLETZ & Cone Biopsy & Hysterectomy	1
LLETZ & Cone Biopsy & PLND	2
LLETZ & Cone Biopsy & PLND & Trachelectomy	1
LLETZ & Hysterectomy & BSO	1
LLETZ & Hysterectomy & Radiotherapy	1
LLETZ & Loop Biopsy	1
LLETZ & PLND	1
LLETZ & PLND & Radiotherapy & Ovarian Transposition	1
LLETZ & Radical Hysterectomy & BSO & PLND	2

Table 6 continued: Type of Treatment(s) Provided

Type of treatment received (A-Z)	N = 216
LLETZ & Radical Hysterectomy & PLND	1
LLETZ & Radical Trachelectomy & PLND	1
LLETZ & Total Hysterectomy	1
LLETZ & Wertheim's Hysterectomy	1
LLETZ & Wertheim's Hysterectomy & BSO	1
LLETZ & Wertheim's Hysterectomy & BSO & PLND	1
LLETZ & Wertheim's Hysterectomy & Ovarian Conservation	4
Loop Biopsy & Chemoradiotherapy	1
Omemtectomy & BSO	1
Radical Hysterectomy	13
Radical Hysterectomy & Bilateral Salpingectomy	1
Radical Hysterectomy & Bilateral Salpingectomy & Chemoradiotherapy	1
Radical Hysterectomy & Bilateral Salpingectomy & PLND & Ovarian Conservation & Uretric Stenting	2
Radical Hysterectomy & Bilateral Salpingectomy & PLND & Radiotherapy & Ovarian Transposition & Uretric Stenting	1
Radical Hysterectomy & BSO	3
Radical Hysterectomy & BSO & Chemoradiotherapy	1
Radical Hysterectomy & BSO & PLND	4
Radical Hysterectomy & BSO & PLND & Brachytherapy	1
Radical Hysterectomy & BSO & PLND & Radiotherapy & Postoperative Procedures	1
Radical Hysterectomy & Chemoradiotherapy	1
Radical Hysterectomy & PLND	16
Radical Hysterectomy & PLND & Brachytherapy	2
Radical Hysterectomy & PLND & Chemoradiotherapy	4
Radical Hysterectomy & PLND & Brachytherapy & Radiotherapy	1
Radical Hysterectomy & Radiotherapy	1
Radical Hysterectomy & Ovarian Conservation	1
Radical Trachelectomy & PLND	5
Radical Trachelectomy & PLND & Chemoradiotherapy	1
Radical Trachelectomy & PLND & Ovarian Transposition & Radiotherapy & Brachytherapy & Uretric Stenting	1
Radiotherapy	4
Radiotherapy & Bracyhtherapy	1
Total Hysterectomy	2

Table 6 continued: Type of Treatment(s) Provided

Type of treatment received (A-Z)	N = 216
Total Hysterectomy & BSO	1
Total Hysterectomy & BSO & PLND	1
Total Hysterectomy & PLND	1
Unknown	4

It is clear that the treatment options are very varied and for most of the women, the treatment they received was individual to them.

Table 7 outlines the ultimate staging of the women and the various treatments as reported by the treating clinicians. For stages 1 to 4, the treatments have been grouped together for ease of presentation. The three private patients are not included and for one woman the ultimate staging was unknown. Therefore, the table below represents 217/221.

Table 7: Ultimate Staging and the Treatment(s) Provided

Ultimate Staging	Treatment received (A-Z)	N = 217
Stage 0 (n=9)	Cone Biopsy	1
	LLETZ (single &/or multiple)	5
	No treatment reported	2
	Total Hysterectomy	1
Stage 1 (n=159)	Chemoradiotherapy/Radiotherapy	9
	Cone/Loop Biopsy & LLETZ	12
	Hysterectomy (Simple, Radical, Total & Wertheims) only	24
	Hysterectomy (Simple, Radical, Total & Wertheims) & other interventions	62
	LLETZ/NETZ (single &/or multiple)	36
	PLND & other interventions	7
	Radical Trachelectomy & other interventions	9
Stage 2 (n=34)	Chemoradiotherapy/Radiotherapy	24
	Chemoradiotherapy & other interventions	6
	Hysterectomy (Simple, Radical, Total & Wertheims & other interventions	3
	Omentectomy & other interventions	1
Stage 3 (n=9)	Chemoradiotherapy/Radiotherapy	3
	Chemoradiotherapy & other interventions	2
	Chemotherapy	1
	Declined Treatment	1
	Hysterectomy (Simple, Radical, Total & Wertheims) & other interventions	1
	Unknown	1
Stage 4 (n=6)	Chemoradiotherapy/Radiotherapy	2
	Chemotherapy	2
	Unknown	2

The treatments provided for six women at stage 0 included LLETZ and cone biopsy. One woman had a total hysterectomy. Two women were reported by their treating clinicians to have received no treatment.

The treatment options for stage 1 ranged from LLETZ to radical hysterectomies with other interventions. These interventions included BSO, PLND, trachelectomy, chemoradiotherapy and brachytherapy.

The treatment option for stages 2 and 3 was mainly chemoradiotherapy. Other interventions included LLETZ, hysterectomy, BSO, PLND, sigmoid colectomy, omentectomy, and ovarian transposition. One woman at stage 3 declined treatment.

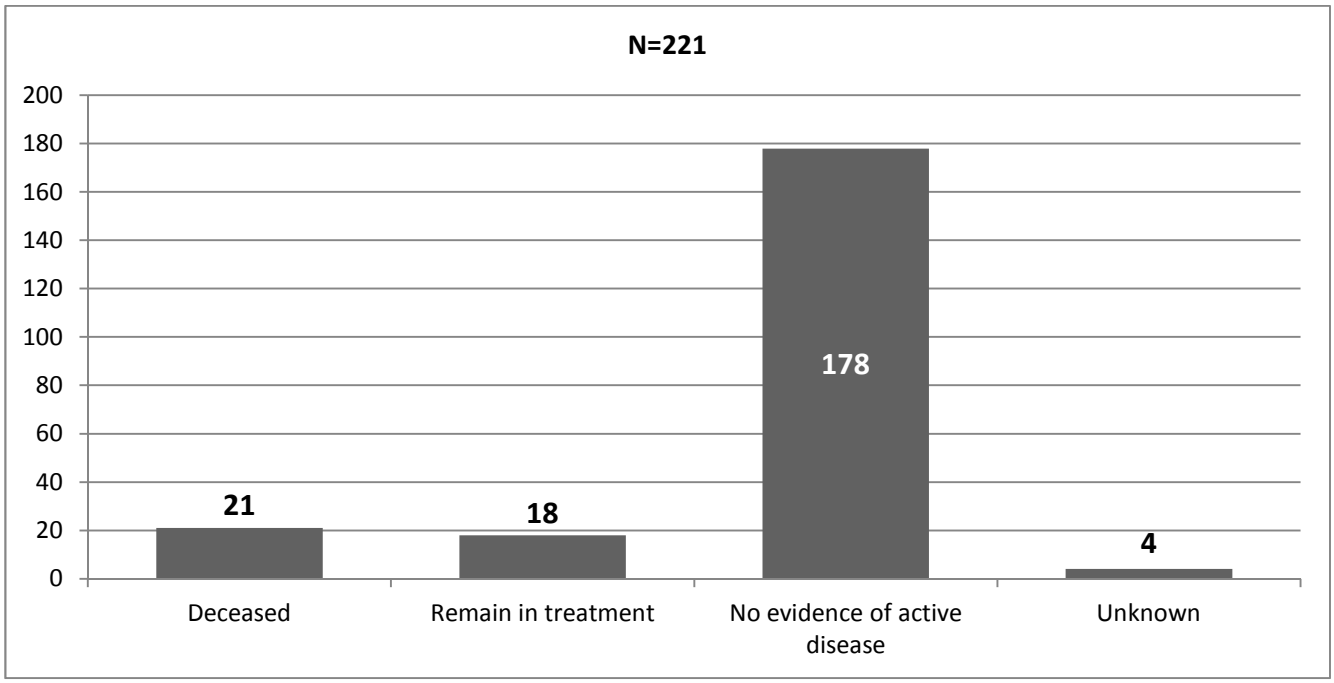
At stage 4, the preferred treatment was chemoradiotherapy.

5.7 Current Health Status of the 221 Women

The following section provides an overview of the current health status of the 221 women.

Twenty one women are deceased. Three of these women did not have cervical cancer as their primary diagnosis; for these women the primary diagnosis was ovarian and endometrial cancer. The age at diagnosis was between 27 and 59 years. The stages of their cancer ranged from stage 1 to 4. Age at death ranged from 30 to 61 years.

Figure 5: Current Health Status



Eighteen women currently remain in treatment (8%). Included in this number are two women who are currently receiving palliative treatment[6] and eight women who were reported to have a recurrence of their cancer.

[6] Palliative treatment may include radiotherapy, chemotherapy or other medications. It aims to shrink the size of the cancer, slow down its growth and/or control associated symptoms and manage pain.

The majority of women (n=178/80%) were reported by their treating clinician to have no evidence of active disease.

The current health status of four women remains unknown for the following reasons: three women are private patients and the other woman did not attend follow-up appointments.

Having no evidence of active disease does not mean that women do not experience short-term and long-term side effects. Every cancer treatment can cause both physical and psychological side effects.

Some treating clinicians provided additional information which indicated that many women continue to be living with complications. Complications can be long-lasting and are not limited to the following: infertility, sexual difficulties, premature and sudden menopause, pain, bladder and kidney problems, incontinence, adhesions, and lymphoedema[7].

The side effects of chemotherapy and radiotherapy are on-going during and after treatment, e.g., nausea, vomiting, diarrhoea, exhaustion, anaemia, itchy skin, stenosis[8], weakened pelvic bones and lowered immune system making the individual more susceptible to infections.

Literature would indicate that for many reasons, women do not experience the same side effects even though they have received the same treatment and because of this it is very difficult to predict one all-inclusive after-care model. Psychological trauma is also a factor that requires consideration, e.g., after treatment some women may find adjusting to permanent body changes difficult.

6. Summary

As stated at the outset, this report does not provide an individual report on each of the 221 women. This was not an audit or a clinical review. A clinical review is currently being undertaken by RCOG. Finally, this report does not provide any opinion on the CervicalCheck audit as this was reported upon in the Scally Report.

CervicalCheck carried out an audit of 1,482 cervical screening tests on women who were diagnosed with cervical cancer between 2008 and 2018. Of the 1,482 women included in this look-back audit, it was found that for 221 women the screening test should have provided a different result or a warning of increased risk or evidence of developing cancer.

Cervical cancer is a young woman's disease and this was reflected in the age profile of the 221 women. The promotion of the uptake of the HPV vaccine to protect girls from developing cervical cancer is vital. The HPV vaccine prevents 7 out of 10 cervical cancers. The target uptake of two doses of the HPV vaccination is ≥80%. The figures for the academic year 2016/2017 indicate that 51% of girls at second level education were recorded as having received the two doses of the vaccine. Increased uptake of the HPV vaccine by Irish girls will significantly reduce the presence of HPV within the population and therefore the incidence of cervical cancer in the future. The vaccine has as yet to be given to boys in Ireland.

[7] Lymphoedema is swelling (oedema) that occurs as a result of damage to or the removal of lymph nodes and the lymph fluid will not drain properly. This causes the fluid to build up and the affected area will become swollen.

[8] Stenosis: Both EBRT and brachytherapy can cause scar tissue to form in the vagina. The scar tissue can make the vagina narrower (called vaginal stenosis), less able to stretch, or even shorter, which can make sex painful.

Regular smear testing is the most important thing a woman can do to prevent cervical cancer. It is estimated that cervical screening can prevent 75% of cervical cancer cases. Cervical cancer is a very treatable gynaecologic cancer and curable if caught early and therefore, the importance of women continuing to attend for cervical screening when invited cannot be stressed enough.

The treatment the women received is dependent on many factors, including the stage of the cancer. The staging of cervical cancer is complex as the sub-divisions within this staging system are an indicator of the progression of the cancer. For the majority of the 221 women, the type of cancer they were diagnosed with classified them at stage 1.

The treatments and interventions for the 221 women were varied and in most cases individual to each woman. Treatment was also dependent on the type of cancer diagnosed, the staging, and the age of the woman. This project highlights the insidiousness of cervical cancer and how invasive the treatments can be, which can have a devastating effect on a woman's life. It is unlikely that two women will experience the same side effects even though they have received the same treatment and because of this it is very difficult to predict one all-inclusive after-care model.

As shown in this report, 178 of the 221 women currently have no evidence of active disease. Twenty one women died from their disease. Eighteen women currently remain in treatment. The current health status of four women remains unknown for the following reasons: three women are private patients and access to their information was not available and the other woman did not attend follow-up appointments.

To conclude, the key message is that the cervical screening crisis should not deter women from continuing to attend when invited for cervical screening.