COLORECTAL CANCER SCREENING PROGRAMME

Monitor 2016

National Monitoring of the Colorectal Cancer Screening Programme

Erasmus MC – NKI / AvL

The screening programme is proceeding well. In 2016, 1,063,651 individuals participated and 3,706 individuals were diagnosed with colorectal cancer. Potential precursors (advanced adenoma) of colorectal cancer were diagnosed in 20,236 individuals. This year was the first in which a large group of individuals was invited to partake in their second screening round. The second screening round participation rate was high as well: 75.9% of the second round invitees participated. The results of this group highlight the importance of repeated screening, as in the second round precursors and colorectal cancers were detected as well. As expected, the numbers were lower than those for the first round participants.

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Summary

In the third year of the screening programme, 1,457,976 (94.5%) individuals of the target population were invited for colorectal cancer screening with the faecal immunochemical test (FIT). Of those invited for the first time, 745,783 (71.8%) participated, and test results were unfavourable for 42,877 (6.0%). Of the individuals in the first round with an unfavourable test result (positive test) and referral for colonoscopy, colorectal cancer was found in 2,944 (8.3%) and advanced adenoma in 16,114 (45.4%) individuals.

Of those invited for the second time, 317,868 (75.9%) participated in screening, and test results were unfavourable for 14,202 (4.5%). Of the people in the second round who received an unfavourable test result and were referred for colonoscopy, colorectal cancer was found in 762 (6.6%) and advanced adenoma in 4,122 (35.5%) individuals.

Introduction

The Dutch colorectal cancer screening programme is coordinated by the National Institute for Public Health and the Environment (RIVM). The RIVM commissioned Erasmus MC and the Netherlands Cancer Institute (NKI)/Antoni van Leeuwenhoek Hospital to carry out an annual national monitoring of the colorectal cancer screening programme. Monitoring ensures the quality of the colorectal cancer screening programme and identifies bottlenecks. Monitoring is conducted using data from ScreenIT, the national information system for the colorectal cancer screening programme. The current monitoring report presents the results of the national colorectal screening programme for 2016, the third year of the programme. This monitor is based on data of individuals invited between 1 January to 31 December 2016 who are followed up until 31 June 2017. The screening programme is carried out by five regional screening organisations, each of which is responsible for several provinces. Data of individuals who objected to the use of their personal data for quality assurance (n= 81) were excluded from the results, except for the total number of invitations sent.

Target population

The colorectal cancer screening programme's target population consists of men and women aged 55 to 75, who once every two years are invited to do a self-test that measures blood in the stool (faecal immunochemical test, FIT) . In case of an unfavourable test result, i.e. when the amount of blood in the stool samples exceeds the cut-off value of 47 µg Hb/g faeces, the participant is invited for a colonoscopy intake interview. The screening programme will be gradually implemented, with a projected roll-out of five years. In 2016, the following groups were invited to take part:

- 937,659 (60.8% of the total) individuals of the birth cohorts 1941, 1945, 1953, 1955 and 1957 received an invitation for the population screening programme for the first time;
- 143,513 (9.3% of the total) individuals of the 2015 target population who had not yet received an invitation;
- 462,051 (29.9% of the total) individuals who received their first invitation during 2014 and were eligible for the second round in 2016.

Terminology

Cut-off value = threshold of concentration of haemoglobin in the faeces at which participants are referred for diagnostic colonoscopy (unfavourable test result), presented according to the international standard in 47 µg Hb/g faeces.

Detection rate = number of colorectal cancers or advanced adenomas found per 1,000 screened individuals.

FIT = faecal immunochemical test; primary test used in the colorectal cancer screening programme

Intake interview = clinic visit in which the consequences of a positive FIT are explained and information about the follow-up procedure is provided.

Unassessable FIT = FIT which cannot be interpreted by the lab, for example due to unreadability of the barcode or because the kit contains too much stool material.

Unreliable FIT test result = FIT whose expiry date has expired or for which the period between stool collection and analysis in the lab exceeded 7 days, with a result below the cut-off value.

Positivity rate = percentage of participants with unfavourable test results (above the cut-off value).

Positive predictive value = Number of participants with colorectal cancer or advanced adenomas divided by the number of participants who underwent a colonoscopy.

ScreenIT = nationwide information system for the colorectal cancer screening programme.

MONITORING THE PARTICIPATION RATE AND RESULTS OF PRIMARY SCREENING

1. Invitees

The target group for 2016 consisted of 1,543,223 individuals. From 1 January until 31 December 2016, 1,457,976 individuals had been invited (invitations and non-participants on pre-invitation letters), encompassing 94.5% of the target population. In total 1,038,997 first round and 418,979 second round invitations have been sent. The remaining 85,247 (5.5%) individuals of the target population of 2016 will be invited in 2017.

2. Participation in screening using FIT, first and second rounds 2016

Of the invited individuals in 2016, 1,063,651 participated. Those invitees who did not participate can be divided into two groups: those who actively opt out of screening (non-participants) and those who did not respond (non-responders). There were a total of 121,748 non-participants and 272,577 non-responders. A reminder letter was sent to 98.5% of the non-responders. Of the 1,051,016 individuals sending in a FIT, 962,752 (91.6%) initially returned an assessable and reliable test. The initially returned test was unassessable (for example due to an excess of faeces) in 2,920 (0.3%) participants, unreliable (return period longer than 6 days) in 8,778 (0.8%) participants and incomplete (for example due to missing or incomplete filled form) in 76,566 (7.3%) participants. Finally, after (repeatedly) sending a new FIT, 1,054,275 (99.1%) participants had an assessable FIT.

First round

Of those who received an invitation for the first time, 745,783 participated. Therefore, the total participation rate of the first round of the screening programme comes to 71.8% (table 1). In total, 98,002 (9.4%) people opted out (non-participants). Of those, 49,692 already opted out upon receipt of the pre-invitation letter. 195,212 (18.8%) individuals did not respond to the invitation (non-responders)

Second round

Of those who received an invitation for the second time, 317,868 participated. Therefore, the total participation rate of the second round of the screening programme comes to 75.9% (table 1). In total, 23,746 (5.7%) people opted out (non-participants) and 77,365 (18.5%) did not respond to the invitation (non-responders).

23,613 first round participants took part in a scientific study within the framework of the population screening programme. As they have been screened with different types of FIT tests and a lower cut-off value, their results will not be reported in the remaining part of this monitor. Therefore, the results in the remaining part of this monitor relate to 1,040,038 participants, of whom 1,030,678 had an assessable FIT.

Table 1: Numbers and percentages men and women who participated in FIT screening by age and screening round (Source: ScreenIT)

Age groups	Men		Women		Total	
First screening round						
55-59 years	74.095	*67.6%*	81.613	*74.4%*	155.708	*71.0%*
60-64 years	160,056	*70.2%*	173,102	*75.3%*	333,158	*72.8%*
65-69 years	18,953	*72.6%*	19,856	*76.3%*	38,809	*74.4%*
70-75 years*	105,831	*70.5%*	112,277	*70.2%*	218,108	*70.4%*
Subtotal	**358,935**	***69.9%***	**386,848**	***73.6%***	**745,783**	***71.8%***
Second screening round**						
60-64 years	7,142	*69.0%*	7,615	*76.6%*	14,757	*72.7%*
65-69 years	147,013	*74.3%*	156,098	*77.8%*	303,111	*76.0%*
Subtotal	**154,155**	***74.0%***	**163,713**	***77.7%***	**317,868**	***75.9%***
All screening rounds						
Total	**513,096**	***71.1%***	**550.564**	***74.8%***	**1.063.651**	***73.0%***

* Including some persons from birth cohort 1940. who were not invited in 2015.
** In the second screening round, not all age groups have been invited yet.

3. FIT findings

Of all invited individuals in 2016, a total of 57,079 participants with an assessable FIT had an unfavourable test result.

First round

Of the first round participants, 42,877 (6.0%) individuals with an assessable FIT had an unfavourable test result (positivity rate). Of these, 25,615 (7.5%) were male and 17,262 (3.9%) were female (table 2). The positivity rate increased with age (Figure 1).

Second round

Of the second round participants, 14,202 (4.5%) individuals with an assessable FIT had an unfavourable test result. Of these, 8,214 (5.7%) were male and 5,988 (3.7%) were female.

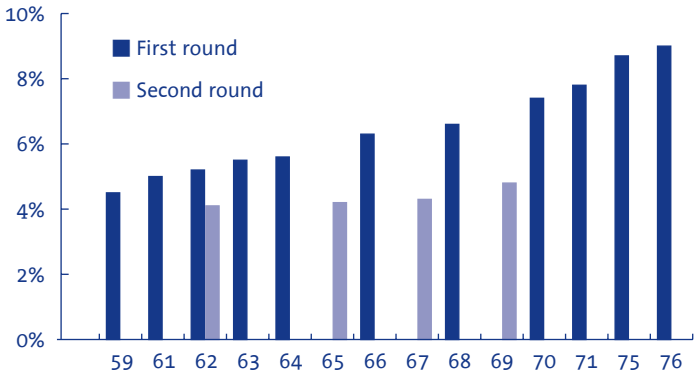

Figure 1: Unfavourable test results (positivity rate) by age group* and screening round (Source: ScreenIT)

* Age groups containing less than 50 persons with an unfavourable test result are not shown in the figure.

Table 2: Numbers and percentages men and women with unfavourable test results (positivity rate*) of persons with an assessable stool sample, by age and screening round (Source: ScreenIT)

Age groups	Men		Women		Total	
First screening round						
55-59 years	3,842	*5.6%*	2,653	*3.5%*	6,495	*4.5%*
60-64 years	10,025	*6.6%*	6,703	*4.0%*	16,728	*5.2%*
65-69 years	1,489	*7.9%*	951	*4.8%*	2,440	*6.3%*
70-75 years**	10,259	*10.0%*	6,955	*6.4%*	17,214	*8.1%*
Subtotal	**25,615**	***7.5%***	**17,262**	***3.9%***	**42,877**	***6.0%***
Second screening round						
60-64 years	356	*5.3%*	249	*3.3%*	605	4.1%
65-69 years	7,858	*5.7%*	5,739	*3.7%*	13,597	4.5%
Subtotal	**8,214**	***5.7%***	**5,988**	***3.7%***	**14,202**	**4.5%**
All screening rounds						
Total	**33,829**	***6.9%***	**23,250**	***3.8%***	**57,079**	***5.5%***

* Denominator of 715.037 participants, due to the exclusion of persons who participated in a study
** Including some persons from birth cohort 1940, who were not invited in 2015.

Part 2

MONITORING THE PARTICIPATION RATE AND RESULTS OF THE DIAGNOSTIC FOLLOW UP

1. Participation intake interview

In total, 57,079 participants had an unfavourable FIT result. Of these, 57,062 (99.97%) were invited for an intake interview for colonoscopy; the other 17 were either sent invitations after 30 June 2016 or had died or migrated before they received the invitation. The initial intake interview was rescheduled by 21,648 (37.9%) of the participants. Appointments were moved to a different time, date or location. Of all those invited for an intake interview, 51,404 (90.1%) participated. Of the remaining invitees, 189 (0.3%) had an intake interview scheduled, 4,530 (7.9%) opted out, and 939 (1.6%) did not show up for their intake interview. Of those who opted out prior to the intake interview, 1,369 (30.2%) did so on the advice of the general practitioner. Reasons were unknown for the remaining 3,156 (69.7%) cancellations.

2. Recommended follow-up strategy from intake interview

Of the 51,404 people who attended the intake interview, 48,108 (93.6%) were advised to undergo a colonoscopy and 788 (1.5%) were advised to undergo CT colonography. 1,075 (2.1%) participants were advised to postpone colonoscopy for the time being or were referred to a different colonoscopy centre. 1,433 (2.8%) participants were advised to not undergo follow-up examination.

3. Participation in colonoscopy

Of the individuals who during the intake interview were advised to undergo a colonoscopy, 47,257 (98.2%) underwent colonoscopy and had colonoscopy reports and/or pathology reports available. Thus, a total of 82.8% participants with an unfavourable FIT result underwent a colonoscopy (Table 3).

Table 3: Numbers and percentages of participants with an unfavourable FIT who underwent a colonoscopy, by age and screening round (Source: ScreenIT)

Age group	Total	
First screening round		
55-59 years	5,505	*84.8%*
60-64 years	14,231	*85.1%*
65-69 years	2,048	*83.9%*
70-75 years*	13,819	*80.3%*
Subtotal	**35,603**	***83.0%***
Second screening round		
60-64 years	491	*81.2%*
65-69 years	11,163	*82.1%*
Subtotal	**11,654**	**82.1%**
All screening rounds		
Total	**47,257**	***82.8%***

*Including some persons from birth cohort 1940, who were not invited in 2015.

4. Colonoscopy findings

Participants were classified according to the most severe abnormality found during colonoscopy. This involved the following sequence (from most severe abnormality to no abnormalities): colorectal cancer, advanced adenomas, non-advanced adenomas, serrated polyps, other malignancies and no polyps or tumours. At national and international level, colorectal cancer and advanced adenomas (collectively referred to as "advanced neoplasia") are considered as relevant findings within a colorectal cancer screening programme.

Table 4 summarizes colonoscopy yield by age group and screening round. During colonoscopy, colorectal cancer was found in 3,706 participants. In 20,236 participants, the most important finding was an advanced adenoma.

First round

During colonoscopy in the first round, 2,944 (8.3%) participants were diagnosed with colorectal cancer. An advanced adenoma was the most important finding in 16,114 (45.4%) participants. Both percentages increased by age. The positive predictive value of the FIT, that is the percentage of participants who underwent a colonoscopy and were diagnosed with colorectal cancer and/or advanced adenoma, was 53.7%. Furthermore, 7,496 (21.1%) participants were diagnosed with non-advanced adenomas, 1,854 (5.2%) with serrated polyps and 15 (0.04%) with other malignancies. No polyps or tumours were found in 7,088 (20.0%) individuals (Figure 2a).

Second round

During colonoscopy in the second round, 762 (6.6%) participants were diagnosed with colorectal cancer. An advanced adenoma was the most important finding in 4,122 (35.5%) participants. The positive predictive value of the FIT was 42.1%. Furthermore, 3,117 (26.9%) participants were diagnosed with non-advanced adenomas, 698 (6.0%) with serrated polyps and 6 (0.05%) with other malignancies. No polyps or tumours were found in 2,906 (25.0%) individuals (Figure 2b).

5. Detection rate of the screening programme

Colorectal cancer or advanced adenomas were found in 23,942 of the 1,063,651 participants. This corresponds to a detection rate of 23.1 per 1,000 screened individuals. Table 5 shows the difference between the detection rates by age groups and the first and second rounds. The detection rate in the first round was 26.4 per 1,000 participants and in the second round 15.4 per 1,000 participants.

Table 5: Detection rate per 1,000 participants by age and screening round (Source: ScreenIT)

Age group	Colorectal cancer		AA	
First screening round				
55-59 years	318	*2.2*	2,432	*16.5*
60-64 years	1,012	*3.1*	6,418	*19.9*
65-69 years	184	*4.7*	938	*24.2*
70-75 years*	1,430	*6.7*	6,326	*29.6*
Subtotal	**2,944**	***4.1***	**16,114**	***22.3***
Second screening round				
60-64 years	21	*1.4*	154	*10.4*
65-69 years	741	*2.4*	3,968	*13.1*
Subtotal	**762**	***2.4***	**4,122**	***13.0***
All screening rounds				
Total	**3,706**	***3.6***	**20,236**	***19.5***

Abbreviations: AA (Advanced adenoma).
*Including some persons from birth cohort 1940, who were not invited in 2015.

Table 4: Colonoscopy yield by age and screening round (PPV) (Source: ScreenIT)

Age group	Colorectal cancer		AA	
First screening round				
55-59 years	318	*5.8%*	2,432	*44.3%*
60-64 years	1,012	*7.1%*	6,418	*45.2%*
65-69 years	184	*9.0%*	938	*45.9%*
70-75 years*	1,430	*10.4%*	6,326	*45.9%*
Subtotal	**2,944**	***8.3%***	**16,114**	***45.4%***
Second screening round				
60-64 years	21	*4.3%*	154	*31.4%*
65-69 years	741	*6.7%*	3,968	*35.7%*
Subtotal	**762**	***6.6%***	**4,122**	***35.5%***
All screening rounds				
Total	**3,706**	***7.9%***	**20,236**	***42.9%***

Abbreviations: PPV (Positive Predictive Value), AA (Advanced adenoma).
*Including some persons from birth cohort 1940, who were not invited in 2015.

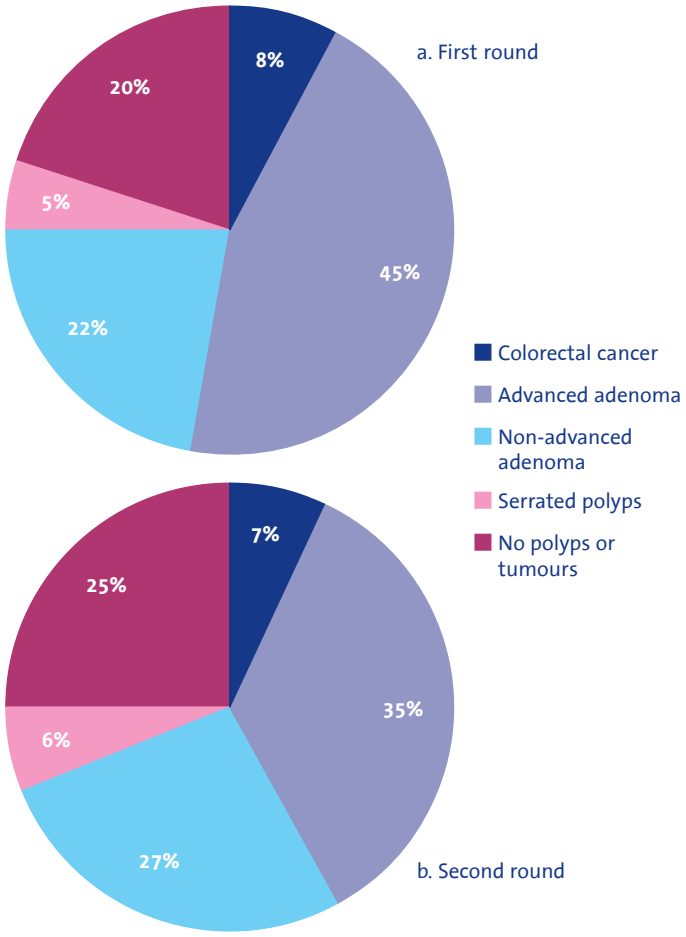

Figure 2: Colonoscopy yield of first and second screening round
As a result of rounding, the total percentages can be over 100%.

6. Stage distribution of screen-detected cancers

Colorectal cancer has several stages, depending on the extent of the tumour and the presence of metastases. This classification has four stages: I, II, III and IV. Stage I concerns a tumour confined to the intestinal wall; stage II concerns a tumour extending beyond the intestinal wall; stage III concerns a tumour extending beyond the intestinal wall with metastasis to local lymph nodes; and stage IV concerns a tumour extending beyond the intestinal wall with metastasis to other organs. Detection of colorectal cancer in an early stage improves the chance of survival.

The stage distribution of the colorectal cancers of the target group 2016 is not yet available at the moment this monitor was completed. Therefore, we present the stage distribution of the screen-detected colorectal cancers of 2015 (Figure 3). People with screen-detected colorectal cancer have a more favourable stage distribution than people with symptom-detected colorectal cancer. This suggests that colorectal cancer screening detects cancers in an earlier stage.

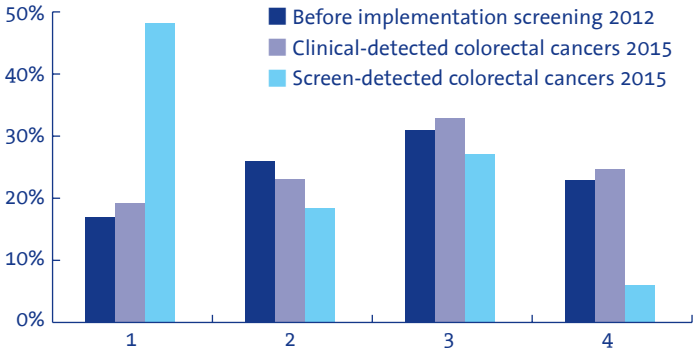

Figure 3: Comparison of stage distribution before the implementation of the colorectal screening programme and during the programme (Source: Dutch Cancer Registry)

7. Complications during or after colonoscopy

The number of participants for whom a complication was recorded during or within 30 days after colonoscopy is shown in Table 6. This contains all colonoscopies performed in 2016 and could therefore contain complications of participants of 2015. The reports are gathered from two different complication registration systems. Originally, all complications were registered in ScreenIT. To prevent extra work, it was decided to register the complications of colonoscopy in the Dutch Registration of Complications in Endoscopy (DRCE). The implementation of the DRCE is not finished yet. Therefore, 2016 and 2017 are transitional years, in which both ScreenIT and DRCE are used to give insight in the complications during or after a colonoscopy. Theoretically, this could result in double counted complications or an underestimation of serious complications. In 2018 the DRCE is expected to be the only data system for complications of the colonoscopy, making the registration more reliable.

Table 6a shows the number of participants with complications registered in ScreenIT. This concerns complications from the endoscopy report and complications entered manually. Table 6b shows the number of participants with complications registered in DRCE. In total, 50,060 colonoscopies were performed in 2016 on account of the screening programme. The following complications are registered: 2 (0.006%) fatal complications (i.e. death of the individual) in ScreenIT (of which 1 also reported in the monitor 2015) and 1 (0.002%) fatal complication in DRCE; 23 (0.045%) serious complications (i.e. hospitalization for more than 10 days) in ScreenIT and 15 (0.034%) in DRCE. The reported colonoscopy complications only include the fatal and serious complications because the data concerning moderate and minor complications are unreliable. The latter complications also include procedural complications that were immediately managed properly, such as a minor bleedings during polypectomy. These have no impact on the patient's treatment or subsequent health status. Therefore, in accordance to national and international guidelines, they cannot be defined as a colonoscopy complication.

Table 6a: Number of colonoscopy complications in 2016 (Source: ScreenIT)

Type	Serious	Fatal
Perforation	12 (0.024%)	-
Bleeding	9 (0.018%)	1 (0.002%)
Other	2 (0.004%)	1 (0.004%)
Total	**23 (0.045%)**	**2 (0.006%)***

* 1 fatal complication has also been reported in the monitor of 2015. As these numbers include all colonoscopy complications in 2016, which also might be complications of invitees 2015.

Table 6b: Number of colonoscopy complications in 2016 (Source: DRCE)

Type	Serious	Fatal
Perforation	11 (0.022%)	-
Bleeding	3 (0.006%)	-
Other	3 (0.006%)	1 (0.002%)
Unknown	-	-
Total	**17 (0.034%)**	**1 (0.002%)**

Part 3

MONITORING PROCESSING TIMES

The various processing times are displayed as averages (in calendar days), the first (Q1) quartile, median (Q2) and third quartile (Q3). The first quartile (Q1) indicates the maximum processing time for the first 25% of individuals, the median (Q2) is the processing time for half of the individuals, and the third quartile (Q3) corresponds to the processing time for the first 75% of individuals.

- The **return period** (the time interval between the self-sampling date and sending the letter with the FIT result to the participant) was on average 2.5 days (Q1: 1 days, Q2: 2 days, Q3: 4 days). *Target value: 7 week days*
- The **waiting time for an intake interview** (the time interval between sending the letter with the FIT result and the date of the initially scheduled intake interview) was on average 23.6 days (Q1: 19 days, Q2: 24 days, Q3: 28 days). *Target value: 42 week days (temporarily extended due to limited colonoscopy capacity)*
- The **average travel distance to the initial scheduled intake interview location** (the distance between an individual's home address and the intake location) was 21.1 km on average (Q1: 9.0 km, Q2: 17.9 km, Q3: 27.6 km). *Maximum limit: 40 km*

The average return period, waiting time and travel distance are all within the defined target values.

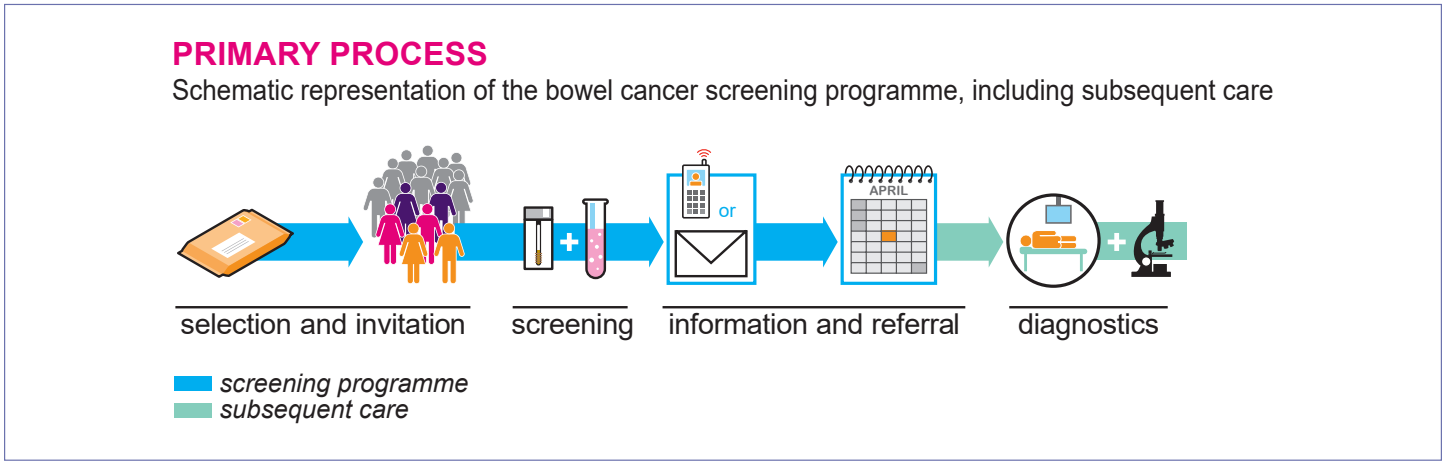

Figure 4: Processing times primary process (Source: ScreenIT)

Part 4

TOTAL SCREENING PROCESS

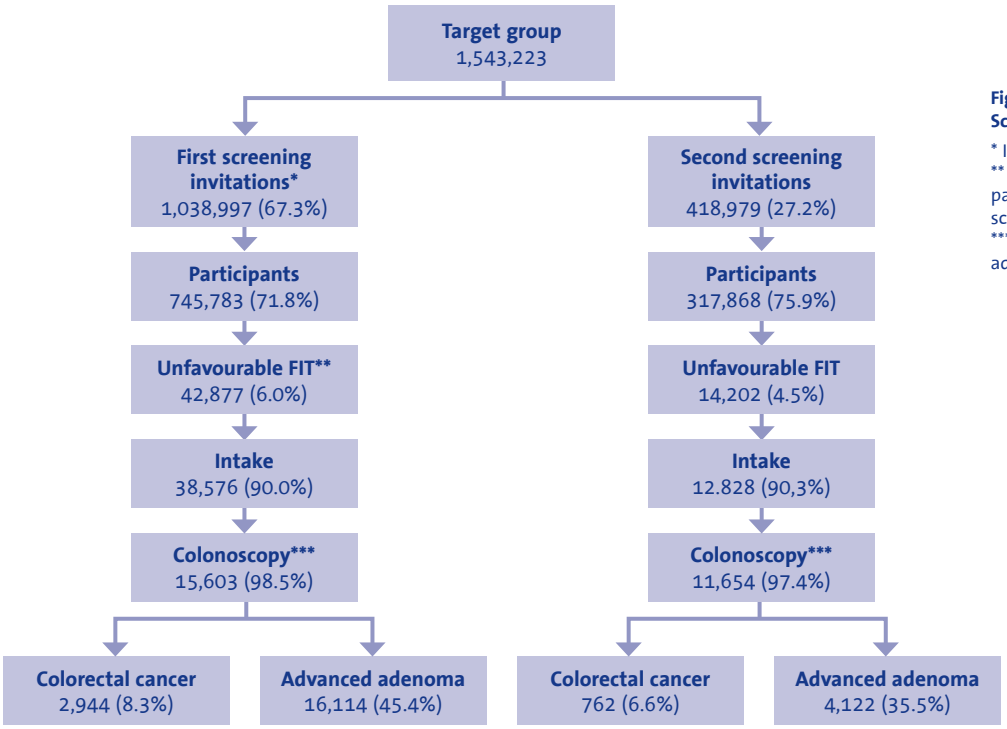

Figure 5: Total screening process invitees 2016 (Source: ScreenIT)

* Including non-participants on pre-invitations letters
** Divided by 715,037 participants, as some participants were exluded because they took part in a scientific study
*** Divided by the number of participants who were advised to undergo colonoscopy.

Part 5

NATIONAL INCIDENCE AND MORTALITY

The incidence of colorectal cancer in 2016 is comparable to that in 2015. In 2013, the year previous to the implementation of the national colorectal cancer screening programme, there were 77.6 new cases (crude incidence rates per 100,000). This rate increased to 89.4 in 2014, to 91.4 in 2015 and to 90.1 in 2016.

At the time this monitor was submitted for publication, mortality rates for 2016 had not yet been made available. In 2013, the mortality rate was 29.4 per 100,000 individuals, in 2014 it was 29.1 per 100,000 and in 2015 it was 30.2 per 100,000.

Part 6

COMPARISON BETWEEN 2014, 2015 AND 2016

The results of the first two years of the national colorectal cancer screening programme have been separately reported in the 2014 and 2015 annual monitors. A comparison between the first two years and the year 2016 gives insight in the programme's continuity and quality (table 7 and figure 6). The comparison includes only individuals from the 2014 monitor who were assessed with the same FIT cut-off value as the present report (47 µg Hb/g faeces).

The comparison shows the results of important indicators such as participation in FIT, positivity rate, detection rate and positive predictive value (PPV).

Table 7: Comparison of results monitor 2014, 2015 en 2016 (Source: ScreenIT)

	2014*	2015*	2016	
Screening round	First	First	First	Second
Participation	71.6%	73.0%	71.8%	75.9%
Mean age participants (years)	66.7	66.1	64.9	67.1
Positivity rate (47 µg Hb/g faeces)	6.4%	6.4%	6.1%	4.5%
Detection rate CRC**	4.9	4.6	4.1	2.4
Detection rate CRC and AA**	25.3	29.7	26.4	15.4
PPV CRC	9.5%	8.8%	8.3%	6.6%
PPV CRC and AA	58.7%	57.2%	53.7%	42.1%

Abbreviations: PPV (Positive Predictive Value), CRC (colorectal cancer), AA (advanced adenoma)
* Results of monitor 2014 en 2015 are based on most recent data (until 1 july 2017). Numbers can deviate from previous reported.
** Detection rate per 1,000 participants

Considering the first round participants of all three years, the participation rate is comparable. The positivity rate and the detection rate for advanced adenomas and colorectal cancer is more or less comparable in the first round participants of all three years. A different age composition due to different invited birth cohorts could explain the small differences. Partly, this could also explain the small decrease in the PPV over the years.

In the second round, the participation rate is increased compared to the first round. As expected, the positivity rate, detection rate and PPV decreased in the second round. Fewer abnormalities are found during colonoscopy, because the prevalence of colorectal cancer and advanced adenoma decreased after a first round of screening.

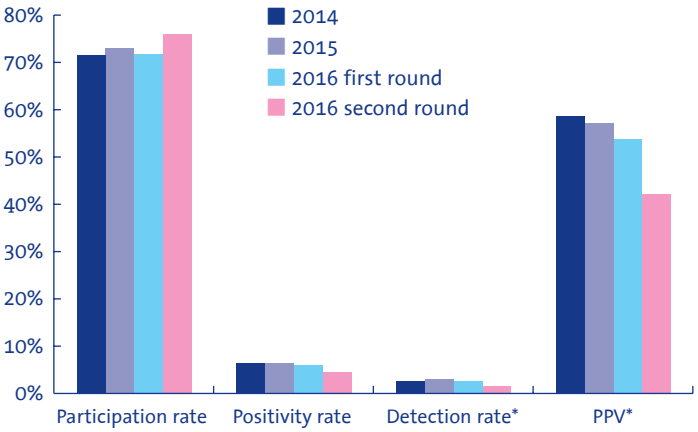

Figure 6: Comparison results monitor 2014, 2015 and 2016 (Source: ScreenIT)

Abbreviations: PPV (Positive Predictive Value)
* Colorectal cancer and advanced adenoma