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Three years of colorectal cancer screening in Denmark

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ABSTRACT

Background: The Danish National Colorectal Cancer Screening Programme was implemented in March 2014 and is offered free of charge to all residents aged 50–74 years. The aim of this study is to compare performance indicators from the Danish National Colorectal Cancer Screening Programme to the recommendations from European Guidelines in order to assure the quality of the programme and to provide findings relevant to other population-based colorectal cancer screening programmes.

Methods: Based on data from the Danish Colorectal Cancer Screening Database, we evaluated all performance indicators for which the European Guidelines provided acceptable level, desirable level or the level from first screening rounds in population-based studies using FIT.

Results: All performance indicators were above the acceptable level and/or in line with the level from the first screening round in population-based studies using FIT. Whenever the European Guidelines provided a desirable level for a performance indicator, the Danish National Colorectal Cancer Screening Programme was close to or above this desirable level.

Conclusions: Compared to the European Guidelines, all performance indicators were above the acceptable level and close to the desirable level. Based on these findings, the implementation of the National Danish Colorectal Cancer Screening Programme is considered a success and the programme is hopefully in the process of reducing colorectal cancer morbidity and mortality in Denmark.

This study provides relevant information for comparisons to other population-based public service colorectal cancer screening programmes as well as for future revisions of guidelines.

1. Introduction

In 2012, Denmark had the fourth highest age-standardised rate for colorectal cancer in the world (40.5 per 100,000) [1]. Results from randomised controlled studies have shown that guaiac faecal occult blood testing (gFOBT) screening reduces colorectal cancer mortality by 18% [2]. Based on this and the fact that faecal immunochemical test (FIT) screening has proved to have a higher participation rate, detection rate and positive predictive value [3–5], it was decided to set up a national colorectal cancer screening programme in Denmark.

The overall aim of colorectal cancer screening is to reduce morbidity and mortality of the disease, but such outcomes are only measurable after several years and rounds of a cancer screening programme. Meanwhile, performance indicators can be set up for continuing evaluation and monitoring of an ongoing screening programme, as e.g. suggested in the European Guidelines for colorectal cancer screening [6].

The aim of this article is to compare outcome from the Danish National Colorectal Cancer Screening Programme to the European Guidelines and to provide findings relevant to other population-based public service colorectal cancer screening programmes.

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2. Methods

The Danish National Colorectal Cancer Screening Programme was implemented 3 March 2014 [7] and is offered free of charge to all residents aged 50–74 years.

All residents with a registered address in Denmark, aged 50–74 years in the period 1 January 2014 – 31 December 2017 were invited to have one screening in the first screening round [8]. To gradually build up the colonoscopy capacity, the first screening round was planned to take 46 months (3 March 2014 – 31 December 2017), and subsequent rounds, were all residents aged 50–74 years will be invited once, are planned to take two years. Citizens are invited randomly according to birth month, meaning that first all citizens born in one month were invited, thereafter citizens born in another month etc. The sequence of months was drawn randomly. Non-invited citizens turning 75 during the first invitation round were invited 1 month before turning 75. Citizens turning 50 during the first invitation round were invited 1–3 months before turning 50 [8]. Each of the five regions in Denmark is responsible for invitations and follow-up procedures in their own region.

All citizens are invited by mail, receiving an invitation letter, an information leaflet with arguments for and against participating, the OC Sensor faecal immunochemical test (FIT) sample bottle and a faeces collection sheet. The invitation letter is a four-page letter including a small instruction cartoon that depicts how to collect the sample and how to label it.

In the invitation letter it is stated that citizens already enrolled in a surveillance programme after being diagnosed with colorectal cancer or adenoma should not participate. It is also stated that citizens with inflammatory bowel disease (IBD) should discuss with the gastroenterologist in charge of their surveillance or treatment of IBD, whether participation is relevant. A citizen can request a new FIT test if the prior one is lost or damaged. Citizens not participating within 45 days receive a written reminder [7].

Returned FIT tests are analysed using the OC Sensor (Eiken Chemical Company, Tokyo, Japan). Citizens returning a test, which cannot be analysed for technical reasons, receive a new test kit by mail. Citizens returning an FIT test containing more than 100 μg haemoglobin(Hb)/L (20 μg Hb/g faeces as the sample bottle collects 10 mg faeces and contains 2 ml buffer) are referred to a colonoscopy. If the colonoscopy is incomplete guidelines say that a CT colonography should be performed on the same or the following day to avoid a new bowel preparation. If the colonoscopy is incomplete due to pain and polyp(s) are detected at this incomplete colonoscopy, a new colonoscopy in general anaesthesia or Propofol sedation is scheduled. Based on these assessments and subsequent histological diagnosis citizens should get either of these five outcomes: colorectal cancer, high risk adenoma, middle risk adenoma, low risk adenoma or clean colon. When the outcome was high- or medium risk adenomas the citizen was referred to follow-up colonoscopy after 1 year (high-risk adenomas) or 3 years (medium-risk adenomas). Otherwise if the outcome was low-risk adenomas no follow-up colonoscopy was scheduled, but the citizen will be invited to participate in the next FIT screening round. When the outcome was clean colon, the citizen will be invited to FIT screening again in 8 years' time.

2.1. Study population

The study population consists of all citizens invited to participate in the Danish National Colorectal Cancer Screening Programme from the start until end 2016 (i.e. 3. March 2014-31. December 2016). As citizens were invited randomly based on birth month, the results from this study population will be representative of the results from the entire first screening round.

2.2. Data

All information is taken from the Danish Colorectal Cancer Screening Database (DCCSD) [9]. DCCSD is a clinical database that was established to monitor the quality of the screening programme. The database only contains data from existing registries, so no data are entered manually in the DCCSD.

Information on invitations is original from the IAM database and include among others: The date of which the invitation letter was generated, whether this was a first invitation/a new invitation or reminder, the date the returned sample was analysed, the amount of blood in the sample, the date of first and second offered colonoscopy. The IAM database further holds information on returned FIT tests, i.e.: the date the sample was analysed, whether the returned sample was positive/negative or analysable; the amount of blood in the sample (samples with $\leq$35 μg Hb/L are reported as 35 μg Hb/L; samples with $\geq$1000 μg Hb/L are reported as 1000 μg Hb/L).

Information of performed colonoscopies, sigmoidoscopies and CT colonographies are found in the Danish National Patient Registry (DNPR). Hospitals are paid for a procedure only if the procedure is reported to DNPR. This probably explains why DNPR is deemed to be a register of high quality [10]. A recent study found that there was a high level of agreement between categories of codes in the DCCSD that were based on DNPR and hospital records, whereas the level of agreement between specific codes in the DCCSD and hospital records varied [11].

We obtained information on colorectal cancers and adenomas from the Danish National Pathology Registry. Evaluation of this register has shown that it is a register of very high quality [12].

2.3. Definitions

"Participants": citizens that return a stool sample within 135 days (an eventual reminder is send 45 days after the first invitation and the citizen hereafter have 90 days to participate) of the invitation.

"Participants with suitable test": citizens that return an analysable stool sample within 135 days of the last invitation.

"Screen positive": participants that return a stool sample with $\geq$100 μg Hb/L.

"Follow-up procedures": screen positives with a *KUJF32* code (colonoscopy), *KUJF35* code (colonoscopy with biopsy), *UXCD80* code (CT colonography), KUJF42 (sigmoidoscopy) or *KUJF45* (sigmoidoscopy with biopsy) in NPR, within 2 months of the date the sample was analysed.

"Colonoscopies": screen positives with a *KUJF32* code (colonoscopy), *KUJF35* code (colonoscopy with biopsy) in DNPR, within 2 months of the date the sample was analysed.

"Screen-detected cancers": "Colonoscopies" which within 6 months of the date on which the sample was analysed have one of these combination of codes in the Danish National Pathology registry: a) *T67*, T68*, T69*, T65900, T65902* (localization: colon, caecum, rectum, anal) and *M8*3* (morphology: malignant); b) *T56** (localization: liver) and *M8*6* (morphology: metastasis).

"Colonoscopies with known completeness": "Colonoscopies" where at least one colonoscopy (KUJF32 or KUJF35 code) was performed and it is registered whether or not the colonoscopy was complete.

"Complete colonoscopies": "Colonoscopies with known completeness" where it is registered that the colonoscopy was complete.

"Adenomas": "Colonoscopies" which do not belong to "Screen-detected cancers" and which within 6 months of the date the faecal sample was analysed have at least one adenoma detected (i.e. one of the following codes: *M8213F* (flat adenoma), *M82110* (tubular adenoma), *M82630* (tubulovillous adenoma), *M82611* (villous adenoma), *M82130* (traditional serrated adenoma), *M8213M* (sessile serrated polyp / adenoma)) together with a code specifying that the localization is colon, caecum, rectum or anal (i.e. *T67*, T68*, T69*, T65900, T65902).*

"High grade neoplasia": An adenom with at least one high-grade