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Protocol

Evaluation of Estonia's enhanced care management program: protocol for a cluster randomized trial

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ABSTRACT

Background: Estonia's aging population faces an increasing burden of non-communicable diseases (NCDs) and a growing population suffers with multiple chronic conditions. These changes have reduced well-being and quality of life for many older Estonians, while increasing the use of high cost specialist and emergency care. In response, the Estonia Health Insurance Fund (EHIF) is working to support primary care physicians to improve care for complex patients with multiple chronic conditions. A new EHIF program, Enhanced Care Management (ECM), trains family physicians to identify complex patients, co-develop proactive care plans with them, and conduct more active outreach and management of these patients.
Methods: In this protocol we describe a randomized controlled trial, developed in partnership with EHIF, to evaluate the impact of ECM training for physicians. The RCT enrolled a randomly selected 97 family physicians out of the 786 family physicians practicing in Estonia. Among those physicians' 6,739 ECM-eligible patients, 2,389 patients were randomly selected for enrolment into the ECM program.
Results: Using administrative records, we evaluated the effects of ECM enrolment on: (1) health care utilization; (2) provider management of tracer conditions; and (3) markers of quality of care such as hospital admission for primary health care-sensitive conditions.
Conclusions: This protocol presents a pre-specified analysis plan for this evaluation of Estonia's ECM program.
Trial registration: First registered with the American Economics Association, AEARCTR-0003661. Registered May 1, 2019. Retrospective secondary registration with www.clinicaltrials.gov P169891. Registered April 26, 2023.

Keywords: NCDs, Health systems, Aging, Chronic illness, Primary health care, Quality of care, Randomized control trial

INTRODUCTION

As the world makes progress on reducing infectious diseases and other drivers of premature mortality, NCDs such as diabetes, hypertension, and cardiovascular diseases have come to account for over 70% of deaths worldwide.[1] High and middle income countries in particular have faced rapidly rising burdens of NCDs, as improving social conditions and advanced medical treatments enable their populations to survive into older age. In these populations, co-occurrence of multiple chronic illnesses, known as multi-morbidity, is also growing. For example, 60% of the adult population in the US and over 91% of the population above the age of 65 have two or more morbidities, while in the European Union (EU), 20-40% of the population have been diagnosed with at least one chronic illness, of which 25-50% have multiple chronic conditions.[2,3] This rise in multi-morbidity can lead to premature mortality, high

expenditure on inpatient and ambulatory services, and reduced functionality and quality of life.[4-6]

These shifts in population health generate major new demands on the health system, as patients with multiple chronic conditions typically require more care, from multiple levels of the health system, over extended periods of time. One response to this challenge in the US and Europe has been a move towards more proactive and comprehensive primary care models for complex patients. These models include more proactive care by primary care providers and their teams, greater efforts to coordinate care for patients based on their specific needs for specialist care, nursing care, and preventive care, improved coordination around care transitions, and greater attention to social and economic needs of patients.

Studies from Australia, UK, US and Sweden highlight different components of these new patient-centered primary care models for complex patients. The first component is to identify patients who are classified as high risk, in order to better target preventive care.[7] The second element of patient-centered care is the creation of multi-provider teams for coordinated care provision of chronically ill patients. A third element is improved self-management by patients. A final element is the process by which providers and teams are trained and mobilized to change practices and care, which can be stimulated through changes in training, payment models, team composition, and coaching.

The evidence on these programs is mixed. Several pilot studies in the US have reduced utilization of emergency care services, with the largest decrease coming from patients with chronic conditions.[8] However, a systematic review of 16 randomized control trials of interventions for multiple chronic illnesses showed limited evidence of improvement to mental health and quality of life, and mixed effects on patient functionality, patient health-seeking behavior, and medicine management.[9]

Estonian policymakers have envisioned a two-pronged approach, to these challenges with increased efforts at disease prevention paired with efforts to reform the health system to better treat these patients.[12] The specific care model developed to improve primary care in Estonia, known as Enhanced Care Management (ECM), builds on the global models described above. ECM program components include physician coaching, risk stratification, co-creation of care plans, proactive follow up with patients between visits and after hospitalizations, and coordination with social services when applicable for patients. ECM's theory of change is that through sustained coaching, physicians can provide better care by following this model. With better management of chronic care conditions, patients will increase appropriate use of primary health care services, and will have reduced need for use of secondary and tertiary services for ambulatory-care sensitive conditions. Over time, this improved care should result in improved health and quality of life for patients, and increased patient satisfaction with care.

This protocol presents a pre-specified analysis plan for the evaluation of the Estonian ECM program. It begins by presenting details of the setting and program, and then describes the evaluation approach and data. It concludes with a short discussion of the strengths and limitations of the study.

Setting

Estonia, with a population of 1.3 million and life expectancy of 78.4 years, is a promising setting for implementation and evaluation of patient-centered care models for chronic illness management.[13] This is in part due to a strong legacy of earlier PHC-focused reforms. After gaining independence from the Soviet Union in 1991, Estonia reformed its healthcare system, creating a national insurance system model via the independent Estonian Health Insurance Fund (EHIF), and implementing a family medicine model for PHC. Additional reforms included introduction of the Quality Bonus Scheme (QBS) to incentivize preventive care provision in 2006, expansion of nursing services, establishment of a digital health system to enable digital access to health services such as prescriptions, lab tests and health records, and adoption of primary healthcare development plans which increased service provision by primary health care providers and focused on chronic illness management and improving care continuity.[14-16] Yet despite these health system achievements, Estonia faces growing challenges. Circa 2017, approximately 50% of the population was above the age of 44, and 50% of the total population had at least one chronic illness. Multi-morbidity is also a growing problem especially among older Estonians. Among individuals between the ages of 0-18, 18.2% had at least one chronic illness and 3.4% had multiple chronic illnesses, while for those over 45, 65.6% had at least one chronic illness and 71% had multiple chronic illnesses. Notably, mortality rates for cardiovascular and circulatory system diseases are much higher than in comparator EU countries, and Estonia has among the higher rates of avoidable hospital admissions in the EU.

ECM intervention

The ECM intervention consists of training and coaching family physicians and their teams to develop holistic care and pro-active outreach plans for chronically ill patients or those vulnerable to developing chronic illnesses. The goal of ECM is to improve the quality of care provided to complex patients, by increasing the use of preventive care, improving coordination of care across health system levels, and increasing patient involvement in care. These elements can improve patient health and quality of life, and may reduce the need for curative medical services-for example, by supporting patients with type 2 diabetes to improve their diet and increase physical activity to limit further deterioration in their health.

ECM practices also aim to improve clinical quality by improving tracking of tests and referrals, follow-up by PHC providers after hospital discharges, tracking of medication adherence, and monitoring of patients between clinic visits. It includes four elements: identifying high-risk patients through risk stratification, developing care management plans by the primary care physician in consultation with the patient, proactively linking care providers together, and developing a team approach between patients and their caregivers. Overall ECM reflects global primary care reforms that aim to focus the health system's attention on high-risk groups and improve the continuity of care for these patients.[17]

A pilot of the program was first conducted in 2017 with 10 providers, focused on patients with multiple chronic conditions including cardiovascular disease (CVD), hypertension, diabetes, elevated blood lipids, and other common chronic conditions. Evaluation of the pilot showed that providers made 40% more calls to patients, and were 11% more likely to follow up within 30 days in the event of an acute CVD incident. Their patients were 11% more likely to have appropriate statin prescriptions, and 25% less likely to be hospitalized for CVD-related conditions.[18] However, this pilot was conducted with a purposively-selected group of 10 doctors who were expected to be highly motivated early adopters, limiting our ability to make inferences about the causal impact of the program, or its likely effectiveness at scale. A larger and more rigorous study is warranted, in order to test whether the impressive results achieved in the pilot can be sustained at scale.

METHODS

ECM IE design overview

This study incorporates a two-stage randomization, first at the clinic level and second at the patient level. The random selection of providers allows us to analyze differences in healthcare utilization, provider practices and markers of quality-of-care outcomes across treatment and control groups. Similarly, the randomization at the patient level allows us to analyze differences in outcomes within the patient population of all providers enrolled in ECM.

Clinic randomization

EHIF identified 421 clinics (786 providers) who were eligible for the ECM program. The study team then excluded clinics which had participated in the pilot study and those which were not currently operational, as well as clinics with five or more practicing providers. From the remaining 546 clinics, we conducted a stratified sampling via coarsened exact matching with two quality of care measurement indicators-the practice's QBS score and a management score given to each clinic.[19] We grouped all the clinics into blocks of similar performance based on the QBS and management score. From each performance block, we randomly selected one-fourth of the clinics into ECM program (We used global misfit handling applied when the number of clinics in a block was not exactly divisible by four. Any performance block with no clinic for comparison was dropped from the sampling frame). Figure 1 shows all the clinics in the primary sampling frame of the study according to their performance block for randomization.

This sampling resulted in 144 providers randomly selected into ECM and 402 providers in the control group. All providers in randomly selected clinics were enrolled in ECM. Since the clinic randomization was completed and providers were invited to join the ECM program, 47 providers have refused or dropped out. The most common reasons were lack of time, or other logistical issues, or in some cases health problems with several providers themselves. Figure 2 provides a mapping of provider randomization including excluded clinics and those who declined to participate at this stage. Since these providers dropped out of the program before the patient classification began, their patient population is excluded from randomization into the program.

Patient randomization

The next stage of randomization was conducted at the patient level. From each participating ECM provider, 25 patients were eligible for selection into the ECM program. (The number of 25 patients was based on EHIF's budgetary limitations for the program). Each year, EHIF's algorithm uses their mini information system portal (MISP) to update the list of at-risk patients who have multiple chronic illnesses. For this project, the providers selected into ECM evaluated these patients and assigned an additional risk score to each of the patients identified in MISP, as follows: 1-Mild/moderate risk of deteriorating health, 2-Severe risk of deteriorating health

Given the mix of mild/moderate and severe patients within each provider, we conduct a stratified random sampling of patients into ECM based on the risk classification, such that every patient within each risk classification group has equal probability of selection, and there are at most 25 patients selected into the ECM program from each provider. All the patients within each provider are divided into two strata-one for mild/moderate risk and second for severe risk. From each strata we then randomly selected patients into the treatment proportional to their share in the strata with a maximum of 25 patients selected in treatment. Five providers had identified fewer than 25 patients who had a risk of deteriorating health. For these providers, all the patients were assigned to treatment. Figure 3 shows the randomization outcome at the patient level, including risk classifications, while Figure 4 shows the mapping of patient randomization and provider dropout at different stages of the patient randomization. The patients assigned to ECM were invited to join ECM by their providers. All patient acceptances and refusals are recorded in their electronic health records (section 3.4.3)

which will be shared with the research team during the analysis phase.

Data

Provider sample

EHIF has a network of approximately 800 primary care providers (family physicians), roughly 70% of whom work in a solo practice clinic.[18] The research team was provided with a dataset of all the clinics, and linked providers, with their annual QBS score. This was the basis of construction the sampling frame for the provider randomization.

In order to construct performance blocks for randomization, we used the QBS data and management scores for 2019. QBS is Estonia's performance-based incentive program. We constructed a need-adjusted QBS score, re-weighting each indicator based on the experience of the scheme, awarding proportional credit to providers at an indicator level and adjusting the coverage rates for providers based on the patient need.[20] The management score is a sum of points awarded on 15 indicators of the clinic's working and managerial practices. The average score per clinic on management indicators is 10 and the average need-adjusted QBS score per clinic is 306. Because the management score was only available at the clinic level, we average the QBS score for the clinic for sampling.

Patient sample

EHIF's MISP is the portal used by EHIF to list patients who have multiple chronic illnesses, and contains information such as the name of patient's family physician, and the number of co-morbidities. We matched this dataset to the list of ECM providers, to generate lists of higher-risk patients. Additionally, every ECM provider gave an additional risk score (mild/moderate or severe risk) to each of the patients in MISP.

EHIF billing data

For all the data on outcomes such as health care utilization, provider management of tracer conditions and markers of quality of care, we use longitudinal digitized billing records. This data includes every health system interaction for Estonian citizens covered by EHIF. This includes electronic billing records for eight health care services categories over a 10 year period (2009 until 2019): primary health care, day care, outpatient care, outpatient nursing care, outpatient rehabilitation care, inpatient care, inpatient nursing care, and inpatient rehabilitation care. Each dataset contains three elements. First, every care type contains a claims summary dataset, identified by a bill number. These are initiated by the provider after every "episode of care". This data includes the duration of a treatment, type of care, and physician and patient details in reference to the care episode. Second, the claims summary dataset is accompanied by a diagnosis dataset that describes all the diagnoses which were relevant to the given care episode. Finally, the third accompanying dataset is the procedures dataset, which describes all the medical procedures that were conducted within a given episode of care. The study team has access to the billing records containing the associated insurance claims and the diagnosis and treatment for each claim filed. In each of these claims we use the international classification of disease (ICD) codes of diagnoses, and procedures.

All the key outcomes of this study will utilize these systems of data, de-identified for compliance with health insurance portability and accountability act (HIPAA) regulations.

Hypotheses

ECM's theory of change is that the program's coaching will enable family physicians and their staff to deliver better care to ECM patients. Patients will increase their use of primary healthcare services, and the care that they receive will be of higher quality. With better management of chronic conditions, patients will have fewer inpatient hospital admissions and re-admissions, and will use fewer ambulatory specialist services, and they will experience better health and higher quality of life.

RESULTS

Given these hypotheses, we focus on three outcome domains: overall healthcare utilization, provider management of tracer conditions, and measures of PHC-sensitive acute care. In domains one and three, we highlight 3 primary outcomes below; the remaining indicators are secondary study outcomes.

Healthcare utilization

This outcome will be continuous and measures the following indicators during the intervention year, at the patient level: number of primary health care interactions (primary outcome), number of inpatient care interactions (hospitalizations) (primary outcome), number of outpatient (ambulatory) services (primary outcome), number of inpatient post-hospitalization services (nursing and rehabilitation), number of outpatient post-visit services (nursing and rehabilitation), number of follow ups by telephone and number of follow ups due to chronic illness.

Provider management of tracer conditions

This outcome measures provider compliance with domain II QBS standards as the measure of quality care provision. QBS has set of guidelines for monitoring and managing type-II diabetes (ICD10 E11), hypertension (ICD10 I12-115) and myocardial infarction (ICD10 I21-I23, I25.2). This outcome measures the share of patients who are

managed in compliance with the guidelines, out of total number of patients who have a diagnosis of 3 conditions in intervention year aggregated at provider level. The guidelines for each condition are described in Table 1.

Example outcomes for this domain include: For type 2 diabetes: monitoring of glycosylated Hb (HbA1C), creatinine, cholesterol level (1 per year). For hypertension high risk patients: monitoring of cholesterol level, cholesterol fractions, glucose/glycosylated Hb, creatinine (1 per year); counselling and appointment with family nurse (1 per year). For myocardial infarction patients: Monitoring of cholesterol level (1 per year), glycosylated Hb (HbA1C) (1 per year), counselling with family nurse (1 per year).

Table 1: QBS compliance guidelines.

Category	Indicator	Description	Measurement
Diabetes-type II	Monitoring	Glycosylated hemoglobin	1 per year
		Creatinine values	
		Cholesterol values	
		Cholesterol fraction values	1 per 3 years
		Counselling for chronic patient	1 per year
Diabetes-type II	Medication	Prescribed for all diabetes type-II patients	6 prescriptions in 14 months
Hypertension I (low risk)	Monitoring	Glucose or glycosylated hemoglobin	1 per 3 years
		Cholesterol	
		Counselling for chronic patient	1 per year
		Appointment by family nurse	
Hypertension II (moderate risk)	Monitoring	Cholesterol determined for patients under 80 years of age	1 per year
		Cholesterol fractions determined for patients under 80 years of age	
		Glucose or glycosylated hemoglobin	
		Creatinine	
		ECG	1 per 3 years
		Counselling for chronic patient	1 per year
		Appointment by family nurse	
Hypertension III (high risk)	Monitoring	Cholesterol determined for patients under 80 years of age	1 per year
		Cholesterol fractions determined for patients under 80 years of age	
		Glucose or glycosylated hemoglobin	
		Creatinine	
		Counselling for chronic patient	
		Appointment by family nurse	
Hypertension medication 1	Medication	Percentage of active ingredients-based prescriptions for hypertension patients (all risk levels)	1 per year
Hypertension medication 2	Medication	Prescriptions for moderate or high-risk hypertension patients	6 prescriptions in 14 months
Myocardial infarction (MI)	Monitoring	Cholesterol	1 per year
		Glucose or glycosylated hemoglobin	
		Cholesterol fractions	
		Counselling for chronic patient	
MI	Medication	Prescription of beta-blockers treatment group (incl combination drugs)	6 prescriptions in 14 months
		Prescription of statins treatment group (including combination drugs)	6 prescriptions in 14 months
Hypothyroidism	Monitoring	TSH (thyroid stimulating hormone) determined	1 per year
Total			

PHC-sensitive acute care

Although we have access to diagnosis and billing records, we will not have access to electronic medical records with relevant clinical information e.g. HbA1C, blood pressure, BMI. However, we will monitor a small set of selected health outcomes on disease progression and healthcare quality indicators. Primarily we will track primary health care quality indicators set by the Organization for Economic Co-Operation and Development (OECD), which are often used as the standard to measure quality of care outcomes for primary care, as well as in previous studies of care integration in Estonia (e.g. World Bank

2015 and the ECM pilot). Based on this, we will construct the following outcomes:[21] Avoidable hospital admissions for asthma, COPD, diabetes, congestive heart failure, and hypertension, defined as the number of hospital admissions with any of the above as primary diagnosis (Primary outcome), emergency department visits (for any condition) (Primary outcome), inpatient readmission within 90 days after any previous inpatient admission (Primary outcome), inadequate follow up care for patients hospitalized for acute inpatient care or surgery: cardiovascular disease, acute myocardial infarction, stroke, hip fracture, cholecystectomy, (this measure is defined as the rate of patients who have follow up from family physician within 90 days of discharge), incomplete discharge from acute in-patient care (for heart failure, acute myocardial infarction, unstable angina), share of prescriptions purchased out of all the prescribed medications by provider and incidence of new diagnosis of tracer conditions.

Statistical model

For outcome (1) and (3), we specify the difference in means using the below specification:

$$Y_{ikjt} = \beta_0 + \beta_1 Patient_j + \pi_1 Strata_i + \epsilon_{jt}$$

Here, Y_{ikjt} is the outcome of patient i, with ECM provider k, in the treatment j at time t. $Patient_j$ is an indicator that the patient is selected into the ECM treatment. $\pi_1 Strata_i$ are the strata level fixed effects. ϵ_{jt} is the mean error term. $\beta_0$is the average healthcare utilization and markers of quality of care outcome in the control group of patients. $\beta_0 + \beta_1$ is the average healthcare utilization and patient health outcome for patients in each strata.

For outcome (2), we specify the difference in means in the intervention period using the below specification:

$$Y_{kpt} = \beta_0 + \beta_1 Provider_p + \pi_1 Block_k + \epsilon_{kt}$$

Here, Y_{kpt} is the provider management of tracer conditions outcome of provider k, in the treatment p at time t. $Provider_p$ is an indicator that the provider is selected into the ECM program. $\pi_1 Block_k$ are the performance block level fixed effects. ϵ_{kt} is the mean error term. β_0 is the provider QBS compliance in the control group of providers. $\beta_0 + \beta_1$ is the average provider QBS compliance for providers in each performance block.

Minimum detectable effect

We calculate the MDE for some of primary outcome variables. For this, we use the claims data from 2018 as the effective baseline in order to calculate the means and standard deviation of each indicator. We use 2018 because it includes one full year of complete claims records before the COVID-19 pandemic.

For hypothesis 1, we calculate the MDE for primary healthcare usage, with a mean of approximate 6 interactions in the year 2018, we can detect a change of 0.37 standard deviations in the utilization statistically significant at 95% and with a power of 80% (Table 2). It is important to note here that primary healthcare interactions, follow-ups and outpatient interactions have a high variance due to outliers. Therefore, the values of total interaction are winsorized to be at the 99th percentile level because of outliers. As in section 3.3.2, all values that are three standard deviations greater than the mean are treated as outliers. We also calculate MDE for secondary and tertiary utilization services such as hospitalizations, ambulance use and find a MDE of 0.14 and 0.28 standard deviations.

For hypothesis 2, we calculate the share of patients managed in compliance with QBS monitoring guidelines for type-II diabetes, all risk levels of hypertension and myocardial infarction, out of all the patients who had a diagnosis recorded in the billing records for 2018 (Table 3). We combine all three risk grades of hypertension since the billing data shared with us does not have risk levels for hypertension.

For hypothesis 3, we calculate the MDE on the share of patients who have recorded at least one hospitalization in which one of the diagnoses was asthma, COPD, type-II diabetes, congestive heart failure, or hypertension. For readmission, we calculate the share of patients who have been readmitted in the hospital within 90 days of a previous admission (Table 4 A and B). The MDE on prescriptions and inadequate follow up once we receive the data on prescriptions and complete the coding.

Table 2 shows the MDE for hypothesis 1 (healthcare utilization). The sample includes all the claims records from 2018 claims data for ECM and non-ECM populations, 175 patients in have no records in primary healthcare for 2018. For these patients, all the utilization indicators are valued as 0. 1,805 patients do not have any records in the outpatient healthcare system for 2018. For these patients, the outpatient utilization will be valued as 0. MDE indicates the minimum conditional difference in means value of 2018 utilization outcomes between ECM and non-ECM patients such that the mean is within the 95% CI with 80%.

Table 3 shows MDE for hypothesis 2 (provider management of tracer conditions). The outcome is the share of patients managed in compliance with QBS monitoring guidelines per provider. The sample includes all the claims records from 2018 claims data for ECM and non-ECM populations. 1 ECM provider has missing records for myocardial infarction for 2018. 2 non-ECM providers have missing data for 2018. The patient aggregates in the tables include all the patients with a diagnosis of type-II diabetes, hypertension and myocardial infarction in 2018. We could not distinguish between the different risk grades from the claims data.

MDE indicates the minimum conditional difference in means value of 2018 utilization outcomes between ECM and Non-ECM patients such that the mean is within the 95% CI with 80% power.

Table 2: MDE on hypothesis 1: healthcare utilization at 80% power.

Total interactions in 2018	ECM			Non-ECM			Difference		MDE
	Mean	N	Var	Mean	N	Var	Difference	SE	95% CI
PHC interactions	5.98	2389	13.96	6.14	4350	13.52	-0.09	0.10	0.37
Nurse telephone follow up	1.01	2389	3.26	0.84	4350	2.73	0.01	0.04	0.14
Telephone follow up	2.99	2389	8.38	3.27	4350	8.91	-0.09	0.07	0.28
Nurse follow up	2.55	2389	8.51	2.57	4350	8.51	0.04	0.07	0.28
Chronic illness follow up	0.52	2389	0.30	0.51	4350	0.30	0.00	0.01	0.05
Hospitalizations	0.17	2389	0.20	0.17	4350	0.21	0.00	0.01	0.05
Ambulance use	0.04	2389	0.04	0.04	4350	0.04	0.00	0.01	0.02
Inpatient nursing and rehab	0.01	2389	0.01	0.01	4350	0.01	0.00	0.00	0.01
Outpatient interactions	3.08	2389	12.65	3.05	4350	11.82	0.10	0.09	0.36
Outpatient nursing, rehab	0.11	2389	0.15	0.10	4350	0.14	0.01	0.01	0.04
Daycare interactions	0.08	2389	0.11	0.08	4350	0.11	0.00	0.01	0.03

Table 3: MDE on hypothesis 2: provider management of tracer conditions at 80% power.

QBS compliant monitoring	ECM			Non-ECM			Difference		MDE
	Mean (%)	N	Var	Mean (%)	N	Var	Difference	SE	95% CI
Type II diabetes	78	96	0.04	72	399	0.06	0.04	0.01	0.06
Completed HbA1c test	84	96	0.02	81	399	0.02	0.02	0.01	0.05
Completed creatinine test	85	96	0.02	81	399	0.02	0.03	0.01	0.05
Completed patient counselling	87	96	0.03	83	399	0.05	0.02	0.01	0.06
Completed total cholesterol test	83	96	0.02	80	399	0.02	0.02	0.01	0.05
Hypertension (I/II/III)	24	96	0.02	21	401	0.02	0.02	0.02	0.06
Completed HbA1c test	29	96	0.03	26	401	0.02	0.02	0.02	0.07
Completed creatinine test	65	96	0.02	62	401	0.02	0.02	0.02	0.06
Completed patient counselling	82	96	0.03	78	401	0.06	0.03	0.02	0.06
Completed total cholesterol test	66	96	0.01	63	401	0.02	0.02	0.01	0.05
Myocardial infarction	72	95	0.05	67	398	0.07	0.02	0.02	0.08
Completed HbA1c test	80	95	0.03	80	398	0.03	-0.02	0.02	0.07
Completed patient counselling	87	95	0.03	83	398	0.06	0.02	0.02	0.06
Completed total cholesterol test	79	95	0.03	78	398	0.03	-0.01	0.02	0.07

Table 4 A: MDE hypothesis 3-patient avoidable hospitalization at 80% power.

#Patients	ECM assigned			Non-ECM assigned			Difference		MDE
At least 1 hospitalisation record	Mean (%)	N	Var	Mean (%)	N	Var	Diff	SE	95% CI
Asthma	0.80	2389	0.008	0.99	4350	0.010	-0.001	0.003	0.010
COPD	0.67	2389	0.007	0.41	4350	0.004	0.003	0.002	0.007
Type-II diabetes	2.55	2389	0.025	1.72	4350	0.017	0.012	0.004	0.015
Congestive heart failure	0.29	2389	0.003	0.34	4350	0.003	0.000	0.002	0.006
Hypertension	8.62	2389	0.079	8.97	4350	0.082	-0.001	0.008	0.030

Table 4 B: MDE hypothesis 3-patient readmission at 80% power.

#Patients	ECM assigned			Non-ECM assigned			Difference		MDE
Readmission within 90 days	Mean (%)	N	Var	Mean (%)	N	Var	Diff	SE	95% CI
Persons readmitted at least once	17	328	0.144	19	588	0.156	0.003	0.032	0.124

The Tables 4 A and B shows the MDE on hypothesis 3 (PHC-sensitive acute care) Table 4 A shows the share of patients that have been hospitalized at least once with asthma, constructive obstructive pulmonary disorder (COPD), type II diabetes, congestive heart failure and hypertension. Table 4 B shows the share of patients that were readmitted into the hospital within 90 days of a previous admission, out of the total number of patients admitted to the hospital at least once. The difference in means is conditional on the strata for the patients for both

tables. MDE indicates the minimum conditional difference in means value of 2018 utilization outcomes between ECM and Non-ECM patients such that the mean is within the 95% CI with 80% power.

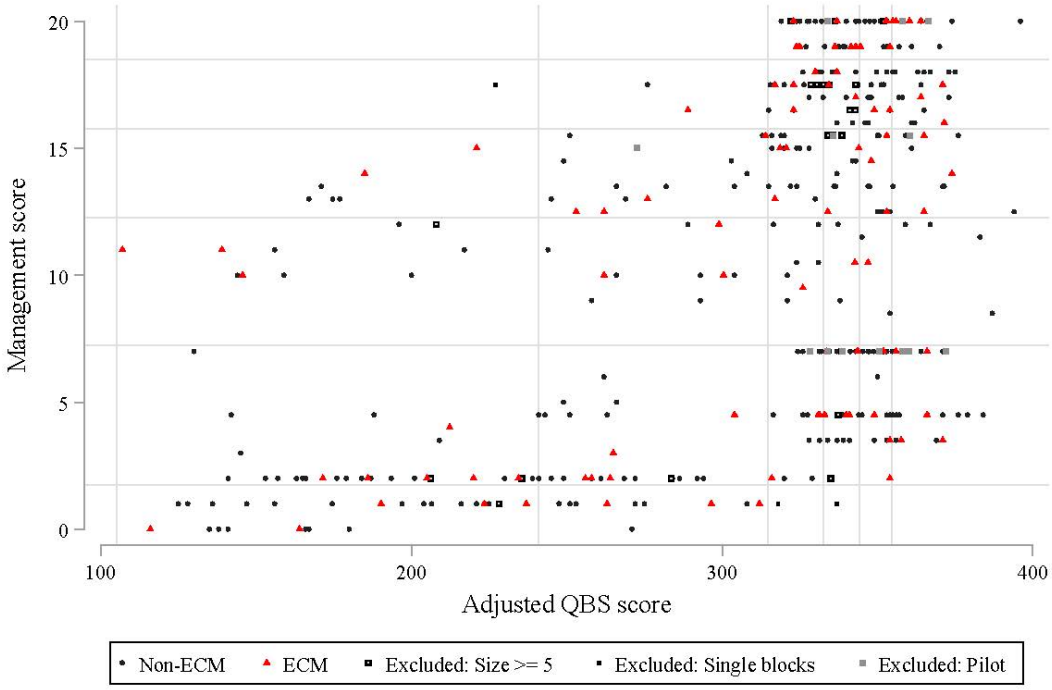

Figure 1: ECM clinic randomization grid.

The above grid shows the sampling status of every clinic in the primary sampling frame of ECM clinics. Each bullet represents a clinic with the adjusted QBS score on the horizontal axis and the management score on the vertical axis. The black dots represent the clinics that were not selected for the ECM program, the red triangle represents clinics that were invited to enroll in ECM and the three squares represent clinics excluded from the sampling frame.

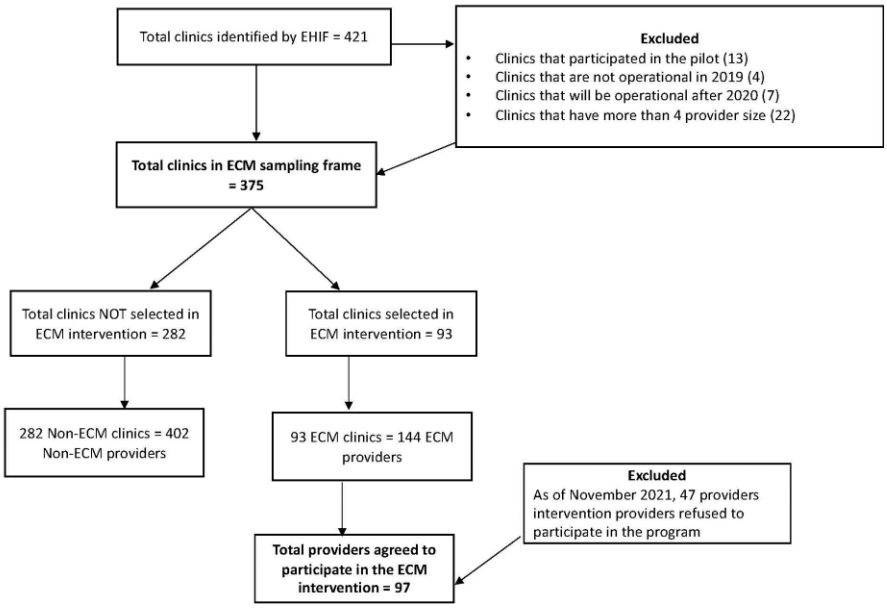

Figure 2: ECM provider randomization mapping.

The above figure displays a flowchart of the sampling frame of clinics and providers in ECM and maps it to the clinics and providers that were randomized in the program and invited to participate in ECM.

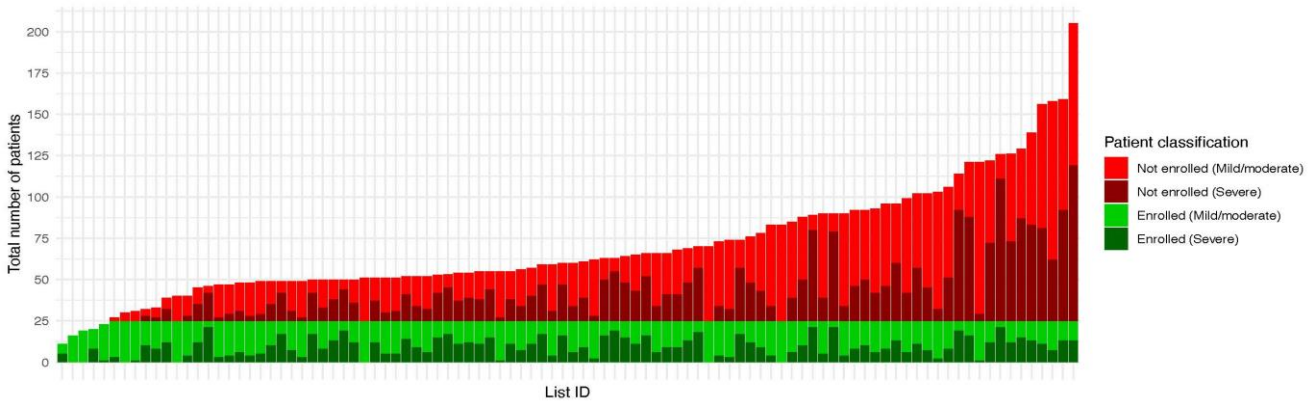

Figure 3: ECM patient randomization.

The above figure shows the randomization outcome at the patient level. Each bar represents each provider participating in the ECM program. The vertical axis represents the total number of patients in the sampling frame from each provider. The area of each bar in red represents the patients who are not selected for ECM, and the area of the bar in green represents the patients who are selected for ECM. For both areas, the darker shade (red or green) represents the patients (not selected or selected) with a severe risk patient risk classification. The lighter shade (red or green) represents patients (not selected or selected) with severe patient risk classifications.

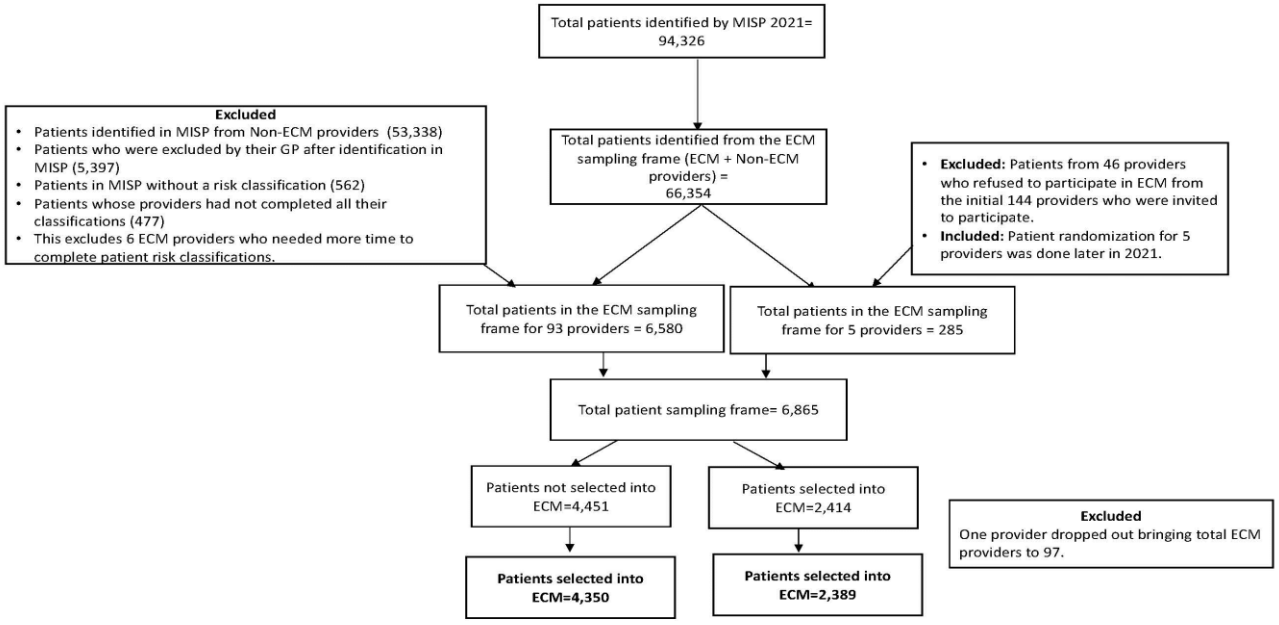

Figure 4: ECM patient randomization mapping.

The above figure displays a flowchart of the sampling frame of patients for ECM and maps it to the patients who were randomized and assigned to ECM and those who were assigned as control.

DISCUSSION

This protocol describes a large cluster randomized trial of the ECM intervention in Estonia. While similar interventions have been widely implemented in settings with large populations facing multiple chronic conditions, high quality evidence about the effects of these programs are still relatively rare. In addition, there have been limited trials of this nature in middle income settings such as Estonia. As such the evidence from this study can inform local decision makers as well as global policy.

Key strengths of the study are that it is a large, well-powered RCT, which includes randomization across and within providers. It also was designed to have strong external validity, since the sampling frame of providers included a large share of family physician clinics in Estonia. Another strength is the trial's reliance on health system billing records. Using this administrative data source has reduced the cost of the trial and means that the methods and outcomes can be used in other studies and the treated cohorts can be studied longitudinally using the same administrative data source.

A key limitation of the study is that the research team does not have access to patient medical records, which limits our ability to directly measure clinical indicators or biomarkers. Also, we will not have patient surveys, meaning that we will be unable to study ECM's effect on patient-reported outcomes such as self-rated health, patient activation, or satisfaction with care received. We also note that this protocol is submitted after patient enrollment has been completed. The trial was pre-registered in the American Economic Association trial registry prior to recruitment, and then in the clinicaltrials.gov registry after recruitment.

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