Evaluation of Estonia's Enhanced Care Management Scheme: Protocol for a cluster randomized trial

Benjamin Daniels[1*], Daniel Rogger[3], Meyhar Mohammed[3], Katre Väärsi[3] and Kevin Croke[2]

[1] Georgetown University, Washington, DC, USA. Email: bd581@georgetown.edu

[2] Department of Global Health and Population, Harvard TH Chan School of Public Health, USA. Email: kcroke@hsph.harvard.edu

[3] Development Impact Evaluation, World Bank, USA. Emails: drogger@worldbank.org, mlnu15@worldbank.org, katrevaarsi@gmail.com.

***Correspondence to:** Benjamin Daniels, Georgetown University email: bd581@georgetown.edu

Date: April 1, 2023

NCT number: to be determined

Keywords

Non-communicable diseases, health systems, aging, chronic illness, electronic health records, primary care quality, randomized control trial

ABSTRACT

Background: Estonia's aging population faces an increasing burden of non-communicable diseases (NCDs) and a growing population suffers with multiple chronic conditions. The Estonia Health Insurance Fund (EHIF) seeks to support primary care physicians to improve care for complex patients with multiple chronic conditions. The Enhanced Care Management (ECM) program entails training family physicians to identify complex patients, co-develop proactive care plans with them, and to undertake more active outreach to and management of these patients.

Methods: In this protocol we describe a randomized controlled trial in partnership with EHIF to evaluate the impact of ECM training for physicians. The study team 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. Using administrative records, we will evaluate 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.

1 BACKGROUND

As the world makes progress on reducing infectious diseases and other drivers of premature mortality, non-communicable diseases (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 old age. In these populations, co-occurrence of multiple chronic illness, also known as multi-morbidity, is also growing. These shifts in population health imply 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 periodsof 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 team, and greater efforts to coordinate care for patients based on their specific needs for specialist care, nursing care, preventive care, improved coordination around care transitions, and greater attention to social and economic needs of patients.

Estonian policymakers have developed a model to improve primary care, known as Enhanced Care Management (ECM). ECM program components include physician coaching, risk stratification, co-creation of care plans, and proactive follow up with patients between visits and after hospitalizations, and coordination with social services when applicable for patient. 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 their appropriate use of primary health care services, and will have reduced need for 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-analysis plan for the evaluation of the Estonian Enhanced Care Management program.

Setting

Estonia's health system faces growing challenges with population aging and growing burden of NCDs. As of 2017, approximately 50% of the population was above the age of 44 and 50% of the total population had at least one chronic illness. Among those aged 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 illness. 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[2].

ECM Intervention

The Enhanced Care Management (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 core goal of ECM is to improve the quality of care provided to complex patients, including 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 include improved tracking of tests and referrals, follow-up by PHC providers after hospital discharges, tracking of medication adherence, monitoring of patients between clinic visits, and greater focus on clinical quality. 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.

2. METHOD AND DESIGN

2.1 ECM IE Design Overview

This study incorporates a two stage randomization, first at the clinic level and second at the patient level.

2.2 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, those 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 Quality Bonus Scheme (QBS) score and a management score given to each clinic[3]. 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.

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. After the clinic randomization and after providers were invited to join the ECM program, 47 providers have refused or dropped out. The most common reasons given were lack of time, or other logistical issues, or in some cases health problems with several providers themselves. Since these providers dropped out of the program before the patient classification began, their patient population is excluded from randomization into the program..

2.3 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. (This number 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 in the ECM group 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 every provider are stratified 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. 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 which will be shared with the research team during the analysis phase.

2.4 Data

2.4.1 Provider Sample

EHIF has a network of approximately 800 primary care providers (family physicians), roughly 70% of whom work in a solo practice clinic[4]. The research team was provided with a dataset of all the clinics, linked providers, with their annual QBS score. This was the basis for 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[5]. The management score is a sum of points awarded on 15 indicators about 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.

2.4.2 Patient Sample

EHIF's Mini Information System Portal (MISP) is the portal used by EHIF to list patients who have multiple chronic illnesses, and contains information such as the 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.

2.1.1 EHIF billing data

For all the data on the 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. We have electronic billing records spread over eight health care services categories - primary health care, day care, outpatient care, outpatient nursing care, outpatient rehabilitation care, inpatient care, inpatient nursing care, and inpatient rehabilitation care over a 10 year period (2009 until 2019). 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, claims summary dataset is accompanied by a diagnosis dataset that describes all the diagnosis which were relevant to the given care episode. Finally, the third accompanying dataset is the procedures dataset that describes all the medical procedures that were conducted within a given episode of care. We have the billing record containing the associated single insurance payer insurance fund claims, 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 the procedures.

All the key outcomes of this study will utilize these systems of data, de-identified in compliance with Health Insurance Portability and Accountability Act (HIPAA) regulations.

2.2 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 the 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 less need for secondary and tertiary services such as (avoidable) inpatient hospital admissions and re-admissions, and ambulatory specialist services, and they will experience better health and higher quality of life.

2.3 Outcomes

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 all secondary study outcomes.

- *1. 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 up by telephone
- number of follow ups due to chronic illness

- *2. Provider management of tracer conditions:* This outcome measures provider compliance with Domain II QBS standards as the measure of quality care provision. The QBS has a set of guidelines for monitoring outlined for managing type 2 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 for monitoring, out of the total number of patients who have a diagnosis of the three conditions in the intervention year aggregated at the 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 (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	
Myocardial infarction (MI)	Medication	Prescription of beta-blockers treatment group (incl combination drugs)	6 prescriptions in 14 months
		Prescription of statins treatment group (incl combination drugs)	6 prescriptions in 14 months
Hypothyroidism	Monitoring	TSH (thyroid stimulating hormone) determined	1 per year
Total			

- *3 PHC-sensitive acute care:* We will monitor a set of selected outcomes which capture quality of primary care, following indicators created by the Organization for Economic Co-operation and Development (OECD). Based on the OECD framework, we will construct the following outcomes:

  - 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
  - Incidence of new diagnosis of tracer conditions

2.4 Statistical model

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

$$Y_{ikt} = \alpha + \beta(ECM_i \times Post_t) + \gamma_1 ECM_i + \gamma_2 Post_t + P_i + \tau_t + \pi_k + (\epsilon_i + \eta_k + \zeta_t)$$

Here, Y_{ikt} is the outcome of patient *i*, with ECM provider *k*, at time *t*. ECM_i is an indicator that the patient is selected into the ECM treatment and $Post_t$ is an indicator that the ECM treatment period has started. Therefore β is the difference-in-difference coefficient of interest. P_i are a vector of patient-level controls, such as prior health care seeking, risk status, or health effects (in various models). τ_t are year fixed effects and π_k are provider controls or fixed effects. Standard errors are clustered with provider-year random effects indicated as $\eta_k + \zeta_t$.

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

$$Y_{kt} = \alpha + \beta(ECM_k \times Post_t) + \gamma_1 ECM_k + \gamma_2 Post_t + \tau_t + \pi_k + (\eta_k + \zeta_t)$$

Here, Y_{kt} is the outcome provider *k*, at time *t*. ECM_i is an indicator that the provider is selected into the ECM treatment and $Post_t$ is an indicator that the ECM treatment period has started. Therefore β is the difference-in-difference coefficient of interest. τ_t are year fixed effects and π_k are provider controls or fixed effects. Standard errors are clustered with provider-year random effects indicated as $\eta_k + \zeta_t$.

Funding statement

This project received funding from the Georgetown University McCourt School of Public Policy Massive Data Institute, the World Bank's Research Support Board, and the World Bank Strategic Impact Evaluation Fund.

Ethics

This study was approved by Harvard Longwood IRB protocol IRB20-114.

References

1. World Health Organization, Noncommunicable diseases: Progress monitor 2020. (2020).

2. World Bank. The state of health care integration in Estonia (2015).

3. Blackwell, M., Iacus, S., King, G., *et al.* CEM: Coarsened exact matching in Stata. *The Stata J.* **9**, 524–546 (2009).

4. Kurowski, C., Chandra, A., Finkel, E., *et al.* The state of health care integration in Estonia: Summary report. (2015).

5. Croke, K., Daniels, B., Rogger, D., *et al.* Improving incentives for fairness in QBS: A "need-adjusted" approach to coverage. (2019).