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Do financial incentives improve the treatment of diabetes in Swiss primary care?

Submission date
14/02/2018

Recruitment status
No longer recruiting

Registration date
20/03/2018

Overall study status
Completed

Last Edited
19/05/2023

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Evidence regarding pay-for-performance (P4P) programs is inconclusive. However, P4P interventions might be an interesting approach to improve adherence to guidelines and improve quality of care in primary care. In a gatekeeping healthcare system such as the National Health System (NHS) of the United Kingdom, the Quality and Outcomes Framework (QOF) introduced financial incentives for evidence based quality indicators (QI) in primary care resulting in an increase of QI achievements. Since the QOF was a nationwide pre-/post-trial without a control group, it remains controversial to which extent the P4P program and to which extent increasing guideline adherence over time was responsible for this improvement. Evidence from P4P programs in a different healthcare setting such as the USA was shown to be conflicting. Current evidence suggests that QI achievements targeting process indicators (e.g. the number of Hba1c measurements) have shown greater effects than financial incentives targeting clinical indicators (e.g. blood pressure values). In Switzerland no data on the P4P approach exists and the role of QIs, especially in primary care has been marginal. The main reason might be that - in contrast to the UK for example - documentation in primary care is still mainly paper-based instead of based on electronic medical records (EMR). The Institute of Primary Care of the University and University Hospital of Zurich founded the research network FIRE (Family medicine ICPC Research using Electronic medical records) with currently 290 primary care physicians (PCPs), voluntarily documenting their consultations based on EMRs. The study team previously demonstrated that the FIRE database offers a valuable database for the calculation of QIs according to the QOF in patients with diabetes. This study aims to test a P4P approach in Swiss primary care using clinical routine data from EMRs. It is thought that financial incentives increase physicians' achievements regarding QIs in diabetes patients more effectively than evidence-based educational feedback reports. Furthermore, differences of P4P on process QIs and clinical QIs will be investigated and the sustainability as well as the effect of a P4P intervention on non-incentivized QIs will be assessed.

Who can participate?
Patients with diabetes of 290 GPs from 14 German-speaking cantons of Switzerland

What does the study involve?
The participating GP practices are randomly allocated into the intervention group or the control

group.
PCPs already receive a bimonthly feedback report on their data. The intervention and control groups receive additional intensified feedback reports on the characteristics of their current diabetic patients. Moreover, the recommendations of the current diabetes treatment guidelines and target thresholds of QI are provided. PCPs in the intervention group are also informed that they will receive a financial incentive 12 months after initial feedback provision for increasing achievements regarding the following two QI: percentage of diabetic patients with blood pressure below 140/85 mmHg (clinical QI), and percentage of patients where HbA1c was measured within the last 12 months (process QI). At the start of the study, the percentage of patients meeting the criteria of each QI is measured. After 1 year, the percentage of patients meeting the QI is again measured. For each improved percentage point, PCPs in the intervention group are entitled to a single payment of 75 Swiss francs (CHF). PCPs in the control group do not receive a financial incentive and are not informed about the provision of incentives in the intervention group. The intervention stops after 12 months, and bimonthly intensified feedback reports continue for another 12 months. After 24 months, performance is measured again in order to estimate the long-term effects of the incentive.

What are the possible benefits and risks of participating?
Participants will only be exposed to the usual care of their medical provider which is generally expected to be best practice even in a non-study setting. Participants taking part might notice a benefit from an improved quality of care as the participating PCPs are motivated to reach higher achievements regarding the QI. No risks are expected.

Where is the study run from?
University of Zurich (Switzerland)

When is the study starting and how long is it expected to run for?
January 2018 to June 2021

Who is funding the study?
Swiss National Science Foundation (Switzerland)

Who is the main contact?
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Study website
http://www.hausarztmedizin.uzh.ch/de/fire2.html

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
407440_167204

Study information

Scientific Title
Impact of financial incentives to improve quality indicators in diabetes patients

Study objectives
The study aims to test a pay-for-performance (P4P) approach in Swiss primary care using clinical routine data from electronic medical records (EMRs). We hypothesize that financial incentives increase physicians' achievements regarding quality indicators (QIs) in diabetes patients more

effectively than evidence-based educational feedback reports. Furthermore differences of P4P on process QIs and clinical QIs will be investigated and the sustainability as well as the effect of a P4P intervention on non-incentivized QIs will be assessed.

Ethics approval required
Old ethics approval format

Ethics approval(s)
According to the local ethics committee of the canton of Zurich, the project does not fall under the scope of the law on human research and therefore no ethical consent is necessary (BASEC-Nr. Req-2017-00797).

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Diabetes mellitus

Interventions
The level of randomization will be at the practice level. The participating practices will be divided into an intervention and control group. Randomization will be stratified by current performance status (clinical QI blood pressure), number of primary care physicians (PCPs) per practice, network participation of the practice and number of diabetic patients.

PCPs contributing to the FIRE database already receive a bimonthly feedback report on their data. Intervention and control group will receive additional intensified feedback reports on the characteristics of their current diabetic patients, including last data of blood pressure and HbA1c measurements. Moreover, recommendations of the current diabetes treatment guidelines and target thresholds of QI will be provided.

After randomization, PCPs in the intervention group will additionally be informed that they will receive a financial incentive 12 months after initial feedback provision for increasing achievements regarding the following two QI:
1. Percentage of diabetic patients with blood pressure < 140/85 mmHg (clinical QI)
2. Percentage of patients where HbA1c was measured within the last 12 months (process QI)

At baseline, the percentage of patients meeting criteria of each QI will be measured. After one year, the percentage of patients meeting the QI will again be measured. For each improved percentage point, PCPs in the intervention group will be entitled to a singular payment of 75 Swiss francs (CHF). PCPs in the control group will not receive a financial incentive and will not be informed about the provision of incentives in the intervention group. The intervention stops 12 months after baseline, bimonthly intensified feedback reports will continue for another 12 months. 24 months after baseline, performance will be measured again in order to estimate long-term effects of the incentive.

Intervention Type
Other

Primary outcome measure
Obtained from the FIRE database at baseline, 12 and 24 months:
1. Proportion of diabetic patients with last blood pressure measurement < 140/85 mmHg (clinical QI)
2. Proportion of diabetic patients with at least one measurement of HbA1c in the preceding 12 months (process QI)

Secondary outcome measures
Obtained from the FIRE database at baseline, 12 and 24 months:
1. Proportion of diabetic patients with at least one blood pressure measurement in the preceding 12 months (process QI)
2. Proportion of diabetic patients with HbA1c levels < 7.5% (clinical QI)
3. Proportion of diabetic patients with at least one cholesterol measurement in the preceding 12 months (process QI)
4. Proportion of diabetic patients with total cholesterol < 5 mmol/l (clinical QI)

Overall study start date
01/01/2018

Completion date
30/06/2021

Eligibility

Key inclusion criteria
Up to December 2017, 290 GPs from 14 German speaking cantons of Switzerland participated in the FIRE project. In December 2017, the database contained data of 3,372,343 encounters of 345,811 patients. The FIRE database, consisting of administrative data, vital signs (blood pressure), lab values (Hba1c), diagnostic codes (ICPC-2), and medication data (ATC codes) provides the database for the project. Structural data on participating GP practices (physicians' age and training, practice type (single-handed, double or group practice) and location, laboratory connection) are collected at individual FIRE project entry.

PCPs are eligible for the current study based on the FIRE database, if the dataset of 2017 is complete and a minimum threshold of 0.1 is achieved for the process indicators HbA1c and blood pressure, to rule out technical problems.

Of the eligible PCPs, primary care patients with diabetes mellitus will be identified from the FIRE database according to the following criteria:

1. Patient with ICPC-2 codes T89 (insulin dependent diabetes mellitus) and T90 (insulin independent diabetes mellitus)
2. Patients with antidiabetic medication (oral antidiabetics and/or insulin) according to the pharmaceutical cost group (PCG) (A10A/A10B)

Participant type(s)
Health professional

Age group
Not Specified

Sex
Both

Target number of participants
or the process QI (HbA1c) we assume an improvement from currently 70% adherence to 85% with a power of 90%. For the clinical QI (proportion of patients with controlled blood pressure defined as <140/85 mmHg) we assume a lower increase and calculated with an improvement from currently 45% to 56% [27]. We account for a cluster effect of 0.04. For the process QI (HbA1c) we would need 70 clusters and 6 observations per cluster (total of 418 patients). For the clinical QI (blood pressure) we will need 70 clusters and an average of 26 observations per cluster (total of 1804 patients). We will therefore include 70 PCPs in in our study. The primary and secondary outcomes 12 and 24 months after randomization will be compared using random effects logistic regression analysis with the individual as the unit of analysis and the PCP included as the random effect to control for the effects of clustering.

Total final enrolment
71

Key exclusion criteria
Incomplete data set of 2017 and/or a minimum threshold of 0.1 is not achieved for the process indicators HbA1c and blood pressure

Date of first enrolment
15/05/2018

Date of final enrolment
15/12/2018

Locations

Countries of recruitment
Switzerland

Study participating centre
Institute of Primary Care, University of Zurich
Switzerland
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Sponsor information

Organisation
Institute of Primary Care

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Sponsor type
University/education

Website
www.hausarztmedizin.uzh.ch

ROR
https://ror.org/029ma5383

Funder(s)

Funder type
Government

Funder Name
Schweizerischer Nationalfonds zur Förderung der Wissenschaftlichen Forschung

Alternative Name(s)
Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, SNF, SNSF, FNS

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

Results and Publications

Publication and dissemination plan
A study protocol will be published soon. Publications in high-impact journals are planned at baseline (baseline data), one year after completing the intervention phase and after completion of the overall study (24 months after baseline).

Intention to publish date
30/06/2022

Individual participant data (IPD) sharing plan
The FIRE database of the Institute of Primary Care, University of Zurich will provide the database for this study.
It consists of following data components:
1. Administrative data (year of birth, gender, dates of each consultation, unique de-identified patient-identification-number)
2. Vital signs: systolic and blood pressure, pulse, height, weight, waist circumference
3. International Classification of Primary Care 2 (ICPC-2): between one to seven codes for reason for encounter and diagnoses per contact date as assessed by the GP
4. Laboratory values: hemoglobin, leukocytes, C-reactive protein (CRP), erythrocyte sedimentation rate, creatinine, total cholesterol, HDL- and LDL-cholesterol, triglycerides, GOT (ASAT), GPT (ALAT), GGT, fasting glucose, HbA1c, prostate-specific antigen; all values including their reference range and date of analysis
5. Medication data: Anatomical Therapeutic Chemical Classification (ATC), medication doses, intake time (morning, noon, evening, night-time), cessation date and comments
Structural data on participating GP practices (physicians' age and training, practice type (single-handed, double or group practice) and location, laboratory connection) are collected at individual project entry. The data retrieved from the different practices is fully anonymized. Therefore the project does not fall under the scope of the law on human research and therefore no ethical consent is necessary. No persistent weblink is available to the public. The data can be accessed at any time by the scientific team member of the institute. For foreign bodies access has to be requested from the head of the institute.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	30/06/2018		Yes	No
Results article		01/04/2021	28/04/2021	Yes	No
Results article	Follow up analysis	26/10/2021	19/05/2023	Yes	No