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Community determinants of COPD exacerbations in elderly patients in Poland: protocol for a retrospective big data observational cohort study

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Keywords:	elderly, COPD, local community, medical Big Data, COPD prevalence, exacerbations

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Title page

Title of the article:

“Community determinants of COPD exacerbations in elderly patients in Poland: protocol for a retrospective big data observational cohort study”

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3 **Title:** Community determinants of COPD exacerbations in elderly patients in
4 Poland: protocol for a retrospective big data observational cohort study
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8 **Abstract**

9 **Introduction**

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12 Analyses of large sets of electronic health related data (Big Data), including local community
13 indicators, may improve knowledge on the outcomes of chronic diseases among patients and
14 health care systems. Our study will estimate the prevalence of chronic obstructive pulmonary
15 disease (COPD) and its exacerbations in elderly patients in the Lodz region, Poland, evaluate
16 local community factors potentially associated with disease exacerbations and will rank the local
17 communities according to health and local community indicators.
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27 **Methods and analysis**

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29 Local community factors, including medical/health, socioeconomic and environmental values
30 potentially associated with COPD exacerbations, will be identified. A retrospective analysis will
31 cover a cohort of about half a million people 65 years old and older, living in local communities
32 of the Lodz region in 2016. Relevant data will be extracted from data bases, including those of
33 the National Health Fund (NFZ), Tax Office (US) and National Statistics Center (GUS). The data
34 will be checked for quality, cleaned and analyzed using data mining techniques. Logistic
35 regression will be used to discover community determinants of COPD exacerbations in elderly
36 patients.
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48 **Ethics and dissemination**

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50 The study protocol has been approved by the Bioethical Committee of Medical University of
51 Lodz (RNN/248/18/KE, 10th July 2018). Our findings will be published in peer-reviewed
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3 journals and reports. Recommendations will disseminated to key stakeholders including local
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5 leaders, decision makers, managers of prevention programs and local community media.
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10 **Strengths and limitations**

- 11
- 12 • This will be a pioneering study of this kind in Poland to explore combined big sets of
13
14 blinded health and local community data, extracted from the electronic databases of
15
16 health-related records.
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- 18
- 19 • The results will be visualized as maps.
20
- 21 • The main limitations relate to the specificity and sensitivity of the COPD coding, gaps in
22
23 databases, short period of observation.
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25
26
27

28 **Key words:** elderly, COPD, local community, medical Big Data, COPD prevalence,
29
30 exacerbations
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32

33 **Abbreviations:**

34 COPD - Chronic Obstructive Pulmonary Disease

35 ICD-10 - International Classification of Diseases

36
37 LC - Local Community (*gmina*)

38
39 LCS - Local Community Status

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41 NFZ - National Health Fund

42
43 US - Tax Office (Revenue Administration Regional Office in Lodz)

44
45 GUS - National Statistics Center (Statistics Poland)

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47 GP - general practice

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49 EHRs - electronic health records

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51 BS - brainstorming

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53 FGD - Focus Group Discussion
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Introduction

The incidence of chronic obstructive pulmonary disease, a non-reversible lung condition characterized by shortness of breath, chronic cough with sputum production, emphysema and systemic pulmonary inflammation, is increasing worldwide.¹ Its worldwide prevalence in adults has been estimated to be 10.1%²; it is currently the fourth leading cause of death worldwide and is predicted to become the third by 2020.³

The burden of the disease and its exacerbations has been studied globally from different perspectives.⁴⁻¹¹ Most studies to place a strong focus on clinical patterns, but others also consider the socioeconomic and environmental local community status of patients (LCS).^{12 13}

Community context has been identified as an important determinant of health outcomes.¹⁴ The term *community* here refers to a neighborhood and group of people living locally, within certain geographic construct boundaries, and is regarded as being synonymous with a *gmina* in Poland, defined by GUS as the basic unit of the three-tier territorial division of the country. The 177 *gminas*, and hence communities, included in our analysis constitute the Lodz voivodship, one of 16 such regions in the country.

Although certain predictors of exacerbations in COPD are well known^{3 15-17}, some community / regional factors are under examination. Pleasants *et al* conducted systematic review of the broad variety of factors to which patients are exposed in their living area.¹³ The amount of data generated and collected routinely has increased significantly in the past decade, as has our ability to analyze and interpret it, especially in medicine. For example, a number of Big Data studies have been performed on Chinese health care, with large populations and the multiple structured and unstructured sources of data, with the aim of improving decision making.¹⁸ It has been proposed that Big Data extracted by combining databases from various sources, including

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3 medical records, clinical and diagnostic results, patient medication records and medicine
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5 purchases, as well as data concerning costs, diagnostic costs and sports habits, could be used to
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7 improve the decision-making process, and thus influence patient health and quality of life.¹⁹
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10 Further analyses of large sets of electronic health records (including indicators of local
11
12 communities, may improve knowledge about the outcomes of chronic diseases among patients.
13

14 **Aims**

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17 1. To estimate the prevalence of COPD and its exacerbations in elderly patients living in the
18
19 Lodz voivodship, Poland.
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21
22 2. To evaluate local community factors potentially associated with disease exacerbations in
23
24 this population.
- 25
26
27 3. To rank the *gminas* in the region according to health and local community indicators.

28 Our study is the pioneering of this kind in Poland, the purpose of which is to provide evidence
29
30 for the potential role of local community factors in the health outcomes of the older population.
31

32 **Methods and analysis**

33 **Study design**

34
35 This will be a retrospective cohort study involving approximately half a million patients aged 65
36
37 years and older living in the Lodz voivodship, Poland, including patients with COPD and its
38
39 exacerbations.
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42 **Data source**

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44 Data will be obtained from Big Data databases, such as National Health Fund with electronic
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46 health records of patients, the Tax Office and National Statistics Center).
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50 Depersonalized data will be subjected to quality control and cleaning.

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52 The scope of associations between the well-known patient-level risk factors and triggers of
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54 exacerbations of COPD, including local community factors will be identified with a literature
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3 review. Local community status factors will then be listed and selected with brainstorming (BS)
4 and Focus Group Discussion (FGD), with the participation of researchers, experts and decision
5 makers in the field of medicine and public health. During the BS and FGD, experts will select
6 and classify factors into three main groups at *gmina* level, according to the 2015 Remington and
7 Catlin methodology: 1) health factors 2) socioeconomic factors and 3) community environmental
8 factors.²⁰ The group of experts will decide on the outline/framework of available databases and
9 the collection of Big Data sets, and this outline will be filled with depersonalized data.

19 **Population**

20 Residents of the Lodz voivodship between 1st January and 31st December 2016, aged 65 and
21 over will be identified from NFZ electronic health record systems, US and GUS using a residence
22 code and assigned to a local community (*gmina*). Patients with COPD will be identified by the
23 International Classification of Diseases (ICD-10) code J44 in their medical records;
24 exacerbations will be defined as cases “hospitalized with the J44 code as a main reason for
25 admission”.

35 **Study variables**

36 This study will reveal a possible association between COPD exacerbations in elderly and local
37 community factors: demographic, health care use, social, economic and environmental factors. It
38 will take into account patient demographic and characteristics, including age, gender, residence
39 code, as well as number of visits to the general practitioner (GP) in 2016, number of GP visits
40 due to COPD in 2016, hospitalization, hospitalization with the J44 code as a main reason for
41 admission, number of deaths, costs of care, patient income per *gmina* and number of GPs per
42 *gmina*.

Patient and Public Involvement

Patients' priorities, experience, and preferences were obtained during previous European Union projects using the method such as Focus Group Discussion, were patient's suggestions to the COPD determinants were discussed and we took them into consideration.

Patients were not directly involved in the design of this study. As this is a protocol for a retrospective cohort study and no participant recruitment will take place, their involvement on the recruitment and dissemination of findings was not applicable.

Result of the study will be available for public through internet and local media.

Analysis

The data obtained from the Big Data databases will be used to characterize patient health status, patient status related to the health care system, and the characteristics of the local community.

Descriptive statistics for the total cohort, and the presence of COPD exacerbation will be calculated, aggregated at *gmina* level and categorized. Health characteristics and health outcomes will be aggregated by *gmina* in the Lodz voivodship, standardized and categorized.

Data mining techniques will be used to examine the relationships between patients and *gmina*; on the basis of which, indexes for each *gmina* will be calculated and normalized. Cross-sectional analysis and multivariable logistic regression (adjusted by demographics and health factors) will be used to test variables significantly associated with exacerbations of COPD. Health outcomes, such as the numbers of non-hospitalized patients with code J44 and numbers of those hospitalized (patients with exacerbation) within the *gmina*, will be categorized as a dependent variable in the regression analysis.

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3 The obtained data will be visualized on a map of 177 *gminas* located in the Lodz region. Local
4
5 community factors significantly associated with exacerbations of COPD will be shown on the
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7 *gmina* map according to each statistically significant factor²⁰. The occurrence of exacerbations of
8
9 COPD 65+ patients will be shown at *gmina* level using colors.

10
11 We will also calculate complex variables for each groups of determinants using the weights from
12
13 the BS and FGD and literature review results. Additionally, the obtained complex variables
14
15 related to health outcome and health determinants (health behaviors; clinical care; social and
16
17 economic factors; and physical environment) for patients aged 65 and more with COPD
18
19 exacerbations will also be visualized on the maps. It is planned therefore to obtain five maps, one
20
21 for each of the five complex variables, illustrating the Lodz voivodship in terms of COPD
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23 exacerbations resolved at the *gmina* level.

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25 All the data will be analyzed using the SAS 7.4 statistical package (SAS Institute, Cary, N.C.,
26
27 USA), MLwiN (Ver. 2.24; Centre for Multilevel Modelling, University of Bristol.), and
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29 STATISTICA 13.1.

30 31 32 33 34 35 **Discussion**

36
37 Our proposed methods will enable quantitative findings to be obtained that can be used to better
38
39 understand the factors associated with exacerbations of COPD in communities.

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41 The community-level contribution identified in the findings might be useful for future planning
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43 and resource allocation. This will be particularly useful if the obtained body of data is regularly
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45 updated by ongoing Big Data analysis of the *gminas* and health care systems.

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47 Combining community and medical data can provide to key for informed recommendations for
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49 improving the quality of patient life in the local community.
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This will be the pioneering study in Poland exploring combined sets of blinded health and local community Big Data, extracted from the electronic databases of health related records. The results will be visualized as maps.

Its main limitations relate to the specificity and sensitivity of the COPD coding, gaps in databases, short period of observation.

Acknowledgments

Special thanks to MSc. Edward Lowczowski for English language corrections.

Authors' contributions

The study concept and design was conceived by MGC, IZ, KK, AK and JG. Analysis will be performed by IZ and MGC. MGC, IZ, KK, AK, JG prepared the first draft of the manuscript. All authors provided edits and critiqued the manuscript for intellectual content.

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Competing interests statement

None declared.

Ethics and dissemination

The study protocol has been approved by the Bioethical Committee of Medical University of Lodz (RNN/248/18/KE, 10th July 2018). Our findings will be published in peer-reviewed journals and reports. Recommendations will disseminated to key stakeholders including local leaders, decision makers, managers of prevention programs and local community media.

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Title page

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8 **Abstract**
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14 indicators, may improve knowledge of the outcomes of chronic diseases among patients and
15 healthcare systems. Our study will estimate the prevalence of chronic obstructive pulmonary
16 disease (COPD) and its exacerbations in elderly patients in the Lodz region, Poland; it will also
17 evaluate local community factors potentially associated with disease exacerbations and rank local
18 communities according to health and local community indicators.
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27 **Methods and analysis**
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29 Local community factors, including medical/health, socioeconomic and environmental values
30 potentially associated with COPD exacerbations will be identified. A retrospective analysis of a
31 cohort of about half a million people 65 years old and older, living in local communities of the
32 Lodz region in 2016 will be performed. Relevant data will be extracted from databases, including
33 those of the National Health Fund (NFZ), Tax Office (US) and National Statistics Centre (GUS).
34 This cross-sectional study will include data for a one-year period, from 1 January until 31
35 December 2016.
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45 The data will first be checked for quality, cleaned and analyzed using data mining techniques,
46 and then multilevel logistic regression will be used to discover the community determinants of
47 COPD exacerbations.
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55 **Strengths and limitations**
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- This will be a pioneering study in Poland to explore combined big sets of blinded health and local community data extracted from the electronic databases of health-related records.
- The results will be visualized as maps.
- The main limitations relate to the specificity and sensitivity of the COPD coding, gaps in databases, short period of observation.
- The other limitation is the age limit of the patients.
- Additional limitations will be addressed when the study is completed.

Key words: elderly, COPD, local community, medical Big Data, COPD prevalence, exacerbations

Abbreviations:

COPD - Chronic Obstructive Pulmonary Disease

ICD-10 - International Classification of Diseases

LC - Local Community (*gmina*)

LCS - Local Community Status

NFZ - National Health Fund

US - Tax Office (Revenue Administration Regional Office in Lodz)

GUS - National Statistics Center (Statistics Poland)

GP - General Practice

EHRs - Electronic Health Records

BS - Brainstorming

FGD - Focus Group Discussion

Introduction

The world is currently seeing a growth in the incidence of chronic obstructive pulmonary disease, a non-reversible lung condition characterized by shortness of breath, chronic cough with sputum production, emphysema and systemic pulmonary inflammation.¹ Its worldwide prevalence in adults has been estimated to be 10%² and is among the leading causes of mortality and morbidity worldwide.³

The burden of the disease and its exacerbations has been studied globally from different perspectives.⁴⁻¹⁰ The prevalence data are limited for Poland, where our study is located.

Although the scope of the problem is well recognized worldwide, its impact seems to be poorly reflected in the Polish research data, so little is known of the exact prevalence of COPD in Poland.

Most studies place a strong focus on clinical patterns, but other also consider the socioeconomic and environmental local community status of patients (LCS).^{11 12}

The community context has been identified as an important determinant of health outcomes.¹³ In the proposed study, the term *community* will be used to refer to a local neighborhood and its inhabitants within certain geographic construct boundaries, and is regarded as being synonymous with a *gmina* in Poland, defined by GUS as the basic unit of the three-tier territorial division of the country. The present analysis covers the whole of the Lodz voivodship, one of 16 in the country; it therefore comprises 177 *gminas*, i.e. communities.

Certain predictors of exacerbations in COPD are well known¹⁴⁻¹⁷ while some community and regional factors remain under examination. Although a systematic review of the broad variety of factors to which patients are exposed in their living area has already been conducted by Pleasants *et al.*¹² the amount of data generated and collected routinely has increased significantly in the

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13 medication records and medicine purchases, as well as data concerning costs, diagnostic costs
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15 and sports habits, could be used to improve the decision-making process, and thus influence
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17 patient health and quality of life.¹⁹ Further analyses of large sets of electronic health records,
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19 including indicators among local communities, may improve knowledge about the outcomes of
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21 chronic diseases among patients.
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26 The members of the patient cohort will be COPD “labelled” patients who had been identified by
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28 the health care system and assigned the code J44 from International Classification of Diseases
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30 (ICD 10). We are aware of the limits of this approach, and that some COPD patients may not
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32 have been coded, and hence not included in the group, but our area of interest is the health care
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34 system dataset reflected by coding. A more detailed picture, and a more correct analysis, can be
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36 obtained by follow-up studies with more precise coding being applied and verified in the future.
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42 Aims

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44 1. To estimate the prevalence of J44 coded chronic obstructive pulmonary disease cases in
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46 elderly patients living in the Lodz voivodship, Poland.
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48 2. To evaluate local community factors potentially associated with disease exacerbations in
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50 this population.
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10 **Methods and analysis**

11 **Study design**

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13 This will be a retrospective cohort study involving approximately half a million patients aged 65
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15 exacerbations. This study will include data for a one-year period, from 1 January until 31
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Data source

Data will be obtained from Big Data databases, such as the electronic health records of patients
from the NFZ (National Health Service), US (Tax Office) and GUS (National Statistics Center).
Depersonalized data will be loaded and subjected to quality control and cleaning.

Individual patient data will be anonymized and assigned to the local communities which are the
basic units of our analysis. We will collect three categories of data: (1) disease-related data, (2)
health care services use-related data, (3) data relevant for selected local community indicators
from restricted and publically-available databases and repositories with limited and unlimited
access. Patient consent is not needed since we will not collect any personally-sensitive data.

Individual patient data will be matched by patient identifier within a single database. Individual
data will not be matched between databases. Data will be matched on the local community level,
and these matched local community data sets will be the units of our analyses.

The scope of associations between the well-known patient-level risk factors and triggers of
exacerbations of COPD, including local community factors, will be identified with a literature

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2
3 review. Local community status factors will then be listed and selected with brainstorming (BS)
4 and Focus Group Discussion (FGD), with the participation of researchers, experts and decision
5 makers in the field of medicine and public health based on the methods described by Osborn^{20 21}
6 and Kitzinger²², respectively. During the BS and FGD, experts will select and classify factors
7 into three main groups at *gmina* level, according to the Remington and Catlin methodology, as
8 follows: 1) health factors 2) socioeconomic factors and 3) community environmental factors.²³
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10 The group of experts will decide on the outline/framework of available databases and the
11 collection of Big Data sets, and this outline will be filled with depersonalized data.
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22 **Population**

23 Residents of the Lodz voivodship aged 65 and over between 1st January and 31st December 2016
24 will be identified from NFZ electronic health record systems, US and GUS using a residence
25 code and assigned to a local community (*gmina*). Patients with COPD will be identified by the
26 International Classification of Diseases (ICD-10) code J44 in their medical records;
27 exacerbations will be defined as cases “hospitalized with the J44 code as a main reason for
28 admission”.
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37 **Study variables**

38 This study will reveal a possible association between COPD exacerbations in elderly and local
39 community factors: demographic, health care use, social, economic and environmental factors. It
40 will take into account patient demographic and characteristics, including age, gender, residence
41 code, as well as the number of visits to the general practitioner (GP) in 2016, number of GP visits
42 due to COPD in 2016, hospitalization, hospitalization with the J44 code as a main reason for
43 admission, number of deaths, costs of care, patient income per *gmina* and number of GPs per
44 *gmina*.
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55 **Patient and Public Involvement**

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3 The priorities, experience, and preferences of the patients and other health professionals were
4 identified by individual interviews, BS and FGD technique in an earlier work.²⁴ The suggestions
5 regarding COPD determinants were discussed and will be taken into consideration in the planned
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10 research.

11 Patients were not directly involved in the design of this study. As this is a protocol for a
12
13 retrospective cohort study and no participant recruitment will take place, their involvement in
14
15 the recruitment and dissemination of findings was not applicable.
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19 The results of the study will be available for the public through internet and local media.
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22 23 24 **Statistical analysis**

25
26 The data obtained from the Big Data databases will be used to characterize patient health status,
27
28 patient status related to the health care system, and the characteristics of the local community.

29
30 Descriptive statistics for the total group, and the presence of COPD exacerbation will be
31
32 calculated, aggregated at *gmina* level and categorized. Health characteristics and health outcomes
33
34 will be aggregated by *gmina* in the Lodz voivodship, standardized and categorized.
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38 Data mining techniques will be used to examine the relationships between patients and *gmina*; on
39
40 the basis of which, indexes for each *gmina* will be calculated and normalized. Cross-sectional,
41
42 case-control multilevel multivariable logistic regression models (adjusted by demographics and
43
44 health factors) will be used to test variables significantly associated with exacerbations of COPD.
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46 Health outcomes, such as the numbers of non-hospitalized patients awarded the code J44 and the
47
48 numbers of hospitalized patients with exacerbation within the *gmina*, will be categorized as a
49
50 dependent variable in the regression analysis.
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54 The obtained data will be visualized on a map of 177 *gminas* located in the Lodz region. Local
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56 community factors significantly associated with exacerbations of COPD will be shown on the
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1
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3 *gmina* map according to each statistically significant factor²³. The occurrence of exacerbations of
4
5 COPD 65+ patients will be shown at *gmina* level using colors.
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7
8 Complex variables will be calculated for each group of determinants using the weights from the
9
10 BS and FGD and literature review results. Additionally, the obtained complex variables related to
11
12 health outcome and health determinants (health behaviors; clinical care; social and economic
13
14 factors; and physical environment) for patients aged 65 and above with COPD exacerbations will
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16 also be visualized on the maps. It is planned therefore to obtain five maps, one for each of the
17
18 five complex variables, illustrating the Lodz voivodship in terms of COPD exacerbations
19
20 resolved at the *gmina* level.
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24 All the data will be analyzed using the SAS 9.4 statistical package (SAS Institute, Cary, N.C.,
25
26 USA), MLwiN (Ver. 2.24; Centre for Multilevel Modelling, University of Bristol.) and
27
28 STATISTICA 13.1.
29

30 **Discussion**

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33 Our proposed methods will enable quantitative findings to be obtained that can be used to better
34
35 understand the factors associated with exacerbations of COPD in communities.
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38 The community-level contribution identified in the findings might be useful for future planning
39
40 and resource allocation. This will be particularly useful if the obtained body of data is regularly
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42 updated by ongoing Big Data analysis of the *gminas* and healthcare systems.
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45 Combining community and medical data can allow recommendations to be prepared for
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47 improving the quality of patient life in the local community.
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50 This will be a pioneering study in Poland exploring combined sets of blinded health and local
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52 community Big Data, extracted from the electronic databases of health -related records. The
53
54 results will be visualized as maps.
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3 The main limitations relate to the specificity and sensitivity of the COPD coding, gaps in
4 databases and short period of observation. We will select our study population based on the
5 codes used by the national health service. We are aware of the bias related to this approach, such
6 as limited code sets, mistaken coding, and errors related to the coding within the public datasets
7 and repositories. Another limitation is fact that the 177 gminas were not randomly selected and
8 were chosen based on their location within the Lodz voivodship.

9
10 Additional limitations and bias may be related to incompleteness and inaccuracy of data in
11 databases; some variables of potential interest might not be available, as well as indicator
12 selection might not be complete. The advantage is an ability to set a pilot framework for study
13 disease in real world community environment.

24 25 26 27 28 **Ethics and dissemination**

29
30 The study protocol has been approved by the Bioethical Committee of Medical University of
31 Lodz (RNN/248/18/KE, 10th July 2018). Our findings will be published in peer-reviewed
32 journals and reports. Recommendations will disseminated to key stakeholders including local
33 leaders, decision makers, managers of prevention programs and local community media.

34 35 36 37 38 39 40 41 42 43 44 **Acknowledgments**

45
46 Special thanks to mgr. Edward Lowczowski for English language corrections.

47 48 49 50 51 **Authors' contributions**

52
53 The study concept and design was conceived by MGC, IZ, KK, AK and JG. Analysis will be
54 performed by IZ (SAS, MLwiN and STATISTICA statistical analyses) and MGC. MGC, IZ, KK,

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3 AK, JG prepared the first draft of the manuscript. All authors provided edits and critiqued the
4
5 manuscript for intellectual content.
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12
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19 **Competing interests statement**

20 None declared.
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BMJ Open

Community determinants of COPD exacerbations in elderly patients in Poland: protocol for a retrospective Big Data observational cohort study

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Primary Subject Heading:	Public health
Secondary Subject Heading:	Health services research
Keywords:	elderly, COPD, local community, medical Big Data, COPD prevalence, exacerbations

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Title page

Title of the article:

“Community determinants of COPD exacerbations in elderly patients in Poland: protocol for a retrospective Big Data observational cohort study”

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3 **Title:** Community determinants of COPD exacerbations in elderly patients in
4 Poland: protocol for a retrospective Big Data observational cohort study
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7

8 **Abstract**
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11 **Introduction**
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13 Analyses of large sets of electronic health related data (Big Data), including local community
14 indicators, may improve knowledge of the outcomes of chronic diseases among patients and
15 healthcare systems. Our study will estimate the prevalence of chronic obstructive pulmonary
16 disease (COPD) and its exacerbations in elderly patients in the Lodz region, Poland; it will also
17 evaluate local community factors potentially associated with disease exacerbations and rank local
18 communities according to health and local community indicators.
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27 **Methods and analysis**
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29 Local community factors, including medical/health, socioeconomic and environmental values
30 potentially associated with COPD exacerbations will be identified. A retrospective analysis of a
31 cohort of about half a million people 65 years old and older, living in local communities of the
32 Lodz region in 2016 will be performed. Relevant data will be extracted from databases, including
33 those of the National Health Fund, Tax Office and National Statistics Centre. This cross-sectional
34 study will include data for a one-year period, from 1 January until 31 December 2016.
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43 The data will first be checked for quality, cleaned and analyzed using data mining techniques,
44 and then multilevel logistic regression will be used to discover the community determinants of
45 COPD exacerbations.
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50 **Ethics and dissemination**
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3 The study protocol has been approved by the Bioethical Committee of Medical University of
4 Lodz (RNN/248/18/KE, 10th July 2018). Our findings will be published in peer-reviewed
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8 journals and reports.
9

10 11 12 **Strengths and limitations**

- 14 • This will be a pioneering study in Poland to explore combined big sets of health and local
15 community data extracted from the electronic databases.
- 16 • The results will be visualized as maps.
- 17 • The main limitations relate to the specificity and sensitivity of the COPD coding, gaps in
18 databases, short period of observation.
- 19 • The other limitation is the age limit of the patients.
- 20 • Additional limitations will be addressed when the study is completed.

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32 **Key words:** elderly, COPD, local community, medical Big Data, COPD prevalence,
33 exacerbations
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35 36 37 **Abbreviations:**

38 COPD - Chronic Obstructive Pulmonary Disease

39 ICD-10 - International Classification of Diseases

40 LC - Local Community (*gmina*)

41 LCS - Local Community Status

42 NFZ - National Health Fund

43 US - Tax Office (Revenue Administration Regional Office in Lodz)

44 GUS - National Statistics Center (Statistics Poland)

45 GP - General Practice

46 EHRs - Electronic Health Records

47 BS - Brainstorming

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FGD - Focus Group Discussion

For peer review only

Introduction

The world is currently seeing a growth in the incidence of chronic obstructive pulmonary disease, a non-reversible lung condition characterized by shortness of breath, chronic cough with sputum production, emphysema and systemic pulmonary inflammation.¹ Its worldwide prevalence in adults has been estimated to be 10%² and is among the leading causes of mortality and morbidity worldwide.³

The burden of the disease and its exacerbations has been studied globally from different perspectives.⁴⁻¹⁰ The prevalence data are limited for Poland, where our study is located.

Although the scope of the problem is well recognized worldwide, its impact seems to be poorly reflected in the Polish research data, so little is known of the exact prevalence of COPD in Poland.

Most studies place a strong focus on clinical patterns, but other also consider the socioeconomic and environmental local community status of patients (LCS).^{11 12}

The community context has been identified as an important determinant of health outcomes.¹³ In the proposed study, the term *community* will be used to refer to a local neighborhood and its inhabitants within certain geographic construct boundaries, and is regarded as being synonymous with a *gmina* in Poland, defined by GUS as the basic unit of the three-tier territorial division of the country. The present analysis covers the whole of the Lodz voivodship, one of 16 in the country; it therefore comprises 177 *gminas*, i.e. communities.

Certain predictors of exacerbations in COPD are well known¹⁴⁻¹⁷ while some community and regional factors remain under examination. Although a systematic review of the broad variety of factors to which patients are exposed in their living area has already been conducted by Pleasants *et al.*¹² the amount of data generated and collected routinely has increased significantly in the

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3 past decade, as has our ability to analyze and interpret it, especially in medicine. For example, a
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5 number of such Big Data studies have been performed using the Chinese healthcare system,
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7 including large populations and multiple structured and unstructured data sources, with the aim of
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9 improving decision making.¹⁸ It has been proposed that Big Data extracted by combining
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11 databases from various sources, including medical records, clinical and diagnostic results, patient
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13 medication records and medicine purchases, as well as data concerning costs, diagnostic costs
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15 and sports habits, could be used to improve the decision-making process, and thus influence
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17 patient health and quality of life.¹⁹ Further analyses of large sets of electronic health records,
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19 including indicators among local communities, may improve knowledge about the outcomes of
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21 chronic diseases among patients.
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26 The members of the patient cohort will be COPD “labelled” patients who had been identified by
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28 the health care system and assigned the code J44 from International Classification of Diseases
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30 (ICD 10). We are aware of the limits of this approach, and that some COPD patients may not
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32 have been coded, and hence not included in the group, but our area of interest is the health care
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34 system dataset reflected by coding. A more detailed picture, and a more correct analysis, can be
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36 obtained by follow-up studies with more precise coding being applied and verified in the future.
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42 Aims

- 44 1. To estimate the prevalence of J44 coded chronic obstructive pulmonary disease cases in
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46 elderly patients living in the Lodz voivodship, Poland.
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48 2. To evaluate local community factors potentially associated with disease exacerbations in
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50 this population.
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52 3. To rank the *gminas* in the region according to health and local community indicators.
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Our study is the pioneering of this kind in Poland, the purpose of which is to provide evidence for the potential role of local community factors in the health outcomes of the older population.

Methods and analysis

Study design

This will be a retrospective cohort study involving approximately half a million patients aged 65 years and older living in the Lodz voivodship, Poland, including patients with COPD and its exacerbations. This study will include data for a one-year period, from 1 January until 31 December 2016. The study reported in the manuscript (data extraction and analysis) will take place from 10 July 2018 until the 29 February 2020.

Data source

Data will be obtained from Big Data databases, such as the electronic health records of patients from the NFZ (National Health Service), US (Tax Office) and GUS (National Statistics Center). Depersonalized data will be loaded and subjected to quality control and cleaning.

Individual patient data will be anonymized and assigned to the local communities which are the basic units of our analysis. We will collect three categories of data: (1) disease-related data, (2) health care services use-related data, (3) data relevant for selected local community indicators from restricted and publically-available databases and repositories with limited and unlimited access. Patient consent is not needed since we will not collect any personally-sensitive data.

Individual patient data will be matched by patient identifier within a single database. Individual data will not be matched between databases. Data will be matched on the local community level, and these matched local community data sets will be the units of our analyses.

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3 The scope of associations between the well-known patient-level risk factors and triggers of
4 exacerbations of COPD, including local community factors, will be identified with a literature
5 review. Local community status factors will then be listed and selected with brainstorming (BS)
6 and Focus Group Discussion (FGD), with the participation of researchers, experts and decision
7 makers in the field of medicine and public health based on the methods described by Osborn^{20 21}
8 and Kitzinger²², respectively. During the BS and FGD, experts will select and classify factors
9 into three main groups at *gmina* level, according to the Remington and Catlin methodology, as
10 follows: 1) health factors 2) socioeconomic factors and 3) community environmental factors.²³
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12 The group of experts will decide on the outline/framework of available databases and the
13 collection of Big Data sets, and this outline will be filled with depersonalized data.
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26 **Population**

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28 Residents of the Lodz voivodship aged 65 and over between 1st January and 31st December 2016
29 will be identified from NFZ electronic health record systems, US and GUS using a residence
30 code and assigned to a local community (*gmina*). Patients with COPD will be identified by the
31 International Classification of Diseases (ICD-10) code J44 in their medical records;
32 exacerbations will be defined as cases “hospitalized with the J44 code as a main reason for
33 admission”.
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42 **Study variables**

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44 This study will reveal a possible association between COPD exacerbations in elderly and local
45 community factors: demographic, health care use, social, economic and environmental factors. It
46 will take into account patient demographic and characteristics, including age, gender, residence
47 code, as well as the number of visits to the general practitioner (GP) in 2016, number of GP visits
48 due to COPD in 2016, hospitalization, hospitalization with the J44 code as a main reason for
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admission, number of deaths, costs of care, patient income per *gmina* and number of GPs per *gmina*.

Patient and Public Involvement

The priorities, experience, and preferences of the patients and other health professionals were identified by individual interviews, BS and FGD technique in an earlier work.²⁴ The suggestions regarding COPD determinants were discussed and will be taken into consideration in the planned research.

Patients were not directly involved in the design of this study. As this is a protocol for a retrospective cohort study and no participant recruitment will take place, their involvement in the recruitment and dissemination of findings was not applicable.

The results of the study will be available for the public through internet and local media.

Statistical analysis

The data obtained from the Big Data databases will be used to characterize patient health status, patient status related to the health care system, and the characteristics of the local community.

Descriptive statistics for the total group, and the presence of COPD exacerbation will be calculated, aggregated at *gmina* level and categorized. Health characteristics and health outcomes will be aggregated by *gmina* in the Lodz voivodship, standardized and categorized.

Data mining techniques will be used to examine the relationships between patients and *gmina*; on the basis of which, indexes for each *gmina* will be calculated and normalized. Cross-sectional, case-control multilevel multivariable logistic regression models (adjusted by demographics and health factors) will be used to test variables significantly associated with exacerbations of COPD.

Health outcomes, such as the numbers of non-hospitalized patients awarded the code J44 and the

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3 numbers of hospitalized patients with exacerbation within the *gmina*, will be categorized as a
4
5 dependent variable in the regression analysis.
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7
8 The obtained data will be visualized on a map of 177 *gminas* located in the Lodz region. Local
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10 community factors significantly associated with exacerbations of COPD will be shown on the
11
12 *gmina* map according to each statistically significant factor²³. The occurrence of exacerbations of
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14 COPD 65+ patients will be shown at *gmina* level using colors.
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16
17 Complex variables will be calculated for each group of determinants using the weights from the
18
19 BS and FGD and literature review results. Additionally, the obtained complex variables related to
20
21 health outcome and health determinants (health behaviors; clinical care; social and economic
22
23 factors; and physical environment) for patients aged 65 and above with COPD exacerbations will
24
25 also be visualized on the maps. It is planned therefore to obtain five maps, one for each of the
26
27 five complex variables, illustrating the Lodz voivodship in terms of COPD exacerbations
28
29 resolved at the *gmina* level.
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33 All the data will be analyzed using the SAS 9.4 statistical package (SAS Institute, Cary, N.C.,
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35 USA), MLwiN (Ver. 2.24; Centre for Multilevel Modelling, University of Bristol.) and
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37 STATISTICA 13.1.
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39 40 **Discussion**

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42 Our proposed methods will enable quantitative findings to be obtained that can be used to better
43
44 understand the factors associated with exacerbations of COPD in communities.
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47 The community-level contribution identified in the findings might be useful for future planning
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49 and resource allocation. This will be particularly useful if the obtained body of data is regularly
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51 updated by ongoing Big Data analysis of the *gminas* and healthcare systems.
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3 Combining community and medical data can allow recommendations to be prepared for
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5 improving the quality of patient life in the local community.
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7 This will be a pioneering study in Poland exploring combined sets of blinded health and local
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9 community Big Data, extracted from the electronic databases of health -related records. The
10
11 results will be visualized as maps.
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14 The main limitations relate to the specificity and sensitivity of the COPD coding, gaps in
15
16 databases and short period of observation. We will select our study population based on the
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18 codes used by the national health service. We are aware of the bias related to this approach, such
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20 as limited code sets, mistaken coding, and errors related to the coding within the public datasets
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22 and repositories. Another limitation is fact that the 177 gminas were not randomly selected and
23
24 were chosen based on their location within the Lodz voivodship.
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27 Additional limitations and bias may be related to incompleteness and inaccuracy of data in
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29 databases; some variables of potential interest might not be available, as well as indicator
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31 selection might not be complete. The advantage is an ability to set a pilot framework for study
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33 disease in real world community environment.
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40 **Ethics and dissemination**

41 The study protocol has been approved by the Bioethical Committee of Medical University of
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43 Lodz (RNN/248/18/KE, 10th July 2018). Our findings will be published in peer-reviewed
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45 journals and reports. Recommendations will disseminated to key stakeholders including local
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47 leaders, decision makers, managers of prevention programs and local community media.
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53 **Acknowledgments**

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Authors' contributions

The study concept and design was conceived by MGC, IZ, KK, AK and JG. Analysis will be performed by IZ (SAS, MLwiN and STATISTICA statistical analyses) and MGC. MGC, IZ, KK, AK, JG prepared the first draft of the manuscript. All authors provided edits and critiqued the manuscript for intellectual content.

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Competing interests statement

None declared.

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