

BMJ Open Multimorbidity in primary care: protocol of a national cross-sectional study in Switzerland

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ABSTRACT

Introduction: With the ageing of the population and the general improvement of care, an increasing number of people are living with multiple chronic health conditions or 'multimorbidity'. Multimorbidity often implies multiple medical treatments. As a consequence, the risk of adverse events and the time spent by patients for their treatments increase exponentially. In many cases, treatment guidelines traditionally defined for single conditions are not easily applicable. Primary care for individuals with multimorbidity requires complex patient-centred care and good communication between the patient and the general practitioner (GP). This often includes prioritising among the different chronic conditions.

Methods and analysis: The main objectives of this study are to describe the burden related to multimorbidity (disease-related burden and burden of treatment) in primary care and to identify the factors influencing it. Other objectives include evaluating patients' perception of treatment burden and quality of life, assessing factors influencing that perception, and investigating prioritisation in the management of multimorbidity from the perspectives of GPs and patients. For this cross-sectional study, patient enrolment will take place in GP's private practices across Switzerland. A convenient sample of 100 GPs will participate; overall, 1000 patients with at least three chronic health conditions will be enrolled. Data will be collected as paper-based questionnaires for GPs and delayed telephone interview questionnaires for patients. GPs will provide demographic and practice-related data. In addition, each GP will complete a paper-based questionnaire for each patient that they enrol. Each patient will complete a telephone interview questionnaire.

Ethics and dissemination: This study has been approved by the research ethics committee of Canton Vaud, Switzerland (Protocol 315/14). The results of the study will be reported in international peer-reviewed journals.

INTRODUCTION

Prevalence of multimorbidity in primary care

Multimorbidity is defined as the co-occurrence of chronic medical conditions within

one person without a single condition being considered the main condition.¹ Caring for multimorbid patients is an important part of general practice. A large population-based study conducted in the UK estimated that 42.2% of the population visiting a general practitioner (GP), including children, had at least one chronic health condition; 23.2% had at least two chronic conditions.² Other studies estimated the prevalence of multimorbidity in primary care between 13% and 75.5% depending on the population, the age group considered, and the definition of multimorbidity applied.^{3–8} The prevalence of multimorbidity is influenced by different factors, including age and socioeconomic status (SES).^{2 9 10} Multiple chronic conditions are more prevalent in the elderly, and multimorbidity develops 10–15 years earlier in the most deprived areas.^{2 11} The ageing of the population, together with the improvement of medical services, has led to the increased survival of people with chronic conditions and to an increased prevalence of multimorbidity.¹² Uijen and Van de Lisdonk¹² observed, on data from a registry including 10 GPs and approximately 13 500 patients, that the proportion of patients with at least four chronic conditions tripled between 1985 and 2005.

Disease-related burden and burden of treatment

Cumulative effects of multiple chronic conditions can be expressed in terms of disease-related burden, or burden of treatment. Studies suggest that the cumulative effect of chronic health conditions is not simply incremental; specific combinations of conditions may have a greater effect on functional status, quality of life and mortality than others.^{13 14} The burden of treatment itself encompasses different aspects, such as

the number of investigations, number of pills to take each day, number of injections to take, number of check-ups or preventive measures, and other care (eg, education or physiotherapy). For instance, an estimated 20% of older adults in the US population take more than 10 different medications each week.^{15 16} Owing to the importance of the disease-related burden and burden of treatment, primary care for people with multimorbidity must address disease-specific issues in the context of coexisting chronic medical conditions and the patient's psychosocial environment. This implies complex, patient-centered care involving patient-provider concordance, effective communication and shared decision-making.^{17 18} One of the main difficulties GPs face is the challenge of following guidelines that are typically developed for single diseases.^{19–21} Sinnott *et al*²² synthesised qualitative research on the perception that GPs and other primary care practitioners have of the management of multimorbidity. Ten studies conducted in seven countries (Belgium, England, Germany, Ireland, Scotland, the Netherlands and the USA), including 275 GPs, were considered. The synthesis emphasised that difficulties in the care of people with multimorbidity mainly arise from disorganisation and fragmentation of healthcare, inadequacy of guidelines and evidence-based medicine, and challenges to patient-centered care and shared decision-making.²²

Prioritisation of care

Prioritisation of illnesses and care for specific diseases should be concordant between patients and their GPs, but may not always be. To date, few studies have addressed prioritisation of care in multimorbid patients.^{18 23} We identified a single study that examined the prioritisation of care in multimorbid patients from the patients' perspective and without an index condition.²³ Health outcome priorities (staying alive, maintaining independence, reducing/eliminating pain and reducing/eliminating symptoms) were evaluated. Maintaining independence was ranked as the most important factor by 76% of the patients. Among those who ranked maintaining independence as the primary factor, 67% ranked symptoms relief as the second. Among those who ranked staying alive as their first concern (11%), 66% ranked maintaining independence as their second concern. A single prospective study including 92 providers and 1004 US veterans examined the correlation between GPs' and patient's prioritisation of health conditions.¹⁸ Patients and GPs provided the three most important concerns among a list of nine conditions chosen based on their prevalence (symptomatic chronic conditions: pain, depression, breathing difficulties; and asymptomatic chronic conditions: hypertension, diabetes, hyperlipidaemia, heart disease or heart failure, obesity and tobacco use). In 72% of cases, the patient's most important concern was represented in the GP's list of three most important concerns. In 60% of the cases, there was a concordance between the patient's

and the GP's prioritisation. Concordance was lower among patients who reported poor health status.¹⁸

Our aim is to assess the burden related to multimorbidity and to describe prioritisation in the management of multiple chronic conditions in the context of primary care practice, taking patients' and GPs' perspectives into account.

METHODS AND ANALYSES

Study objectives

Primary objective 1: Burden related to multimorbidity—We will assess the importance of the burden related to multimorbidity (ie, disease-related burden and burden of treatment) among patients in a primary care setting, identify the determinants of an increased burden related to multimorbidity, and examine the agreement between patients' and GPs' perceptions of this burden.

Primary objective 2: Prioritisation of care—We want to evaluate the concordance between the problems related to the prioritisation of treatment for multiple chronic conditions as assessed by GPs and as perceived by patients. We will assess prioritisation established by patients and by GPs in the handling of chronic conditions among multimorbid patients in primary care, and identify patient-related or GP-related determinants that influence this prioritisation achieved by patients and GPs, respectively.

Secondary objective: Gender study—We will examine whether the gender of GPs or patients is a determinant of variations in patients' and GPs' perceived burden in relation to multimorbidity, and its related treatment in primary care.

Study design

This is an observational study with a cross-sectional design.

Study population

Participants: The study will involve GPs throughout Switzerland and their multimorbid patients. We will enrol 1000 patients through a convenience sample of 100 GPs in private practice. Each participating Institute of Family Medicine will organise the recruitment of 20 GPs from small or large practices in both urban and rural settings, in their respective regions of Switzerland (figure 1). As no Institute of Family Medicine exists in the Italian-speaking part of the country, we restricted our study to the French-speaking and German-speaking regions.

Eligibility: All multimorbid patients visiting a participating GP during the inclusion period and meeting the inclusion criteria are eligible. We considered three chronic conditions as the minimum number of conditions for which a prioritisation of care could be necessary.

Inclusion criteria

- ▶ To be aged 18 years or older;
- ▶ To have been followed by the GP for at least 6 months before the index encounter;

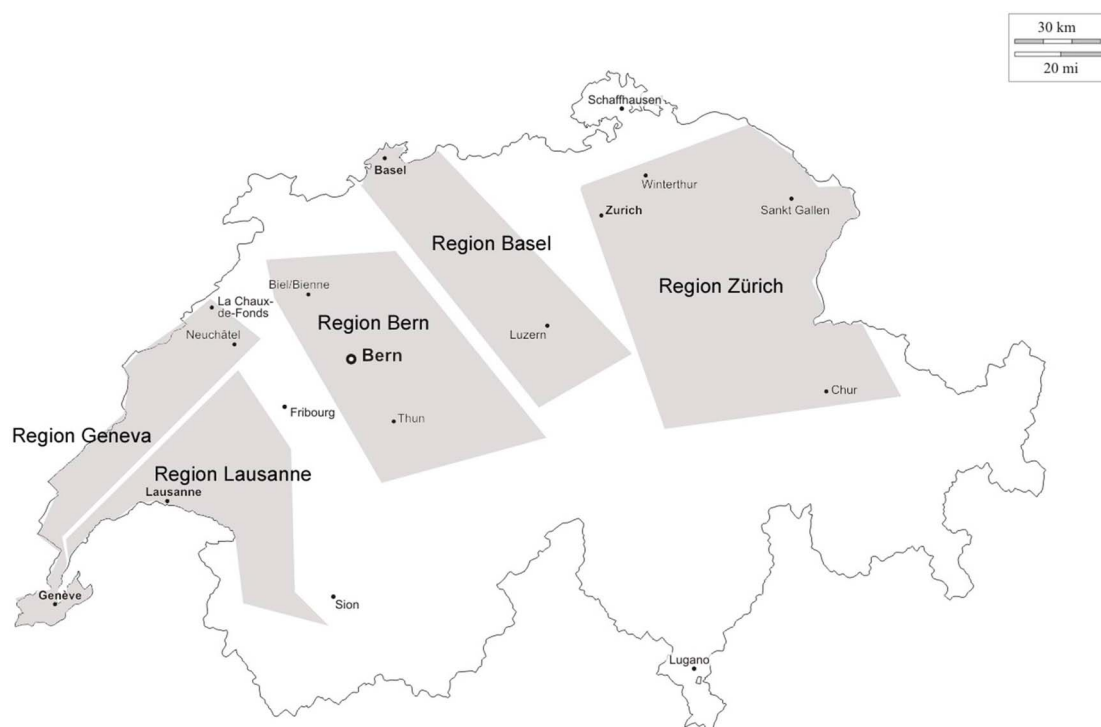


Figure 1 Schematic representation of the regions of Switzerland covered by each Institute of Family Medicine. Each Institute of Family Medicine (Geneva, Lausanne, Bern, Basel, Zürich) will organise the enrolment of 20 general practitioners (GPs) located within its region.

- ▶ To have enough knowledge of French or German to be able to complete the questionnaire;
- ▶ To suffer from at least three chronic conditions identified from a list of 75 conditions (table 1);
- ▶ To consent to participate in the study and to sign the informed consent form.

Exclusion criteria

- ▶ To suffer from a major cognitive or psychiatric disorder, and as such be unable to answer the questionnaire;
- ▶ To be unable to read and/or to understand French or German;
- ▶ To suffer from an emergency or acute life-threatening condition (physical or psychological);
- ▶ To refuse to participate to the study after initial approval and consent.

Table 1 Number of items in each category of the ICPC-2 used to identify multimorbid patients

ICPC-2 category	Number of items
General and unspecified	3
Blood, blood forming organs and immune mechanism	3
Digestive	7
Endocrine/metabolic and nutritional	5
Neurological	10
Skin	1
Musculoskeletal	4
Urological	3
Respiratory	4
Eye	3
Ear	2
Cardiovascular	10
Psychological	17
Female genital	2
Male genital	1

ICPC-2, International Classification of Primary Care, V.2.

Sampling

Recruitment of patients (figure 2): Each GP will include 10 patients meeting the inclusion criteria. Recruitment will take part over a maximum period of 10 weeks per GP. The data collection process will start on 12 January 2015 and will end on 30 September 2015. Each GP will be provided a randomisation calendar specifying which patient to enrol for each half-day of the recruitment weeks. We selected half-days for the recruitment of patients to match GPs' schedule as accurately as possible, and to take into account the fact that many GPs work either part-time or have a variety of professional activities (teaching, home visits, etc). We wanted to make sure that the GP was seeing patients at his practice during the entire time slot considered. Patients' recruitment is based on patients who are scheduled for each half-day of recruitment. The randomisation calendar gives the ordered number of the consultation to consider, and

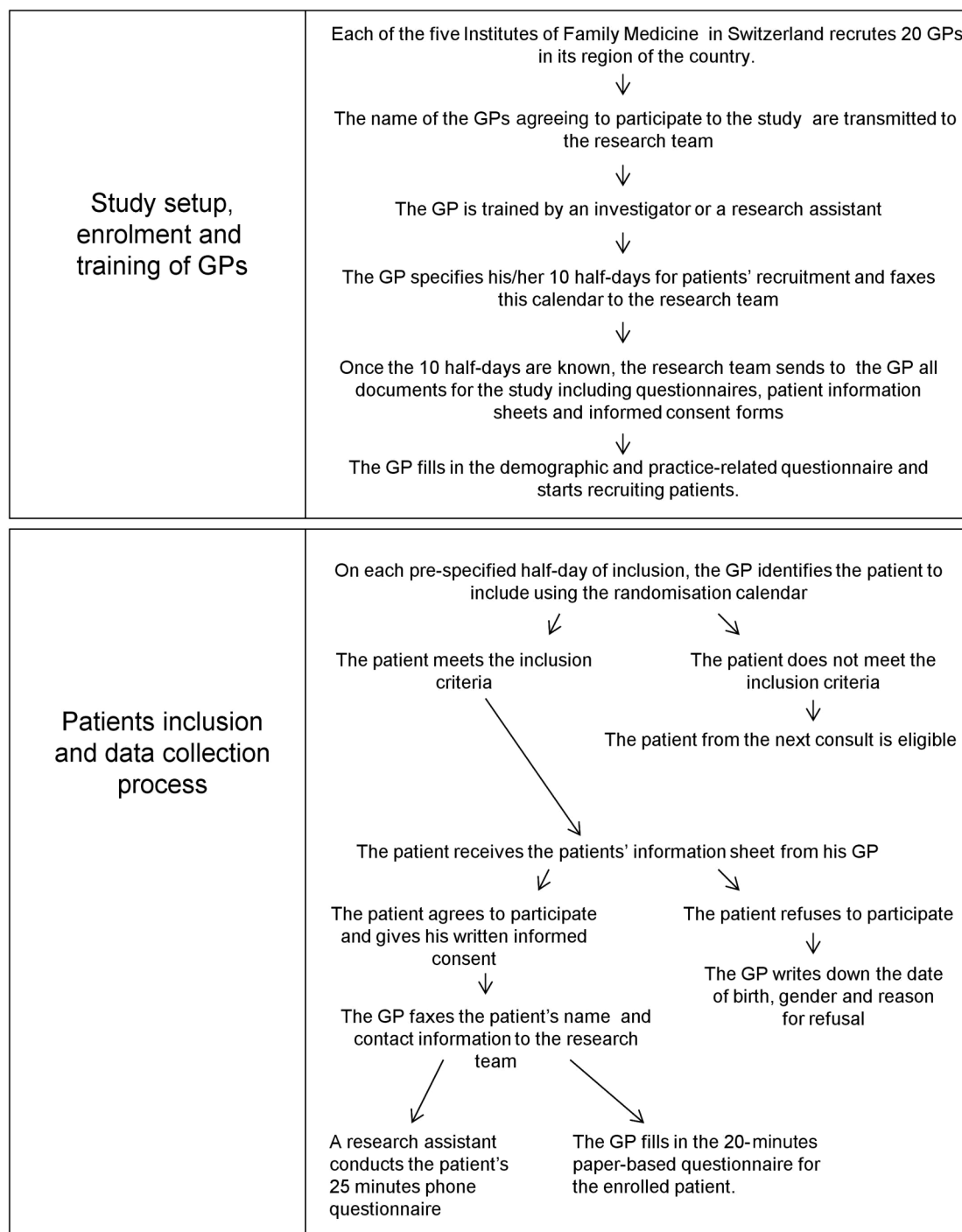


Figure 2 General practitioners' (GPs') and patients' recruitment process and general study procedure.

the GP includes the patient of this consultation if he/she meets the inclusion criteria. If the randomised patient does not meet the inclusion criteria, the next patient who fulfils the inclusion criteria is eligible. If no patient is included at the end of the half-day, the recruitment process will be postponed to the next half-day of consultations. The patient will be asked to consent to participate to a telephone interview questionnaire that will take place within 48 h after the visit to the GP. The patient's name and phone number will then be transmitted to a research assistant. If an eligible patient refuses

to participate, their date of birth, sex and reason for refusing participation will be documented.

Procedure (figure 2): Once the GP agrees to participate, he/she will be trained by a research assistant or an investigator to ensure the aim of the study and data collection processes are clearly understood. Training will include detailed information on the procedure to follow, include patients using the randomisation calendar, and the list of 75 conditions provided. GPs will also be instructed on the data collection process using the questionnaires. Data collection from GPs will take place at the GPs'

Table 2 All variables collected using the three different questionnaires

Variable	Measure
<i>GP-related variables (paper-based questionnaire)</i>	
Age	Date of birth
Sex	Sex
Place of graduate training	City, country
Place of postgraduate training	City, country
Type of practice	Independent/on-a-contract GP, group practice, healthcare network
Years of practice 1	Year medical diploma was obtained
Years of practice 2	Year started independent practice
Other activity	Aside from medical practice (eg, research; teaching; practice in a specific context, such as prison, hospice for elders, school in a company, etc)
City/countryside	Location of the practice (urban, sub-urban, rural) + zipcode
Number of consultations	Mean number of consults per week
Mean age of patients	Mean age of patients in the practice population as determined using the electronic filing or electronic billing system
Subspecialty	Medical board specialty other than that of General Internal Medicine
<i>Patient-related variables assessed through the GP survey (paper-based questionnaire)</i>	
Age	Date of birth
Sex	Sex
Visits to GP in the last year	Number of visits to the GP in the last 12 months
Visits to GP in the last month	Number of visits to the GP in the last month
Time followed by GP	Number of years that the patient has been treated by the GP
Hospitalisations	Number of hospitalisations in the last 12 months
Number of chronic conditions	Number of chronic conditions from the list provided
List of chronic conditions	List of chronic conditions by decreasing order of importance
Conditions important to the patient	List of the 3 chronic conditions the most important to the patient, according to the GP
Severity of each chronic condition	Evaluated using the cumulative illness rating scale
Treatment	Current treatment plan
Renouncement	Conditions voluntarily left untreated or suboptimally treated by the GP
Interdisciplinarity	Specialist MD/nurse/physiotherapist/rehabilitation therapist/caregiver
Treatment burden	Subjective estimation of the patient's treatment burden on a 0 to 10 scale (0= burden not important at all; 10= very important burden)
<i>Patient-related variables assessed through the patient survey (telephone interview questionnaire)</i>	
Age	Date of birth
Sex	Sex
Marital status	Patient's marital status (single, married, separated or divorced, widow(er))
Place of education	City, country
Mother tongue	Patient's first language(s)
Education	Highest schooling level achieved (primary school, secondary school, practical training, high school or equivalent, superior degree non-university, university, other)
Size of the household/living situation	Number of adults (≥ 18 years old) and children (< 18 years old) living with the patient
Number of MDs	Number of medical doctors (GPs and specialists) involved in the patient's treatment
Medical and social assistance	Does the patient receive medical and/or social assistance?
Pillbox	Use of a pillbox (Y/N)
Interdisciplinarity	Cleaning help or meal delivery system
Health literacy	Health literacy will be assessed using the short 6-item HLS-EU questionnaire
Prioritisation	Most important and second most important conditions
Quality of life	Quality of life will be assessed using the EQ-5D-3L questionnaire
SES	SES will be assessed using the DipCare questionnaire
Treatment burden	Treatment burden will be assessed using the treatment burden questionnaire

GP, general practitioner; HLS-EU, The European Health Literacy Survey; SES, socioeconomic status.

private practices using paper-based questionnaires. For patients, we will use delayed phone interview questionnaires. Each GP will first complete a survey providing demographic and practice-related data. Patient enrolment will take place during a visit to the GP. Randomly identified patients will be informed of the study by their

GP and if they agree to take part, they will provide written informed consent. Enrolled patients will complete a 25 min telephone-based questionnaire. For each patient who is enrolled, the GP will complete a 20 min paper-based questionnaire. All data will be coded during the data collection process. Patients' names and phone

numbers will be destroyed after data collection is completed. Research assistants will conduct all patients' telephone interviews, in French or German, from the Institute for Family Medicine in Lausanne. The research team in Lausanne will train the research assistants to conduct the telephone interviews and to collect the data, in collaboration with the Pedagogical Unit of the Faculty of Biology and Medicine of Lausanne. Training will include conducting and handling phone interviews, including the management of negative emotions that may arise during the interview. A patient-actor will participate in this training. The training will include learning to ask questions exactly as written on the questionnaires to ensure homogeneity of the data collection between patients and between research assistants. Research assistants will also be trained to record data using the Epidata V.3.1 software.

Variables

We will collect GP-related and patient-related variables (table 2). We describe the more complex variables below. All questionnaires for which a German or French version did not exist were translated using a translation/back-translation procedure.

Patient-related variables assessed through the GP survey include the number and list of chronic conditions, severity of each chronic condition, current treatment and renouncement of treatment.

Number and list of chronic conditions: The International Classification of Primary Care, V.2 (ICPC-2), is a classification of symptoms and diagnostics specifically designed for use in primary care.²⁴ We will employ a list of 75 chronic conditions identified in the ICPC-2 following a methodology described elsewhere (N'Goran *et al*, in preparation). Briefly, we conducted a nationwide survey of GPs using a modified Delphi method.²⁵ We used experts from five different regions: Basel, Bern, Geneva, Vaud and Zürich. We started with all 686 items of the ICPC-2 and proceeded to a step-by-step elimination. First, a focus group of five experts removed from the ICPC-2 items that were irrelevant in the context of chronic conditions. Then, three rounds of online survey were conducted: experts had to score the chronic aspect of each remaining item first as chronic, not chronic or in between, and second on a scale of 1–9 (2 rounds); and then assess the relevance of the chronic items in the context of multimorbidity (1 round). To analyse data, we used the median values and the inter-percentile range adjusted for symmetry (IPRAS) for agreement/disagreement between experts.²⁵ Items reaching a median value of 6 and agreement between experts were retained in the final list.

Severity of each chronic condition: For each patient enrolled, the GP will provide a quantitative estimate of impairment for each organ area using the cumulative illness rating scale (CIRS).²⁶ The CIRS involves rating the impairment of 14 organs or systems. Medical problems are compiled and quantified by organ system,

resulting in the computation of a cumulative score that represents the degree of impairment to the whole person. The CIRS has been used in studies involving multimorbid patients and been validated for use in primary care.^{27–30}

Current treatment: The GP will provide a list of all medications, preventive measures and rehabilitative measures prescribed. The actual treatment will be considered.

Renouncement of treatment: The GP will provide a list of conditions for which he/she consider the treatment as suboptimal, because it had to be adapted due to potential drug interaction, treatment burden or lack of compliance from the patient or following a shared decision with the patient.

Patient-related variables assessed through the patients' survey include prioritisation, quality of life, SES, health literacy and treatment burden.

Prioritisation: We will assess the prioritisation of chronic conditions from the patient's perspective by asking if he/she had the power to remove one health condition, which one he/she would choose first and then second. It is possible that one or both answers to this question will not refer to chronic conditions; however, we expect this to be the case only for a restricted number of patients.

Quality of life: We will evaluate the burden related to multimorbidity from the patient's perspective using the EQ-5D-3L quality-of-life scale.^{31–33} The EQ-5D-3L is a short, validated questionnaire for the self-assessment of quality of life for which population reference values are available for Switzerland.^{34 35}

SES: The SES of enrolled patients will be assessed using the deprivation in primary care questionnaire (DipCare), which was developed and validated in the French-speaking part of Switzerland³⁶ and translated into German. An overall score of deprivation will be then computed.

Health literacy: We will use the six-item questionnaire from the European Health Literacy Survey project (HLS-EU 6) to assess health literacy.³⁷ These items were selected based on content and difficulty experienced from the 47-question survey (HLS-EU 47).^{37 38} The HLS-EU 6 was developed on a random subsample of the HLS-EU 47 survey (N=3411), and cross-validated with another random subsample (N=3383) (HLS-EU consortium, personal communication, 2014). Answers to each question from the HLS-EU 6 are given in the form of a four-point Likert scale (1=very difficult, 2=fairly difficult, 3=fairly easy, 4=very easy). Although no population-based data exist for Switzerland, data do exist for neighbouring countries.

Treatment burden: The treatment burden questionnaire (TBQ) was developed recently to assess the overall burden related to the treatment of chronic conditions.³⁹ It consists of 13 questions whose answers are each scored from 0 to 10, with 0 corresponding to no burden and 10 to a very important/considerable burden. The global (summed) score of treatment burden ranges from 0 to

130. No Swiss population-based data exist for this questionnaire.

Planned analyses

Primary objective 1: Burden related to multimorbidity

- ▶ To identify patient-related or GP-related determinants that influence the disease-related burden (number of chronic conditions, CIRS and EQ-5D-3L) or TBQ
- ▶ To analyse the relationship between the perceptions of patients and the GPs regarding the burden related to multimorbidity using the number of chronic conditions identified, the CIRS and the EQ-5D-3L questionnaire
- ▶ To assess the burden of treatment in terms of the number of pills prescribed per day, and to test whether it relates to the patients' evaluation using the TBQ, and to GPs' evaluation of the burden of treatment
- ▶ To assess whether the number of conditions treated is related to TBQ scores using univariate and multivariate models

Primary objective 2: Prioritisation of care

- ▶ To evaluate whether in multimorbid patients some chronic conditions are left untreated by comparing the list of chronic conditions diagnosed with the list of treatments prescribed.
- ▶ To describe the subgroup of patients with conditions left voluntarily untreated or suboptimally treated, and compare it to the group of patients in which no conditions were left untreated
- ▶ To test whether the two conditions classified as most important by GPs and patients are concordant. We will obtain a series of concordant and discordant patients'/GPs' pairs; describe and compare the subgroups of patients/GPs with concordant pairs versus discordant pairs; and evaluate whether the concordance between patients' and GPs' evaluations of the most important chronic conditions correlates with the TBQ scores.

- ▶ To identify the patient-related or GP-related determinants that have an influence on concordance in the prioritisation achieved by patients and GPs, respectively.

Secondary objective: Gender study

- ▶ To examine whether gender of patients or GPs influences the TBQ or the GPs' evaluation of the burden of treatment
- ▶ To examine whether gender influences the concordance between GPs' and patients' prioritisations of chronic conditions

Statistics

Patients' sample size. The sample size estimation is based on reported proportions of patients with different numbers of chronic conditions from studies conducted in primary care. We evaluated the number of patients whom we would include with different numbers of chronic conditions, given possible sample sizes of 500, 750 and 1000 patients, if the repartition of patients was similar to that in any of the three studies considered. Based on this data, a sample size of 1000 is enough to allow for potential subgroup analyses. The estimates are reported in [table 3](#). This sample size is also coherent considering that a statistical model requires approximately 15 patients per variable.

Descriptive statistics. Descriptive statistics will be performed to describe the sample of GPs and the sample of patients. All collected measures and derived variables will be summarised using usual descriptive statistics and the associated 95% CI. For categorical variables, the description will consist (at minimum) of the sample size; numbers of missing data; valid data, median, upper and lower quartiles; and the frequency and percentage of each category.

Exploratory data analysis. t-Test will be used for continuous normally distributed variables; one-way analysis of variance will be used if we need to compare more than two groups. For continuous variables not normally distributed,

Table 3 Estimates for sample size evaluation

Reference	Coding system used	Age, years	Number of chronic conditions	Number of patients	Percentage	Expected number		
						Sample size of 500	Sample size of 750	Sample size of 1000
Barnett <i>et al</i> , 2012 ²	Read codes	No age limit	3	99 487	0.418	209	314	418
			4	60 417	0.254	127	190	254
			5	35 641	0.150	75	112	150
			6	20 507	0.086	43	65	86
			7	11 080	0.047	23	35	47
			≥8	10 846	0.046	23	34	46
Rizza <i>et al</i> , 2012 ⁴⁰	ICPC-2	≥20	3	2319	0.48	240	360	480
			>3	2513	0.52	260	187	520
Glynn <i>et al</i> , 2011 ⁵	ICPC-2	>50	3	636	0.47	233	349	466
			4	367	0.27	134	202	269
			≥5	362	0.27	133	199	265

ICPC-2, International Classification of Primary Care, V.2.

we will use non-parametric tests: the Mann-Whitney U test to compare two groups, and the Kruskal-Wallis test to compare three or more groups. For categorical variables, we will employ the χ^2 test or Fisher's exact test, depending on the number of observations obtained in each category considered. All tests are two-sided unless otherwise specified, and $p < 0.05$ will be considered statistically significant. Correlation between variables will be assessed using the Pearson correlation coefficient for normally distributed variables or the Spearman correlation otherwise. We will evaluate the level of agreement between two of the same parameter using agreement tables, scatter plots and Cohen's κ statistic.

Univariate tests will be used to select variables according to the p value obtained ($p < 0.25$) to include in the multivariate analyses. For the multivariate analyses, generalised linear regression models will be used: Poisson regression for outcome variables in the form of scores, multinomial logistic regression for non-dichotomous categorical variables, or logistic regression for dichotomous variables, as appropriate. Mixed effects multilevel models that take clustering and between-site differences into account will be considered. These models will include two levels of clustering in order to take into account the variability caused by regions and GPs. Models will be compared and the best model will be selected on the basis of likelihood ratio tests.

Ethical aspects

The study protocol and study documentation, including all questionnaires and the informed consent, were accepted by the ethical committee of the Canton of Vaud acting as the lead ethical committee for Switzerland. The protocol was then transmitted to the local ethical commissions of the different regions involved in the study.

We anticipate no direct benefits for the patients. Indirect benefits include contribution to understanding the mechanisms underlying the handling of patients with multimorbidity, which will eventually improve the management of patients. No important risk is foreseen as a direct result of the survey. GPs will handle the healthcare of included patients as normal.

Potential biases and limits

We will use a convenience sample of 100 GPs, and thus will not follow a randomised sampling for the identification of GPs. As a result, participating GPs may not be representative of the overall population of GPs practising in Switzerland. Sociodemographic data collected, such as sex, age and location of practice, will allow for the characterisation of the participating GPs and the evaluation of external validity. Recruitment of patients will follow a strict randomised procedure, and no selection bias is foreseen. In addition, demographic data will be collected from patients who refuse to participate in the study, as well as their reasons for non-participation. Data will mainly be collected through self-assessment

questionnaires. This leaves the potential for information bias. However, as both GPs and patients will have no detailed knowledge of the objectives of the study, or of the analyses planned, we anticipate that information bias will not be significant or will only lead to non-differential misclassification. We will use standardised tests of proven high internal validity. However, for some tests, such as the CIRS, the TBQ and the HLS-EU 6 questions, no data in Switzerland have been reported, as yet. For tests for which no Swiss data are available, data from populations close to the Swiss population (German and French speaking) are available. The TBQ test was developed and used in a single French population. No German version has been developed and used previously.

Pilot phase

A pilot phase is planned for this study. We will enrol five pilot patients through a convenience sample of five GPs across Switzerland based on their willingness to participate. We will ask each patient to complete the telephone interview questionnaire and each GP to complete the paper questionnaire. The pilot phase aims to evaluate the feasibility of the study, to recognise and solve potential issues with the use of questionnaires, and to better define specific aspects of the training of research assistants.

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Contributors All the authors developed the study's objectives and defined the list of variables to be collected. AD-L, AAN, BB, PB, NS, DW, LH, PF and RT developed the questionnaires in French and German. AD-L, AAN and LH drafted the protocol and oversaw submission of the protocol to the ethics commission. AD-L, AAN and LH developed the necessary study documents for the ethics commission. All authors contributed to the revision of the manuscript and the decision to submit for publication.

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Competing interests None declared.

Patient consent Obtained.

Ethics approval Research ethics committee of Canton Vaud, Switzerland (Protocol 315/14).

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