

## Title Page

### Title:

*Predicting non-response in patient-reported outcome measures - results from the Swiss quality assurance program in cardiac inpatient rehabilitation*

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### Header:

Non-response in PROMs

## Title

Predicting non-response in patient-reported outcome measures - results from the Swiss quality assurance program in cardiac inpatient rehabilitation

## Abstract

**Background:** Quality assurance programmes measure and compare certain health outcomes to ensure high quality care in the health care sector. The outcome health related quality of life (HRQOL)

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is typically measured by patient-reported outcome measures (PROMs). However, certain patient groups are less likely to respond to PROMs than others. This non-response bias can potentially distort results in quality assurance programmes. Our study aims to identify relevant predictors for non-response during assessment using the PROM MacNew Heart Disease questionnaire in cardiac rehabilitation.

**Methods:** This is a cross-sectional study based on data from the Swiss external quality assurance programme. All patients aged 18 years or older who underwent inpatient cardiac rehabilitation in 16 Swiss rehabilitation clinics between 2016 and 2019 were included. Patients' sociodemographic and basic medical data were analysed descriptively by comparing two groups: non-responders and responders. We used a random intercept logistic regression model to estimate associations of patient characteristics and clinic differences with non-response.

**Results:** Of 24,572 patients, there were 33.3% non-responders and 66.7% responders. The mean age was 70; 31.0% were women. The regression model showed that being female was associated with non-response (odds ratio (OR) 1.22; 95% confidence interval (95% CI) 1.14–1.30), as well as having no supplementary health insurance (OR 1.49; 95% CI 1.39–1.59). Each additional year of age increased the chance of non-response by an OR of 1.02 (95% CI 1.02–1.02). Not being a first language speaker of German, French, or Italian increased the chance of non-response by an OR of 6.94 (95% CI 6.03–7.99). Patients admitted directly from acute care had a higher chance of non-response (OR 1.23; 95% CI 1.10–1.38), as well as patients being discharged back into acute care after rehabilitation (OR 3.89; 95% CI 3.00–5.04). Each point on the cumulative illness rating scale (CIRS) total score increased the chance of non-response by an OR of 1.05 (95% CI 1.04–1.05). Certain diagnoses also influenced the chance of non-response. Even after adjustment for known confounders, response rates differed substantially between the 16 clinics.

**Conclusion:** We have found significant non-response bias among certain patient groups, as well as across different treatment facilities. Measures to improve response rates among patients with known barriers to participation, as well as among different treatment facilities need to be considered, particularly when PROMs are being used for comparison of providers in quality assurance programmes or outcome evaluation.

**Keywords:** Non-response, Patient-Reported Outcome Measures, Cardiac Rehabilitation, Quality Assurance, Health Care, Switzerland

## Introduction

In recent years, patient-reported outcome measures (PROMs) have received increased attention as a tool to measure healthcare outcomes. PROMs focus on patients' perspectives and are the only way to address personal satisfaction and health related quality of life (HRQOL). The use of PROMs is associated with many useful applications in clinical care (i.e. shared decision-making and individualised treatment adjustments) and quality improvement (1-3). In external quality assurance programmes, PROMs are used to compare treatment results by different health care providers; in health care systems they are used as indicators for public reporting and performance-based contracting (4, 5). Several PROM initiatives increasingly promote the standardisation and institutionalisation of the patients' perspective in the health systems (e.g. EORTC, ICHOM, PaRIS, PROMIS). This focus on the patients' perspective when measuring health was closely related to the implementation of the International Classification of Functioning, Disability and Health (ICF) in 2001 (6) to promote the biopsychosocial model of health. Although PROMs have great potential to anchor the patient perspective more firmly in medical care and quality assurance, their usability has limitations due to high rates of non-response (7, 8). Non-response is not necessarily problematic for

the representativeness of data, however it becomes problematic when non-response is systematic and certain groups are underrepresented (non-response bias) (9-11). For national health reporting or comparison of health providers, it becomes particularly relevant if these subgroups are for example in poorer condition or achieve better treatment results than the responders. Systematic non-response biases such as these can lead to over- or underestimation of health status or treatment outcomes (12, 13).

The rehabilitation sector has a long tradition of collecting PROMs due to its early adoption of the biopsychosocial model offered by the ICF. External quality assurance programmes in rehabilitation in Germany and Switzerland use PROMs as outcome quality indicators for many years already, such as the MacNew Heart Disease questionnaire (MacNew Heart) to measure HRQOL of patients with heart disease (14, 15).

In this paper, we analysed MacNew Heart response rates of patients undergoing cardiac rehabilitation in Switzerland. The aim was to explore whether a non-response bias exists and whether this non-response bias is due to specific patient characteristics or features of the clinic, or both.

## Methods

### Study design & setting

In 2009, the Swiss National Association for Quality Development in Hospitals and Clinics (ANQ) was founded as a collaboration of all major partners in the Swiss healthcare system (Swiss Hospital Association H+, insurance associations, all 26 Swiss cantons, and the Principality of Liechtenstein) ([www.anq.ch](http://www.anq.ch)). The ANQ is responsible to conduct external quality assurance for the Swiss inpatient health sector, and amongst others, for rehabilitation clinics. The rehabilitation sector is further divided into several functional departments, for which the ANQ developed detailed measurement schemes. In order to measure HRQOL the ANQ decided to use PROMs within a number of departments, alongside functional assessments reported by clinicians and performance tests. For quality assurance within cardiac rehabilitation the chosen PROM is the MacNew Heart questionnaire.

For this cross-sectional study we analysed data from all patients within the functional department of cardiac rehabilitation from 2016 to 2019. The cardiac rehabilitation facilities admit patients for inpatient treatment after being in acute care due to cardiac events or surgery, as well as patients with severe chronic cardiac diseases for conservative management. Patients are supported by an interdisciplinary team and receive intensive, multimodal rehabilitation treatment which lasts on average three weeks. After admission and before discharge, patients were requested to complete the MacNew Heart. The questionnaire was administered as paper-pencil licenced version in German, French, and Italian, which are official languages of Switzerland.

Additionally, clinics submit socio-demographic information, basic medical data (minimum medical data set of the Swiss federal statistical office (16)), and a measurement for comorbidity based on the cumulative illness rating scale (CIRS total score) (17) for each patient.

### Eligibility criteria

All cardiac rehabilitation patients in Switzerland aged 18 years or older, who were admitted into a rehabilitation clinic between 2016 and 2019, and for whom rehabilitation treatment has been completed, were eligible for this study. Cases where treatment was discontinued or shorter than seven days were categorised as dropouts and not eligible for analysis. Reasons for discontinuation of

treatment were, death of a patient, transfer to an acute care clinic for more than 24 hours, or a request for discontinuation of treatment by the patient.

Furthermore, patients were only included if socio-demographic, basic medical, and CIRS data were available. Additionally, the MacNew Heart questionnaire had to be sufficiently completed by the patient, or refusal or inability of the patient to complete the questionnaire had to be recorded by clinic personnel (recorded non-response).

### Outcome: Recorded non-response of the MacNew Heart

The MacNew Heart consists of 27 items; each item can have values between 1 (“severe restriction”) and 7 (“no restriction at all”). The total score is calculated from the mean value of all completed items (a minimum of 50% of the items must be filled-in).

If a patient is unable to complete the questionnaire, clinics must record this as a “non-response”. All patients recorded as non-responders at admission or discharge were categorised as non-responders, whereas all patients who filled in the questionnaire at admission *and* discharge were categorised as responders.

### Exposure and covariates

Covariates were collected from socio-demographic and basic medical data, which clinics have to submit to the federal statistical office (BFS) for each patient.

We used the following socio-demographic variables as exposure and covariates: age [in years], gender [female or male], and supplementary health insurance [yes or no]. Residents in Switzerland may purchase supplementary health insurance on top of their compulsory health insurance which guarantees a single or double room in hospital and treatment by a head physician. We coded language proficiency of German, French, or Italian [L2 (second language) vs. L1 (first language) speaker] based on the nationality of each patient. We categorised patients as L1-speakers if their nationality corresponded with a country that has one of these three languages as official language.

Furthermore, we used the following variables to capture comorbidities and health status of the patients: CIRS total score [in points], length of rehabilitation [in days], patient location before admission [home vs. acute care], patient location after discharge [home vs. acute care], and main diagnosis of each patient [categorised into eight groups of diagnoses]. Finally, we adjusted for the year in which the rehabilitation treatment was concluded [2016 - 2019].

Reporting of our study followed the STROBE checklist (18) and the Good Epidemiological Practice guidelines (19).

### Statistical analysis

Statistical analyses were conducted using R 4.1.2 (20), using lme4 (21) and performance (22).

We used descriptive statistics to determine patients’ characteristics in the full sample, as well as stratified by non-responders versus responders. Additionally, to get an impression of how much the response rates vary by each clinic, we showed the percentages of non-response for each clinic in each year.

The associations of patients’ socio-demographic and health characteristics with being categorised as non-responder were tested using a random intercept logistic regression model. We estimated odds ratios (ORs) as well as corresponding 95% confidence intervals (95% CIs) and p-values. In the regression model we used all covariates and stratified by clinic.

## Results

### Participants

Between 2016 and 2019 data of 29,086 cardiac rehabilitation patients was collected. We excluded 1,998 dropouts, as well as 321 patients with incomplete MacNew Heart questionnaires and 1,477 patients with no records for the MacNew Heart. Another 718 patients were excluded because their socio-demographic and basic medical data was missing or incomplete. Our analysis included 24,572 cardiac rehabilitation patients (Figure 1).

*[Figure 1 here]*

### Clinics

All 16 cardiac rehabilitation clinics that treated patients between 2016 and 2019 were included in the analyses. Some clinics submitted data for all four years, while others only submitted data for a number of years (Figure 2).

### Descriptive data

Descriptive statistics are shown for the full sample ( $n = 24,572$ ), as well as stratified by response status ( $n_{\text{non-responders}} = 8,172$  (33.3%);  $n_{\text{responders}} = 16,400$  (66.7%)) in Table 1. Non-responders were more often female, less often L1-speakers of Italian, French, and German, and had less often supplementary health insurance. Non-responders also scored higher on the comorbidity scale (CIRS total score) and were more likely to be discharged back into acute care.

*[Table 1 here]*

Non-response rates vary largely between the 16 clinics: some clinics have considerably lower non-response rates while others have non-response rates well above the average (Figure 2). There is also variation within each clinic over the years.

### Inference Statistics

*[Table 2 here]*

The intraclass correlation coefficient (ICC) in the regression model, the marginal and the conditional  $R^2$  showed that about half of the total explained variance (0.10 of 0.196) can be explained by differences at clinic level (level 2) (Table 2). The model showed an overall  $R^2$  of 0.196 and thus a high goodness of fit since an  $R^2$  above 0.2 is considered excellent (23).

All socio-demographic predictors were relevant and statistically significant. Female patients had a higher chance of non-response, as well as patients without supplementary health insurance. The chance of non-response was further increased by age. Finally, not being native speaker of German, French, or Italian increased the chance of non-response.

A number of medical exposures also showed significant associations: Those admitted directly from acute care had a higher chance of non-response, as well as those being discharged back into acute care instead of being discharged home. Each additional point of CIRS total score increased the chance of non-response. A number of different diagnoses also increased or decreased the chance of non-response, compared to the diagnosis "Chronic ischaemic heart disease". Every additional day of rehabilitation treatment increased the chance of non-response slightly. Compared to the year 2016, the chance of non-response remained similar in 2017, decreased in 2018, and increased in 2019.

## Discussion

### Statement of principal findings

On individual level, our results show that there were significant differences between patients who completed the MacNew heart (responders) and those who did not (non-responders). The most striking finding was that patients who spoke German, French, or Italian (language of the questionnaire) as second language had a higher chance of non-response. Women, older patients, and patients without supplementary health insurance also had a higher chance of non-response. Being able to afford supplementary health insurance could indicate higher income and could be interpreted as a proxy for higher socioeconomic status.

Furthermore, indicators that directly or indirectly measure disease severity were shown to be important: Patients who received longer rehabilitation treatment and those with a higher comorbidity score had an increased chance of non-response. Patients admitted to a rehabilitation clinic from an acute care hospital and those discharged back into acute care after rehabilitation were also less likely to respond.

On clinic level, our results show that there were substantial differences in response rates between each facility. In fact, they accounted for about half of the explained variance in the full model.

### Strengths and limitations

Several limitations of this study must be considered: The available confounding factors do not cover all potential reasons for non-response such as, marital status, education, and complete information on socioeconomic status. Another limitation is potential misclassification of language status. The only information available was the patient's nationality and not their first language. Patients who are Swiss-born or naturalised Swiss citizens may not have the linguistic resources to answer the questionnaire but, according to this metric, would be considered first language speakers. Moreover, a patient may be fluent in German, French, or Italian despite holding a passport from a country where these are not official languages.

Furthermore, a lack of information on clinic conditions (number of beds, staffing levels) means it was difficult to explain possible differences between clinics. Additionally, the number of level-2 units (16 clinics) is rather small. Including level-2 predictors would probably not lead to a better model fit. We thus decided to estimate random intercept logistic regression models despite the small number of level-2 units since the ICC is rather high (28), and the assumption of independence of errors would thus be violated when using logistic regression models without a second level.

The main strength of our analysis is the data set on which this study was based. As the Swiss quality assurance programme for inpatient rehabilitation is a comprehensive survey, the data gives a thorough overview of all patients in Swiss cardiac inpatient rehabilitation. Socio-demographic and basic medical data was (mostly) available, even for non-responders. The data furthermore included information about where each patient was treated. We can thus show how much of the explained variance is due to individual-level factors (such as age, gender, or language status) and how much variation occurs *between* the clinics.

### Interpretation within the context of the wider literature

Our results are consistent with existing research that found language barriers to be important predictors of non-response when using PROMs. Burrus et al. (10) found being a non-native speaker led to higher non-response rates in vocational rehabilitation patients in Switzerland. This was also found for patients in an orthopaedic outpatient setting in Australia (24), for a cohort with total joint

arthroplasty in the USA (8), and for patients who underwent elective surgery in England (11). Several national health surveys found higher non-response rates among ethnic minorities, immigrants and their descendants (7, 25).

Our finding that patients without supplementary insurance had a higher chance for non-response is in line with a study in which American patients who had Medicare or Medicaid are more often non-responders than patients with commercial medical insurance. Schamber et al. (8) interpreted this as proxy for lower socioeconomic status. Additionally, several studies also identified that more deprived people were less likely to respond (7, 11, 25, 26).

The association of non-response with poorer health status and higher levels of comorbidity, was also reported in several surveys. A higher need for personal assistance during completion of the PROM was reported for patients with health-related disabilities (8, 10, 11, 26).

Contrary to our findings several studies found that non-responders are more often male (11, 25, 26), or no association between gender and response rate was reported (7, 8). Our result that elder patients have higher odds for non-response is in line with existing research (7, 8, 24), others found the opposite (11, 26). These discrepancies are possibly due to the differing sub-populations which were evaluated.

Based on our results we cannot conclude whether non-responders have in fact lower outcomes pertaining to HRQOL after rehabilitation treatment, as information on this was not available for non-responders. Only a few studies could show that non-response was systematically associated with worse overall health condition (7) or lower results in outcome measurements (27, 28). The observed differences in response rates between clinics (provider-effect) is also in line with existing research. Two studies (12, 13) have found large differences between single providers in their analysis of pre-operative PROM data from the National Health Service in England. Both studies were unable to report on specific clinic conditions that could potentially be responsible for differing response rates. Further evidence can also be found in an experimental study by Ho et al. (26) where eight cohorts of patients were asked to complete a PROM under differing conditions, resulting in non-response rates between 13% and 81% among the eight groups.

### Implications for policy, practice, and research

Non-response bias may seem like a predominantly methodological problem. However, it has strong implications for the question of how much confidence we should have in the correctness of our results (9). High non-response rates in specific clinics lead to small case numbers and could lead to smaller (and non-significant) differences. Additionally, the samples may not represent the true population since certain groups, such as people who are not L1-speakers, less affluent patients, and more severely ill patients, are underrepresented.

Results of PROMs and clinic comparisons based on these results must be interpreted carefully, with attention being paid to non-response rates and non-response bias.

Methodologically, these issues can be approached with multiple imputation techniques (13, 29). However, the question is whether imputation on the outcome variable is desirable in a quality assurance context. In fact, complete data should be one aspect of good quality. The indicator would then be the response rate. When action is being taken to increase response rates of PROMs, subgroups with higher chance of non-response should be addressed specifically (7), as non-response bias can remain even with high response rates (9).

The importance of systematic integration of PROMs into the organisational procedures and treatment process should be emphasized in quality assurance programmes. Results should also be discussed with the patient, which can lead to shared decision-making, more adherence, and a





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## Tables

Table 1: Sample characteristics: full sample and stratified by response status MacNew Heart questionnaire

	Full Sample (n=24,572)			Non-Responders MacNew Heart (n=8,172)			Responders MacNew Heart (n=16,400)		
	N	%	Median (IQR)	N	%	Median (IQR)	N	%	Median (IQR)
<b>Age (years)</b>	24,572		70 (45)	8,172		71 (44)	16,400		69 (45)
<b>Gender</b>									
<i>female</i>	7,623	31.0		2,771	33.9		4,852	29.6	
<i>male</i>	16,949	68.9		5,401	66.1		11,548	70.4	
<b>German, Italian, or French L1-speaker</b>									
<i>no</i>	1,144	4.7		797	9.8		347	2.1	
<i>yes</i>	23,428	95.3		7,375	90.2		16,053	97.9	
<b>Suppl. health insurance</b>									
<i>yes</i>	17,667	71.9		6,489	79.4		11,178	68.2	
<i>no</i>	6,905	28.1		1,683	20.6		5,222	31.8	
<b>CIRS (total score)</b>	24,572		16 (24)	8,172		17 (25)	16,400		15 (24)
<b>Length of stay (days)</b>	24,572		20 (23)	8,172		20 (25)	16,400		20 (21)
<b>Pre-rehabilitation location</b>									
<i>acute care</i>	22,677	92.3		7,535	92.2		15,142	92.3	
<i>home</i>	1,895	7.7		637	7.8		1,258	7.7	
<b>Post-rehabilitation location</b>									
<i>acute care</i>	297	1.2		193	2.4		104	0.6	
<i>home</i>	24,275	98.8		7,979	97.6		16,296	99.4	
<b>Main diagnosis</b>									
<i>Chronic ischaemic heart disease</i>	7,414	30.2		2,504	30.6		4,910	29.9	
<i>Other ischaemic heart diseases</i>	4,963	20.2		1,629	19.9		3,334	20.3	
<i>Nonrheumatic mitral valve disorders</i>	1,827	7.4		485	5.9		1,342	8.2	
<i>Nonrheumatic aortic valve disorders</i>	4,816	19.6		1,489	18.2		3,327	20.3	
<i>Other forms of heart disease</i>	2,727	11.1		1,023	12.5		1,704	10.4	

<i>Diseases of arteries</i>	1,483	6.0	499	6.1	984	6.0
<i>Other disorders of the circulatory system</i>	1,030	4.2	383	4.7	647	3.9
<i>Other diseases</i>	312	1.3	160	2.0	152	0.9
<b>Year</b>						
2016	6,033	24.6	1,845	22.6	4,188	25.5
2017	6,109	24.9	1,989	24.3	4,120	25.1
2018	6,169	25.1	2,006	24.5	4,163	25.4
2019	6,261	25.5	2,332	28.5	3,929	24.0

IQR = Interquartile Range

Table 2: Predicting non-response to the MacNew Heart questionnaire – Random intercept logistic regression model.

<b>Predictors</b>	Random intercept logistic regression model		
	OR	Non-Response MacNew Heart 95% CI	P
<b>Intercept</b>	0.02	0.02 – 0.04	<0.001
<b>Gender:</b> female (ref: male)	1.22	1.14 – 1.30	<0.001
<b>Age</b> (years)	1.02	1.02 – 1.02	<0.001
<b>German, Italian, or French L1-speaker:</b> yes (ref: no)	6.95	6.04 – 8.00	<0.001
<b>Suppl. health insurance:</b> yes (ref: no)	1.49	1.39 – 1.59	<0.001
<b>Length of stay</b> (days)	1.01	1.00 – 1.01	0.008
<b>Pre rehabilitation location:</b> acute care (ref: home)	1.23	1.10 – 1.38	<0.001
<b>Post- rehabilitation location:</b> acute care (ref: home)	4.14	3.12 – 5.50	<0.001
<b>CIRS</b> (total score in points)	1.05	1.04 – 1.05	<0.001
<b>Main diagnosis</b> (ref: <i>Chronic ischaemic heart disease</i> )			
<i>Other ischaemic heart diseases</i>	1.01	0.93 – 1.10	0.858
<i>Nonrheumatic mitral valve disorders</i>	0.85	0.75 – 0.96	0.010
<i>Nonrheumatic aortic valve disorders</i>	0.97	0.89 – 1.05	0.436
<i>Other forms of heart disease</i>	1.25	1.13 – 1.38	<0.001
<i>Diseases of arteries</i>	1.15	1.01 – 1.31	0.031
<i>Other disorders of the circulatory system</i>	1.18	1.02 – 1.37	0.031
<i>Other diseases</i>	2.09	1.62 – 2.70	<0.001
<b>Year</b> (ref: 2016)			
2017	0.98	0.90 – 1.06	0.562
2018	0.90	0.83 – 0.98	0.018
2019	1.09	1.00 – 1.19	0.040
<b>Random effects</b>			
$\sigma^2$	3.29		
$\tau_{00}$	0.38	clinic	
N groups	16	clinic	
N observations	24,572		
<b>Model Indices</b>			
ICC	0.10		
Marginal R <sup>2</sup> / Conditional R <sup>2</sup>	0.103 / 0.196		
AIC	27,927.981		
BIC	28,090.169		
RMSE	0.438		

## Figure Legend

Figure 1: Flow of participants

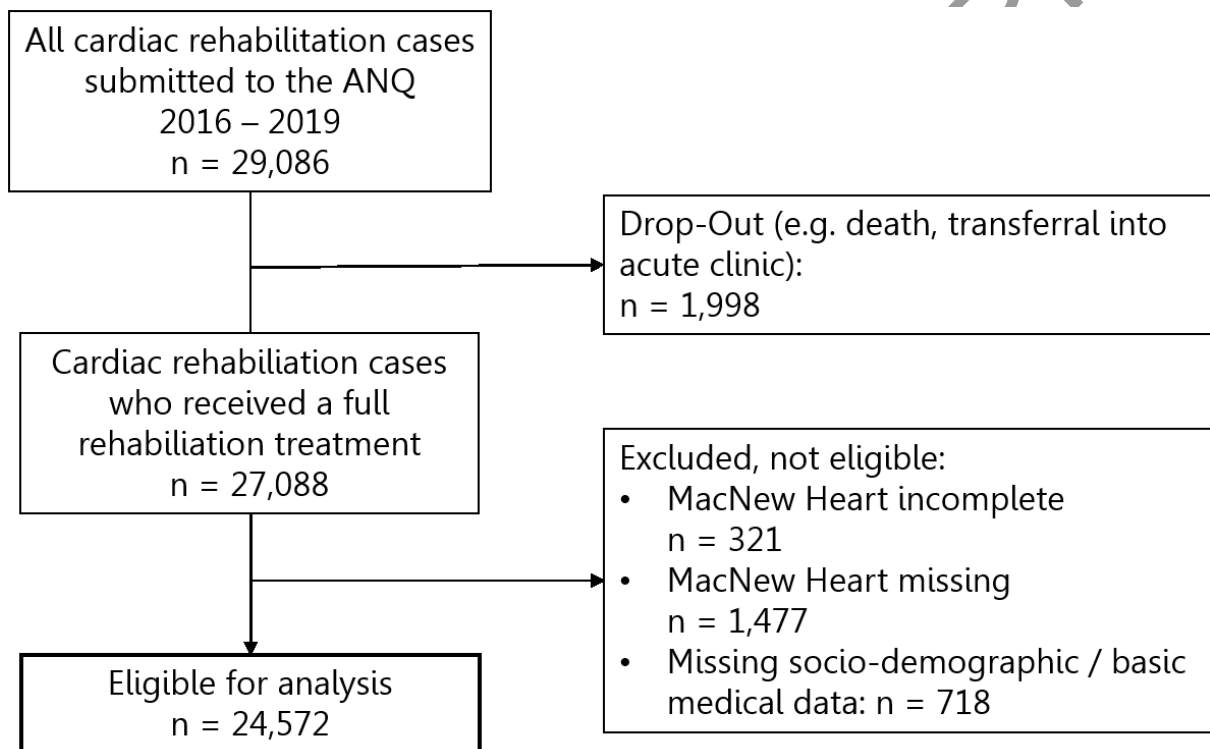
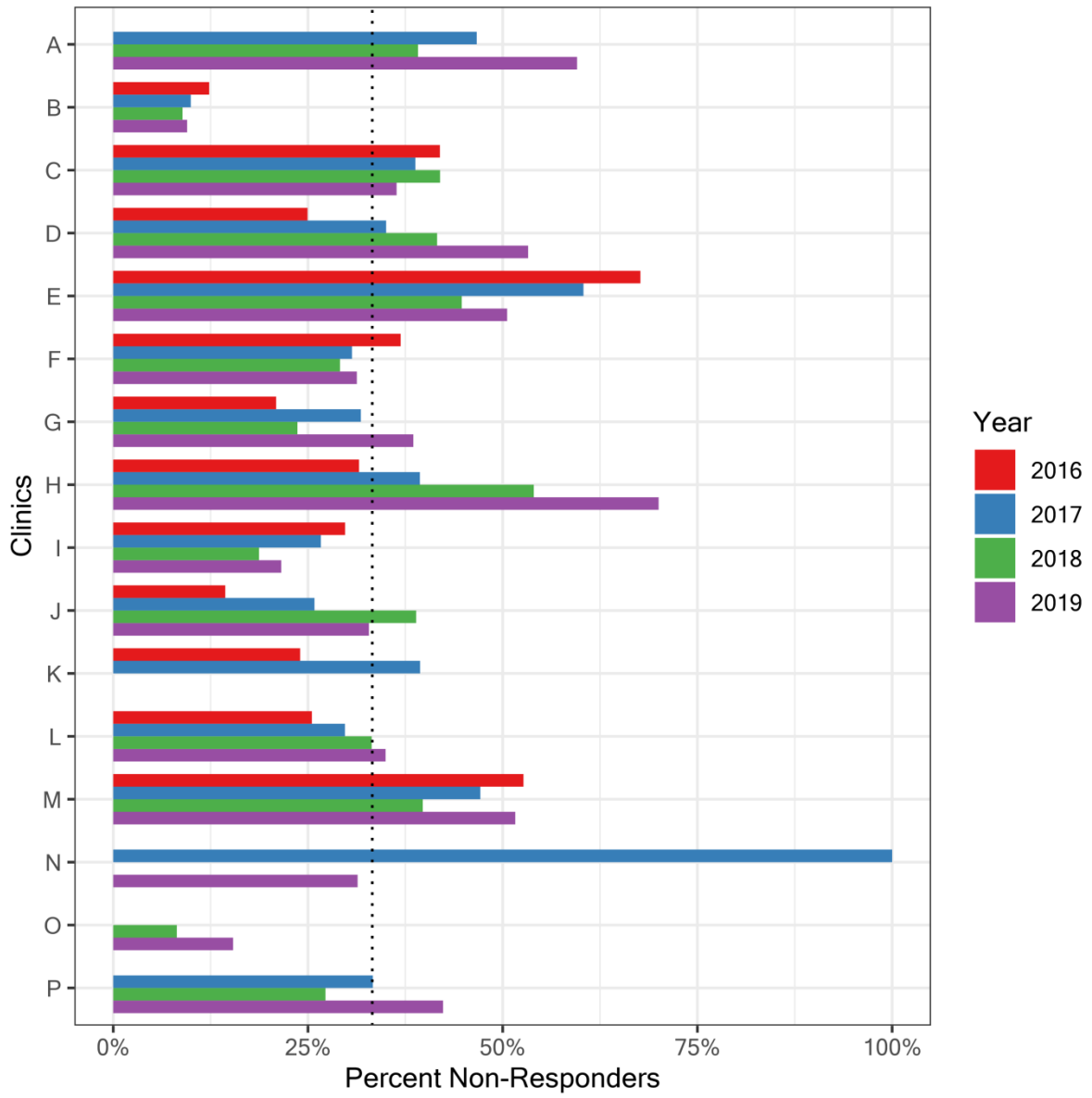


Figure 2: Patient non-response at clinics in percent, dotted line depicts the overall rate of non-response



ACCEPT

## Contributorship

All authors made substantial contributions to data collection, study conception and interpretation of results. Data analysis was performed by Anna Schlumbohm, Stefanie Köhn and Manuela Marquardt. The first draft was written by Stefanie Köhn, Anna Schlumbohm, Manuela Marquardt, and Anke Scheel-Sailer (introduction) and the manuscript was revised critically for important intellectual content by Anke Scheel-Sailer, Stephan Tobler, Jan Vontobel, and Luise Menzi. Necessary revision to the first draft was taken over by Stefanie Köhn, Anna Schlumbohm and Manuela Marquardt. All authors read and approved the final version of the manuscript.

## Ethics and other permissions

This study does not require the approval of an ethics committee since the data is part of the Swiss national quality assurance program.

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## Conflict of interests

No known conflict of interest. Anke Scheel-Sailer, Stephan Tobler, and Jan Vontobel are members of the ANQ rehabilitation quality committee and work in different clinics. Luise Menzi is head of rehabilitation at the ANQ. Anna Schlumbohm, Stefanie Köhn, and Manuela Marquardt work at the Charité and are responsible for analysing the data collected for the Swiss quality assurance program managed by the ANQ. The ANQ had no influence on the interpretation of data and the conclusions drawn.

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## Data availability statement

Data are available upon request from the Head of Rehabilitation at ANQ, Luise Menzi (luise.menzi@anq.ch).