

Le consentement général : une source de biais ?

Cristina Boehm-Bosmani & Marco Pettinger



CENTRE DE
RECHERCHE CLINIQUE



Agenda

Introduction

- Consentement
- Consentement général
- Biais

Projet initial: REPRESENT Geneva

- Hypothèse
- Méthodologie
- Résultats

Projet national: REPRESENT Switzerland

- Autres études
- Hypothèse
- Méthodologie & projet

Introduction: consentement

Types de consentement

- Consentement spécifique
- Consentement élargi
- (- Exemption de consentement)

Introduction: consentement

Obligation

Ethique et légale

Quelles lois régulent le consentement éclairé?

- Loi sur les professions médicales (LPMéd)*
- Loi sur la protection des données (LPD)*
- Constitution de la Confédération suisse*
- Loi relative à la recherche sur l'être humain (LRH)*

Introduction: consentement

Obligation

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Introduction: consentement

Obligation

Ethique et légale

consentement

0/0



**Loi fédérale
sur les professions médicales universitaires¹**

Introduction: consentement

Obligation

Légale:

- LPD Art. 6
- Constitution Art. 118b
- LRH Art. 7

« *Constitution de la Confédération suisse, Art. 118b :*

[...]

2 Elle respecte les principes suivants en matière de recherche en biologie et en médecine impliquant des personnes:

a. un projet de recherche ne peut être réalisé que si la personne y participant ou la personne désignée par la loi a donné son consentement éclairé [...] »

Introduction: consentement

Obligation

Légale:

- LPD Art. 6
- Constitution Art. 118b
- LRH Art. 7

« *Loi sur la protection des données*

6 Lorsque le **consentement** de la personne concernée est requis, celle-ci ne consent valablement que si elle exprime librement sa **volonté** concernant un ou plusieurs traitements déterminés et **après avoir été dûment informée.**»

Introduction: consentement

Obligation

Légale:

- LPD Art. 6
- Constitution Art. 118b
- LRH Art. 7

« *Loi relative à la recherche sur l'être humain, Art. 7:*

1 La recherche sur l'être humain peut être pratiquée uniquement si la personne concernée a donné son consentement éclairé [...]

2 La personne concernée peut en tout temps refuser de participer à un projet de recherche ou révoquer son consentement sans avoir à justifier sa décision. »

Introduction: consentement

Obligation

Légale:

- LPD Art. 6
- Constitution Art. 118b
- LRH Art. 7

« *Constitution de la Confédération suisse, Art. 118b point 2. a.:*

2 Elle respecte les principes suivants en matière de recherche en biologie et en médecine impliquant des personnes:

*a. un projet de recherche ne peut être réalisé que si la personne y participant ou la personne désignée par la loi a donné son consentement éclairé; **la loi peut prévoir des exceptions**; un refus est contraignant dans tous les cas; [...]*»

Introduction: consentement

Exemption

- Constitution Art. 118b
- LRH Art. 34

« *Loi relative à la recherche sur l'être humain, Art. 34:*

Lorsque les exigences posées au consentement et à l'information au sens des art. 32 et 33 ne sont pas remplies, le matériel biologique et les données personnelles liées à la santé peuvent être réutilisés à titre exceptionnel à des fins de recherche aux conditions suivantes:

- a. l'obtention du consentement ou l'information sur le droit d'opposition est impossible ou pose des difficultés disproportionnées, ou on ne peut raisonnablement l'exiger de la personne concernée;*
- b. aucun document n'atteste un refus de la personne concernée;*
- c. l'intérêt de la science prime celui de la personne concernée à décider de la réutilisation de son matériel biologique ou de ses données. »*

Introduction: consentement *général*

Alternative

LRH Art. 17, 32, 33

« Art. 32 **Réutilisation de matériel** biologique et de données génétiques

1 Le matériel biologique et les données génétiques peuvent être réutilisés pour un projet de recherche sous une forme non codée lorsque la personne concernée ou, le cas échéant, son représentant légal ou ses proches ont donné leur **consentement éclairé**. [...]

Art. 33

1 Les données personnelles non génétiques...»

Introduction: consentement *général*

Historique

- 2012: Premier consentement général de la bio banque du Centre Hospitalier Universitaire Vaudois (CHUV)
- 2014: Entrée en vigueur de la LRH
- 2017: Template Swissethics & Académie suisse des sciences médicales (ASSM)
- 2018/9: Harmonisation entre les 5 hôpitaux universitaires suisses
- 2018-2023: EOC, KSSG, UKBB, HFR

Introduction: consentement *général*

Historique

- 2012: Premier consentement général de la bio banque du Centre Hospitalier Universitaire Vaudois (CHUV)
- 2014: Entrée en vigueur de la LRH
- 2017: Template Swissethics & Académie suisse des sciences médicales (ASSM)
- 2018/9: Harmonisation entre les 5 hôpitaux universitaires suisses
- 2018-2023: Autres hôpitaux cantonaux (EOC, KSSG, UKBB, ...)

Déclaration de consentement pour l'utilisation des données de santé et des échantillons à des fins de recherche

.....
Nom et prénom du/de la patient-e

.....
Date de naissance

J'accepte

que mes données de santé et mes échantillons biologiques résiduels collectés durant les soins (consultations ambulatoires et hospitalisations) soient utilisés à des fins de recherche

OUI NON

J'ai compris :

- les explications sur la réutilisation de mes données cliniques et échantillons biologiques à des fins de recherche, détaillées dans l'information ci-dessus (version x, date).
- que mes données personnelles sont protégées.
- que mes données et échantillons biologiques peuvent être utilisés dans des projets de recherche nationaux et internationaux, dans les secteurs public et privé.
- que les projets peuvent inclure des analyses génétiques sur mes échantillons, à des fins de recherche.
- que je pourrais être recontacté-e dans le cas où des résultats pertinents me concernant seraient mis en évidence.
- que ma décision est volontaire et n'a pas d'effet sur mon traitement médical.
- que ma décision est valable pour une durée illimitée.
- que je peux retirer mon consentement à n'importe quel moment sans avoir à justifier ma décision.

.....
Lieu et date

.....
Signature du patient, si capable de discernement

Introduction: consentement *général*

Procédure

Hétérogénéité: canton, hôpital, département, service, interlocuteur, ...

Exemple HUG

- 2018-2019: flyers, information orale, selon département
- 2019-2023: lettre personnalisée, toute hospitalisation, CH
- 2023- : lettre personnalisée, CH

Introduction: consentement *général*

Challenge

- Etudes rétrospectives

Introduction: consentement *général*

Challenge

- Etudes rétrospectives

3 Overview of all projects submitted to BASEC in 2022 (AS1)

Table 2: Total number of research projects **submitted via BASEC in 2022** (analysis set AS1), including information on type of research and the legal basis.

Type of research	Legal basis	n	% _{col}
Clinical trial	ClinO or ClinO-MD	591 ¹	24.6
Research involving persons, but not a clinical trial	HRO, Chapter 2	797 ²	33.1
Further use of health-related personal data and/or biological material	HRO, Chapter 3	990	41.1
Research involving deceased persons	HRO, Chapter 4	29	1.2
Research involving embryos and fetuses from induced abortions or stillbirths	HRO, Chapter 5	0	0.0
Total number		2407	100.0

¹ 60 of these projects also include an application for further use of data/biological material.

² 193 of these projects also include an application for further use of data/biological material.

2022

kofam.ch

Introduction: consentement *général*

Challenge

- Etudes rétrospectives

Table 20: Stratification of **projects involving further use of data/biological material** by ethics committee.

	Total	
	n	% _{total}
Consent		
Prior consent exists	309	28.7
Consent to be sought	234	21.7
No consent for some/all data	535	49.6
Total number	1078	100.0

Note that there are regional differences in time point of the introduction of the 'general consent' and some hospitals have not introduced it yet.

2018

kofam.ch

Introduction: consentement *général*

Challenge

- Etudes rétrospectives

Table 20: Stratification of **projects involving further use of data/biological material** by ethics committee.

Table 18: Overview of characteristics of all approved 'further use' projects.

				Total	
		n	% _{total}	n	% _{total}
Genetic data/biol. material	Yes	226	21.4	309	28.7
	No	832	78.6	234	21.7
Coding (HRO Art. 25–27)	Coded	959	90.6	535	49.6
	Open, non-coded	99	9.4		
Consent (HRO Art. 28–32)	Consent for all data	632	59.7	1078	100.0
	Consent for some but not all data (partially Art. 34 HRA)	326	30.8		
	No consent for all data, Art. 34 HRA	100	9.5		

2018

2022

hospitals have not introduced it yet.

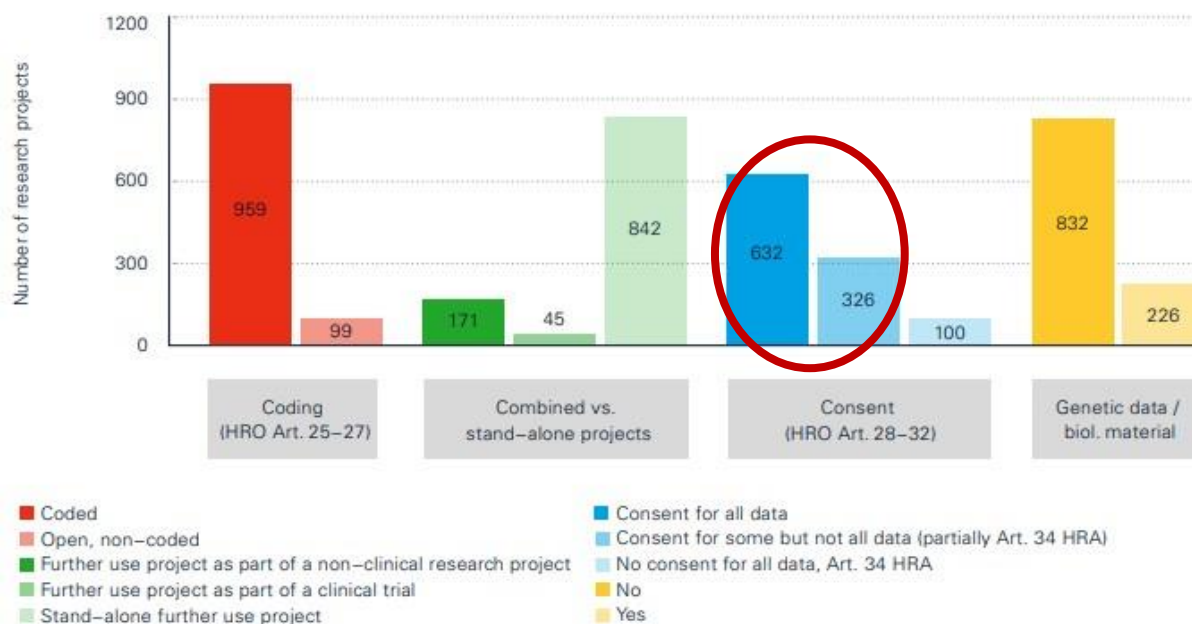
kofam.ch

Introduction: consentement *général*

Challenge

- Etudes rétrospectives

Figure 2: Overview of characteristics of all approved 'further use' projects separately for all research projects.



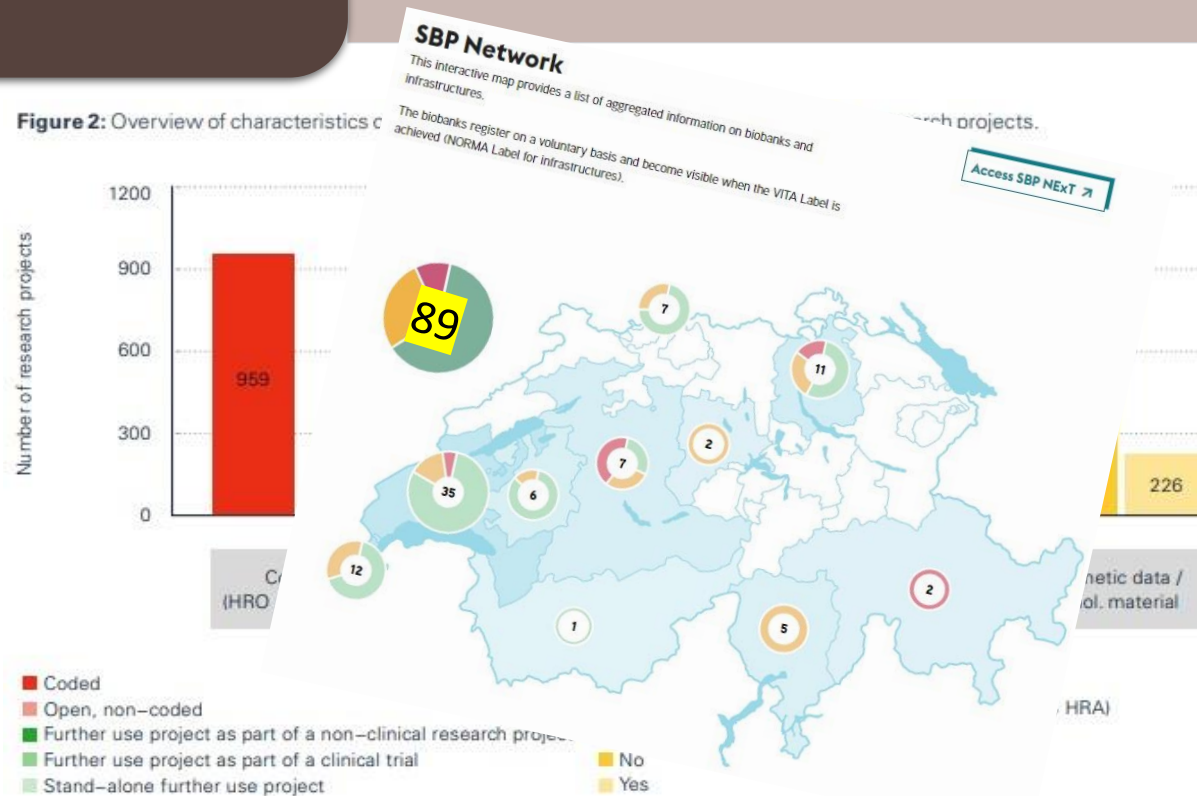
2022

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Introduction: consentement *général*

Challenge

- Etudes rétrospectives
- Bio banques

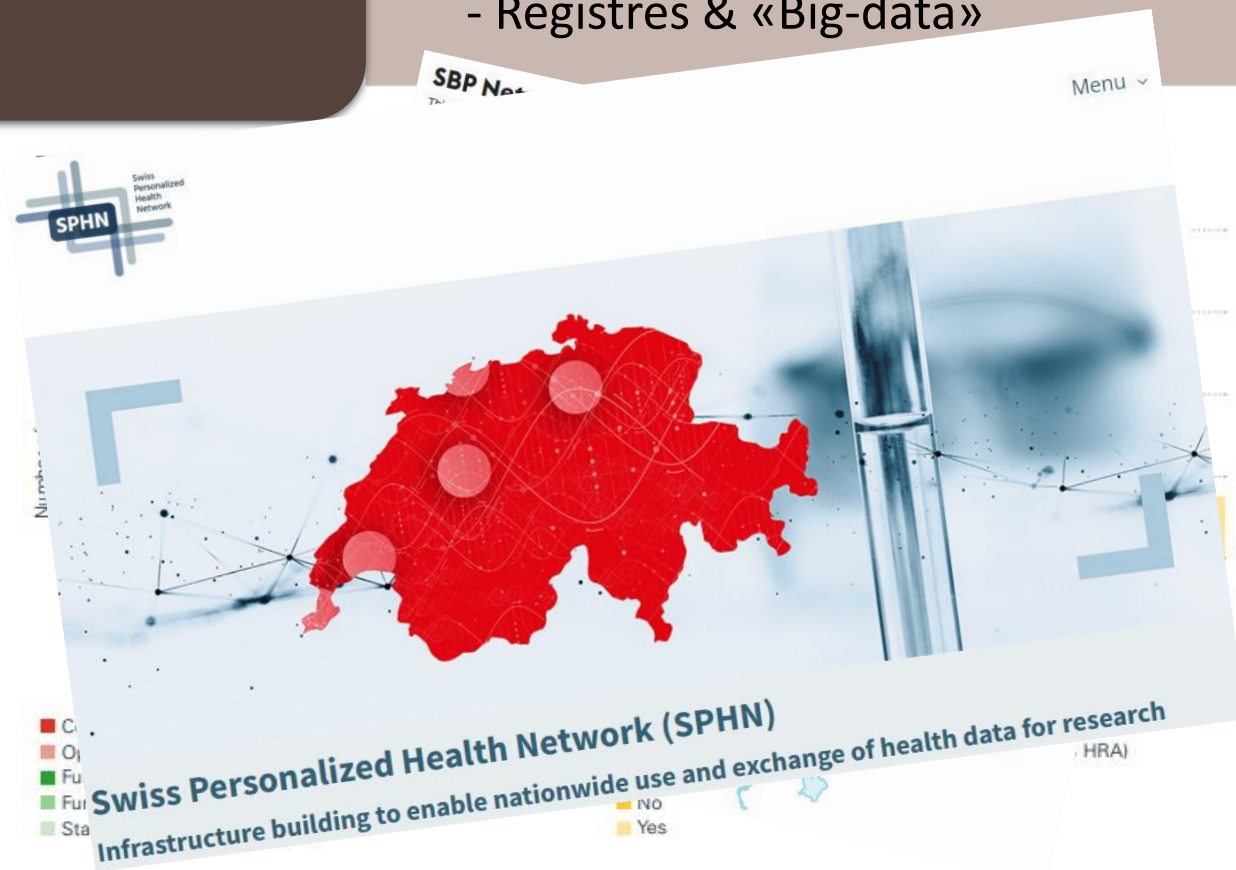


swissbiobanking.ch

Introduction: consentement *général*

Challenge

- Etudes rétrospectives
- Bio banques
- Registres & «Big-data»



sphn.ch

Introduction: source de biais

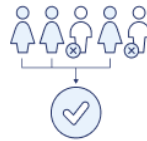
Types of selection bias

Bias due to factors related to the study's participants, such as the choice of population or sampling and recruitment methods.



Sampling bias

Occurs when some members of the intended population are less likely to be included than others



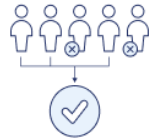
Attrition bias

Occurs when participants who drop out of a study systematically differ from the ones who remain.



Volunteer bias

People with specific characteristics are more likely to participate than others



Survivorship bias

Successful observations or people are more likely to be represented in the sample than unsuccessful ones



Non-response bias

People who refuse to participate or drop out systematically differ from those who take part.



Undercoverage bias

Some members of a population are inadequately represented in the sample



Introduction: source de biais

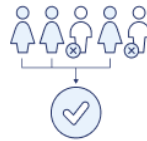
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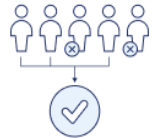
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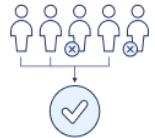
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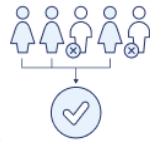
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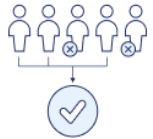
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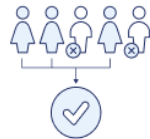
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REPRESENT Geneva

Bosmani et al. *BMC Medical Ethics* (2023) 24:10
<https://doi.org/10.1186/s12910-022-00877-7>

BMC Medical Ethics

RESEARCH

Open Access

REPRESENT: REPresentativeness of RESearch data obtained through the 'General Informed ConsENT'



Cristina Bosmani^{1*}, Sonia Carboni¹, Caroline Samer², Christian Lovis⁴, Thomas Perneger⁵, Angela Huttner^{1,3} and Bernard Hirschel⁶

Financement:



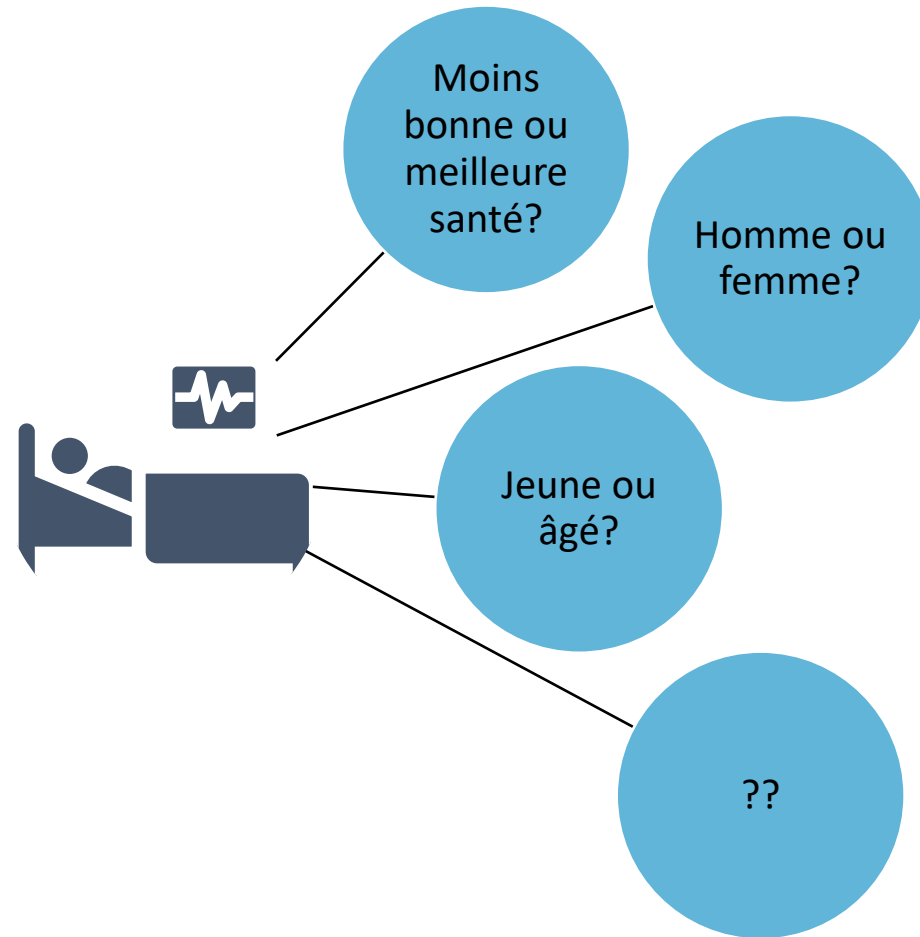
Direction médicale (PRD)
CCER

REPRESENT GE: Questions de l'étude

Quel est le profil des patients qui donnent leur consentement?

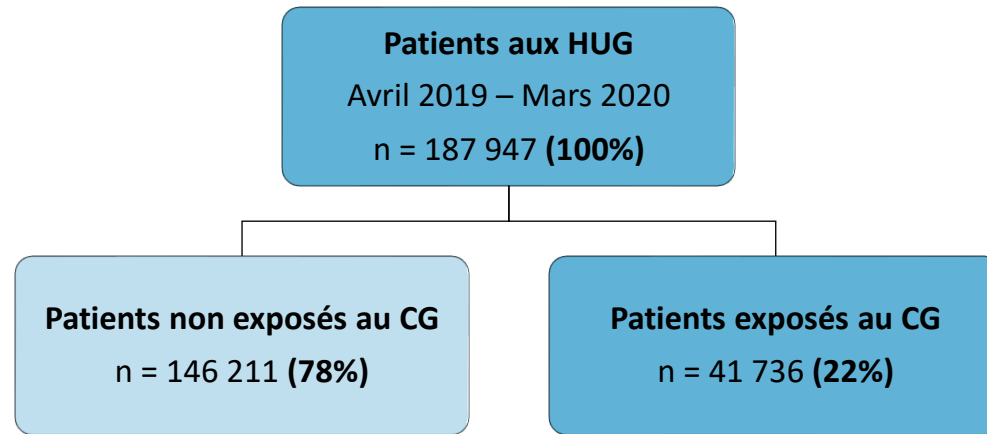
Sont-ils différents ou similaires des autres patients (refuseurs, non-exposés, non-répondeurs)?

REPRESENT GE: Hypothèses

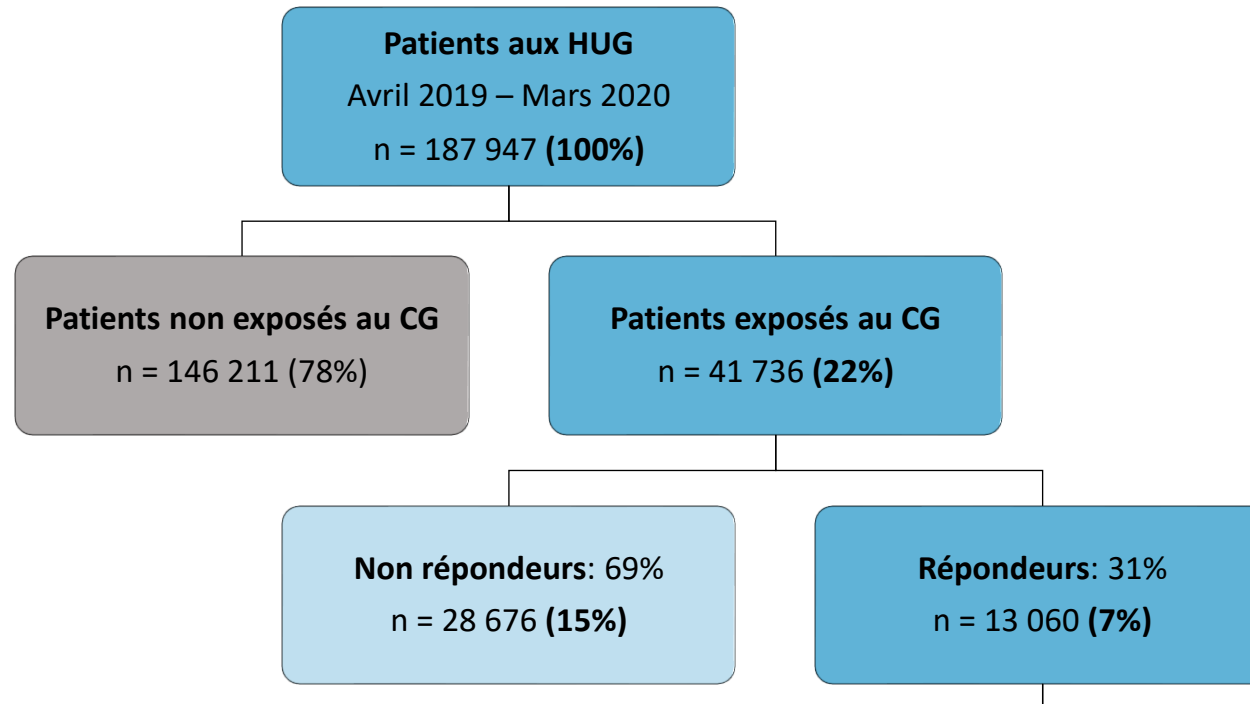


Kho et al., BMJ, 2009
Tu et al., N Engl J Med., 2004
Macleod et al., BMC Med Res Methodol., 2008
Elwood et al., Cancer Epidemiol., 2019

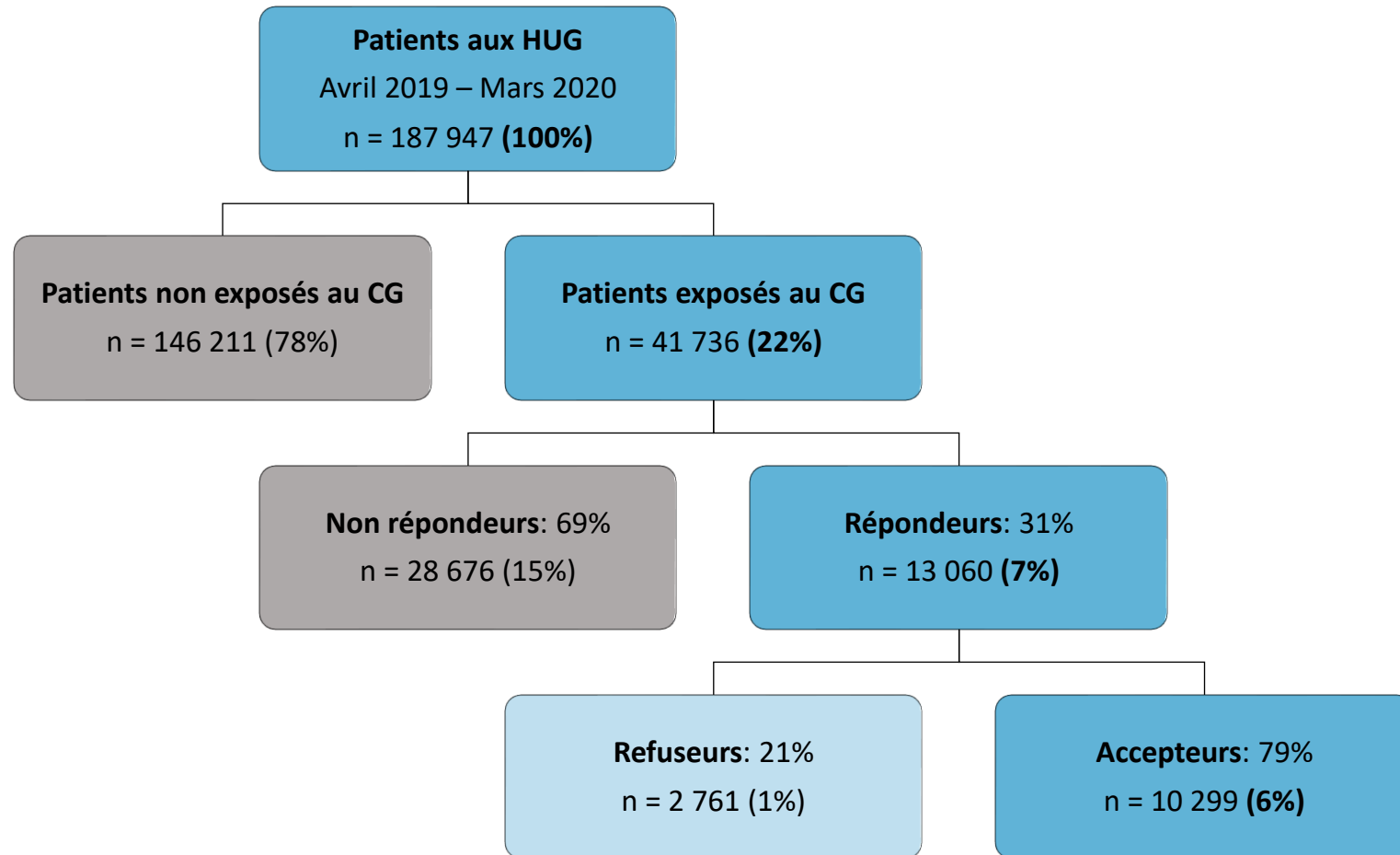
REPRESENT GE: Méthodologie et populations



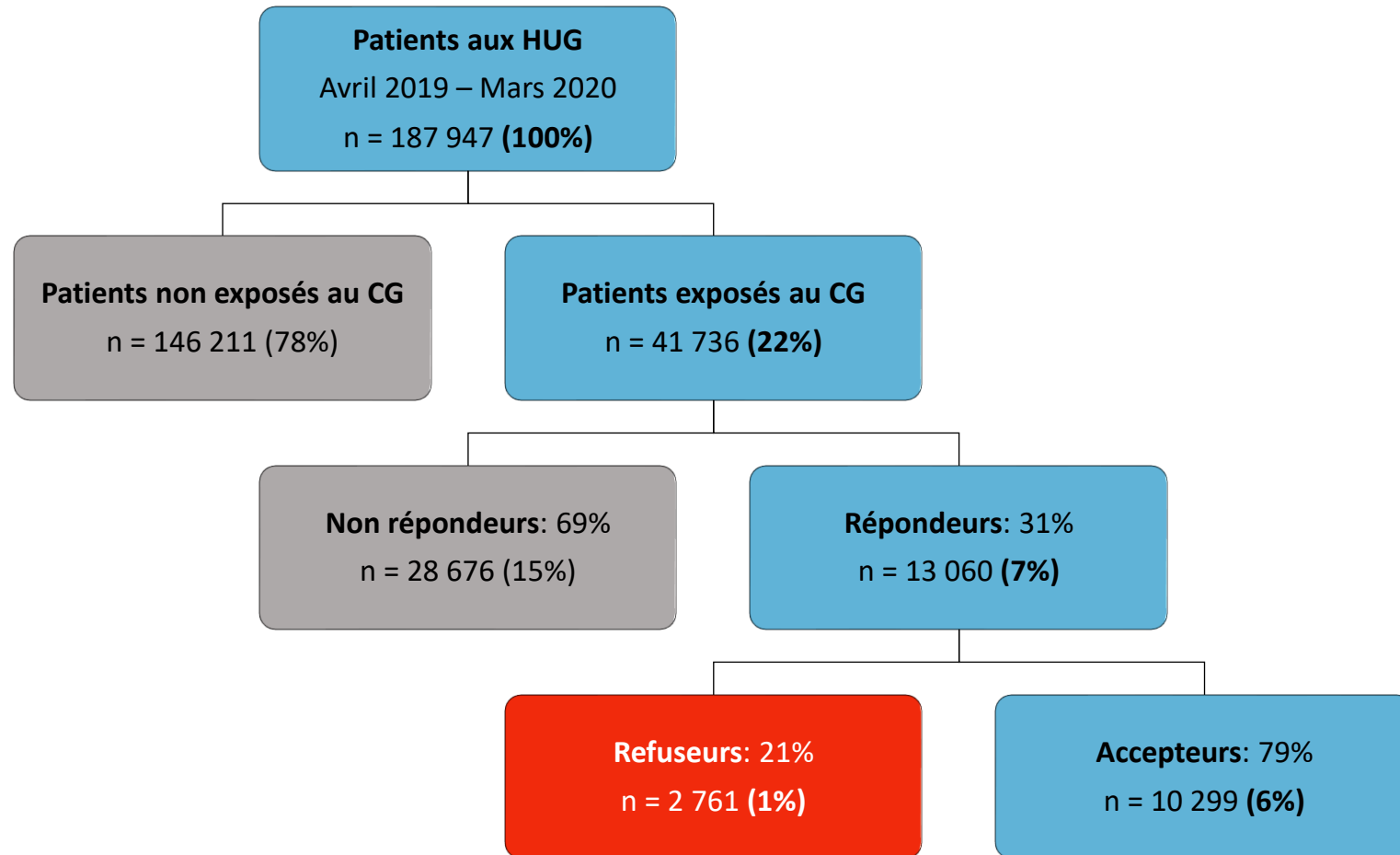
REPRESENT GE: Méthodologie et populations



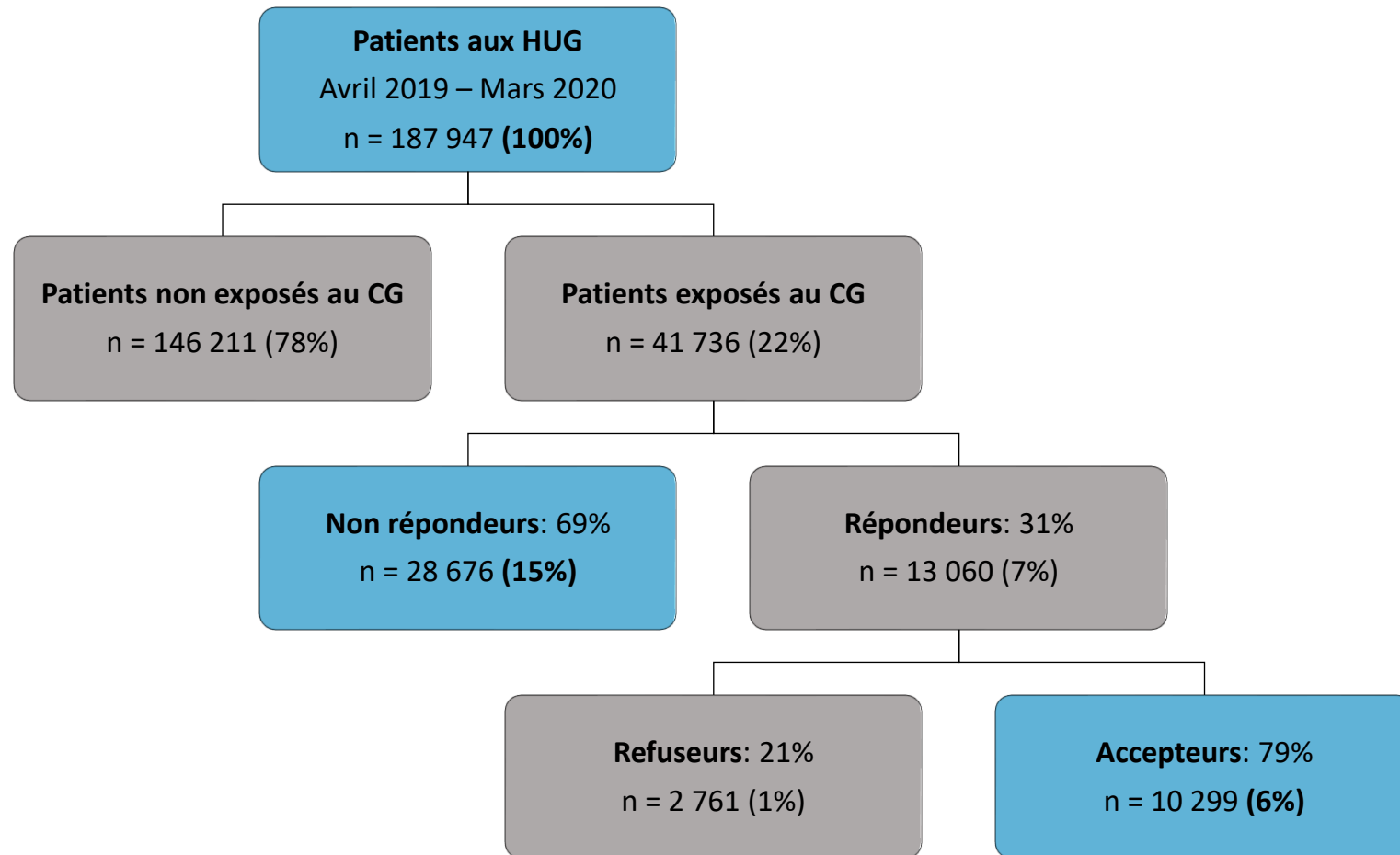
REPRESENT GE: Méthodologie et populations



REPRESENT GE: Méthodologie et populations



REPRESENT GE: Méthodologie et populations



Bosmani et al. 2023

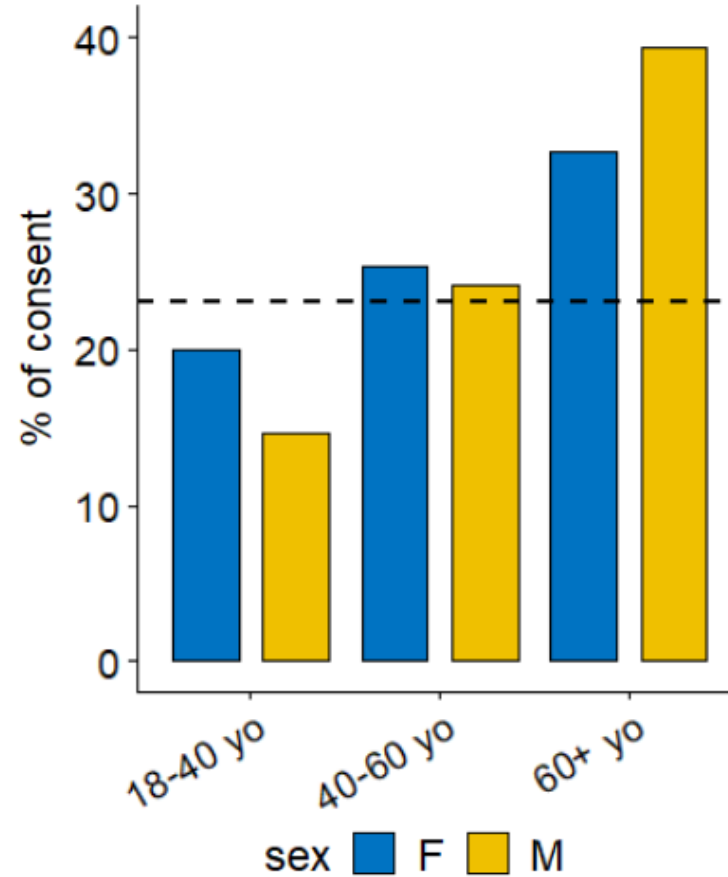
REPRESENT GE: Age et Sexe

Table 1 Baseline characteristics of patients approached for general consent

Characteristic	Overall n = 38,975	Signatories n = 10,299	X ² /t-test p Value
Sex			
Women, n (%)	21,907 (56.2)	26.3	0.56
Men, n (%)	17,068 (43.8)	26.6	
Median age, years (IQR)	46 (33–63)	54 (38–72)	< 0.0001

Bosmani et al. 2023

REPRESENT GE: Age et Sexe



Bosmani et al. 2023

REPRESENT GE: Nationalité et Langue

Table 1 Baseline characteristics of patients approached for general consent

Characteristic	Overall n = 38,975	Signatories n = 10,299	X ² /t-test p Value
Country of origin			
Switzerland, n (%)	20,405 (52.4)	32.3	Swiss vs. other: <0.0001
Other, n (%)	18,454 (47.3)	19.9	
Spain, n (%)	1348 (3.5)	22.1	
France, n (%)	2174 (5.6)	26.1	
Italy, n (%)	1879 (4.8)	26.9	
Portugal, n (%)	3211 (8.2)	20.3	
N/A, n	116		

Bosmani et al. 2023

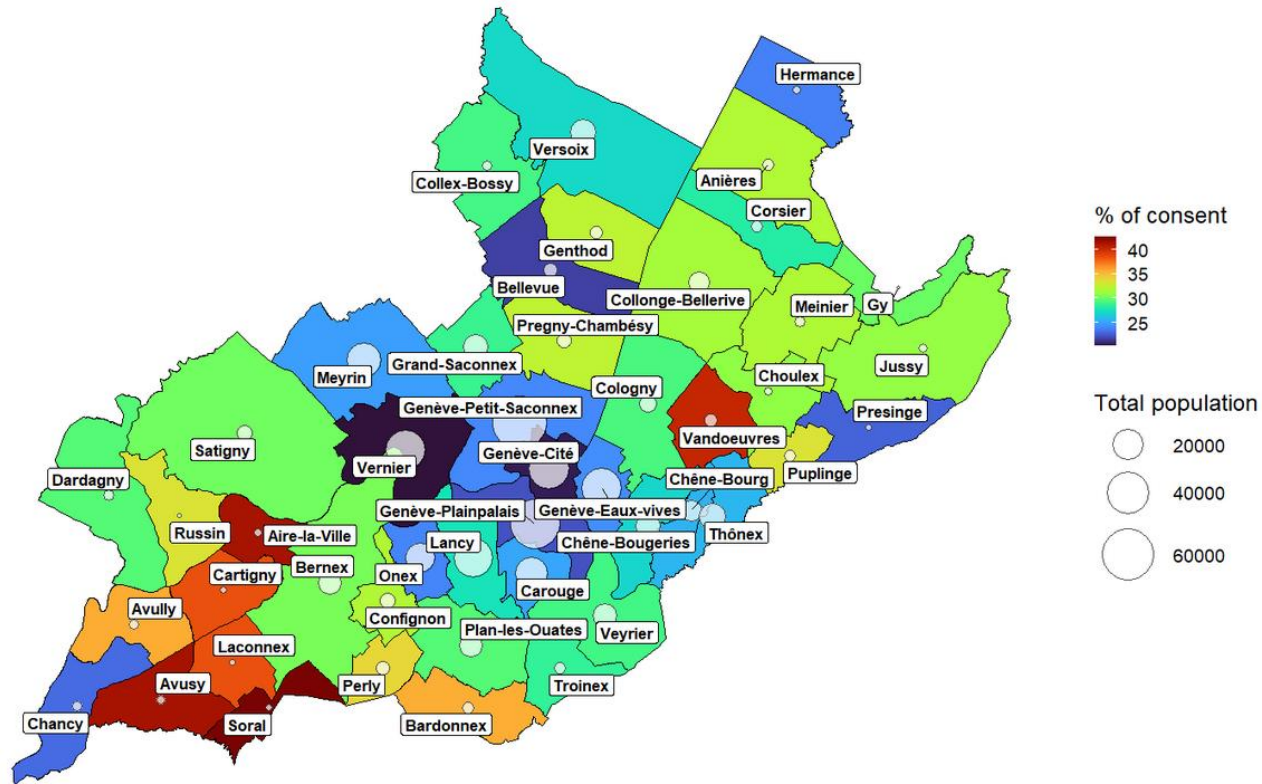
REPRESENT GE: Revenu du ménage

Table 1 Baseline characteristics of patients approached for general consent

Characteristic	Overall n = 38,975	Signatories n = 10,299	χ^2 /t-test p Value
Median household income of the commune of residence			
0-100 k CHF, n (%)	5283 (14.7)	23.5	> 200 k vs. 0-100 k: < 0.0001
100-200 k CHF, n (%)	28,605 (79.6)	26.1	
> 200 k CHF, n (%)	2034 (5.7)	31.6	

Bosmani et al. 2023

REPRESENT GE: Revenu du ménage



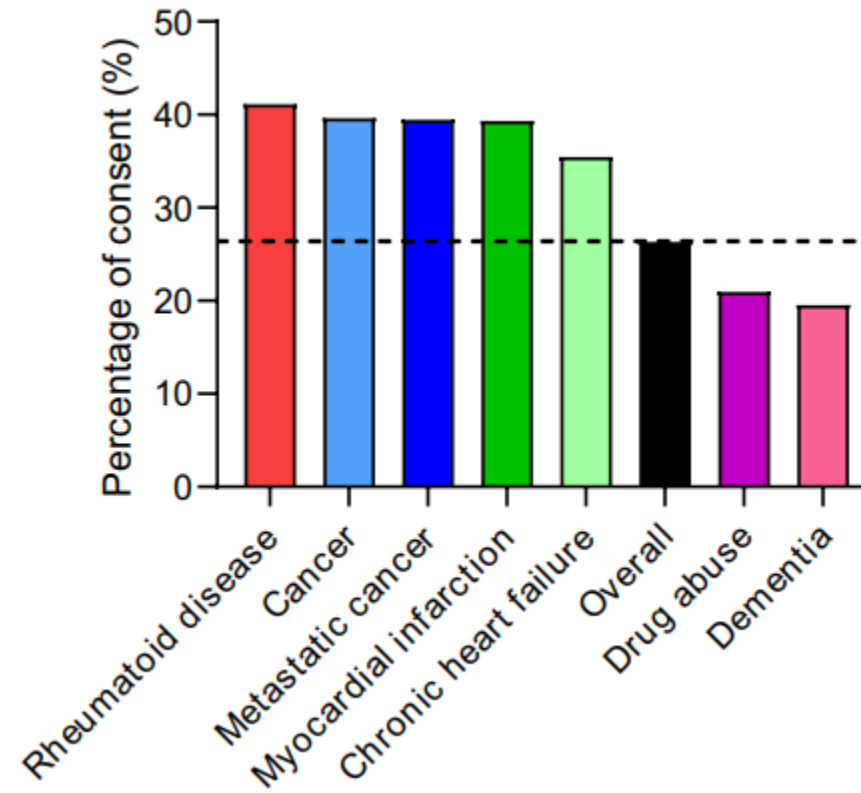
REPRESENT GE: Comorbidités

Table 2 Clinical characteristics

Characteristic	Overall	Signatories % or median (IQR)	χ^2 /t-Test p value
Number of hospital encounters per patient			
1–5, <i>n</i> (%)	20,945 (53.7)	24.7	1–5 vs > 10: < 0.0001
6–10, <i>n</i> (%)	10,429 (26.8)	27.7	
> 10, <i>n</i> (%)	7601 (19.5)	29.5	
Charlson comorbidity index			
Score 0, <i>n</i> (%)	30,969 (79.5)	24.2	Score 0 vs 1 – 4: < 0.0001
Score 1–4, <i>n</i> (%)	7526 (19.3)	34.7	
Score \geq 5, <i>n</i> (%)	480 (1.2)	36.7	
Elixhauser comorbidity index			
Score 0, <i>n</i> (%)	26,356 (67.6)	23.6	Score 0 vs 1 – 4 < 0.0001
Score 1–4, <i>n</i> (%)	9521 (24.4)	32.2	
Score \geq 5, <i>n</i> (%)	3098 (7.9)	33.2	

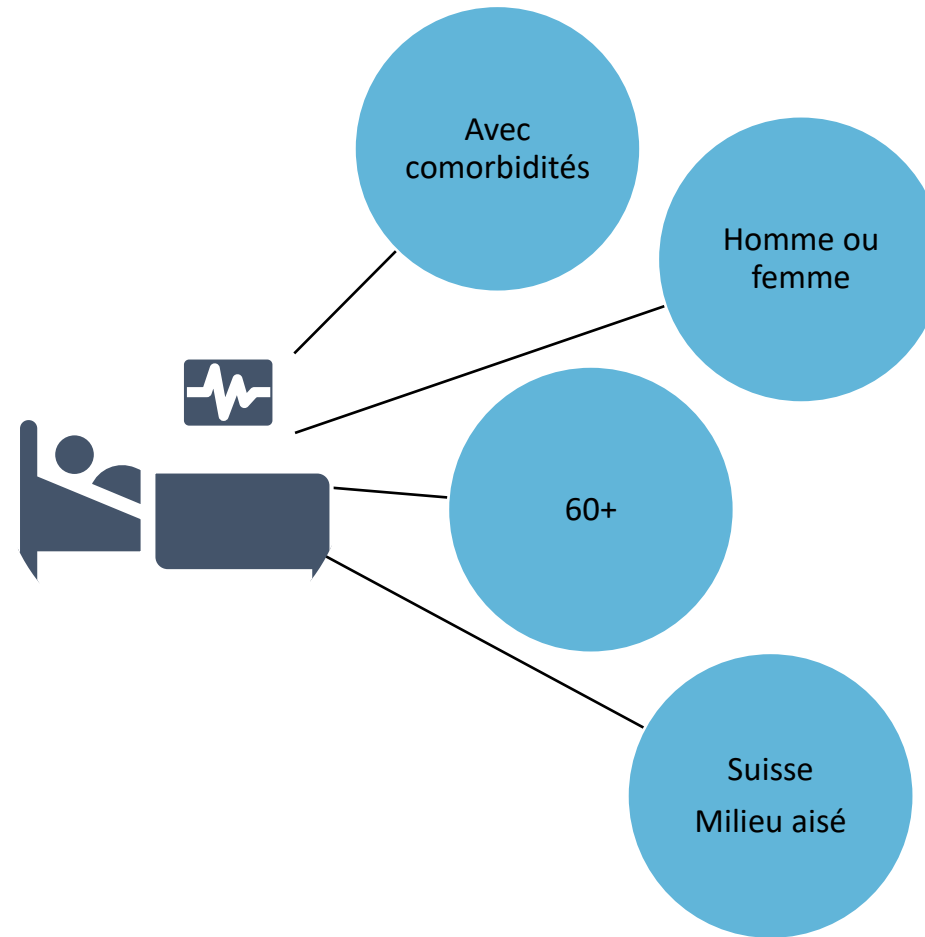
Bosmani et al. 2023

REPRESENT GE: Comorbidités



Bosmani et al. 2023

REPRESENT GE: Conclusions



Bosmani et al. 2023

REPRESENT GE: Conclusions

Limitations

- Accepteurs vs. non-répondeurs → Refuseurs?
- Consentement par poste → biais

REPRESENT GE: Conclusions

Limitations

- Accepteurs vs. non-répondeurs → Refuseurs?
- Consentement par poste → biais

Perspectives

REPRESENT: Switzerland

REPRESENT: Switzerland

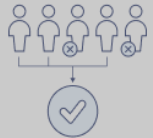
Types of selection bias

Bias due to factors related to the study's participants, such as the choice of population or sampling and recruitment methods.



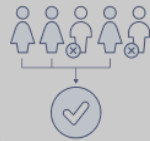
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Volunteer bias

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Undercoverage bias

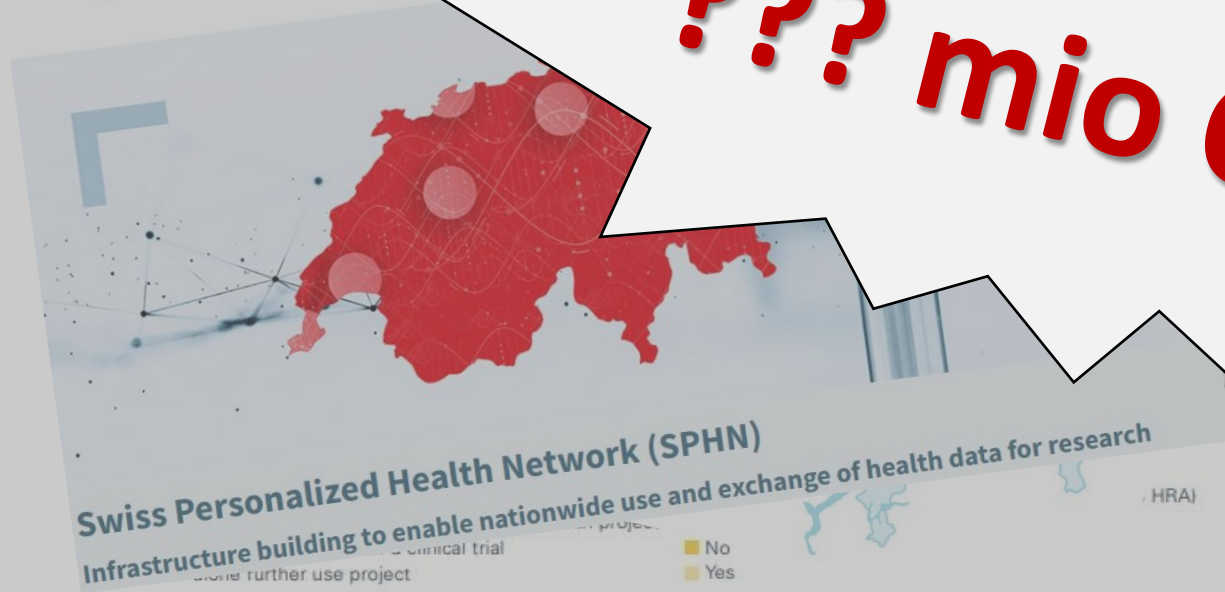
Some members of a population are inadequately represented in the sample



REPRESENT: Switzerland

Challenge

- Etudes rétrospectives
- Biobanques
- Régulations & «P...



REPRESENT Switzerland: Zurich

Swiss Medical Weekly

Formerly: Schweizerische Medizinische Wochenschrift

An open access, online journal • www.smw.ch

Original article | Published 14 April 2022 | doi:10.4414/SMW.2022.w30159

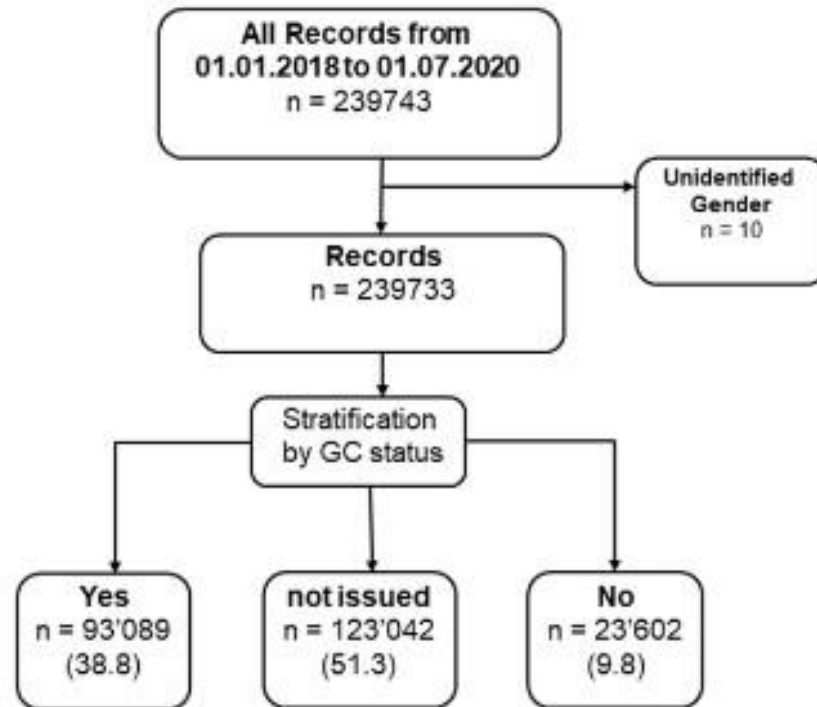
Cite this as: Swiss Med Wkly. 2022;152:w30159

The concept of General Consent in Switzerland and the implementation at the University Hospital Zurich, a cross-sectional study

Alexandra Griessbach^{abc*}, Annina Bauer^{ad*}, Francisca Jörger Lebet^a, Regina Grossmann^a

REPRESENT Switzerland: Zurich

Figure 1: General Consent data processing workflow.



Griessbach et al. 2022

REPRESENT Switzerland: Zurich

Table 1:

Multinomial logistic regression – General Consent status: consented vs. not issued.

Variable	OR	CI	p value
Age (in 10 year intervals)	1.07	1.06; 1.08	<0.001
Sex (female)	1.02	1.00; 1.04	0.018
Number of diagnoses	1.55	1.54; 1.57	<0.001
Visits	1.11	1.10; 1.11	<0.001

Reference group: "not issued"

CI = confidence interval; OR = odds ratio of positive General Consent choice (consented)

Table 2:

Multinomial logistic regression – General Consent status: declined vs. not issued.

Variable	OR	CI	p value
Age(in 10 year intervals)	1.01	1.00; 1.02	<0.001
Sex (female)	1.23	1.25; 1.33	<0.001
Number of diagnoses	1.52	1.51; 1.53	<0.001
Visits	1.10	1.09; 1.12	<0.001

Reference group: "not issued"

CI = confidence interval; OR = odds ratio of negative General Consent choice (declined)

Table 3:

Logistic regression – General Consent status: declined vs. consented.

Variable	OR	CI	p value
Age (in 10 year intervals)	1.05	1.0; 1.07	<0.001
Sex (female)	0.79	0.76; 0.81	<0.001
Number of diagnoses	1.02	1.02; 1.03	<0.001
Visits	1.00	1.00; 1.01	0.013

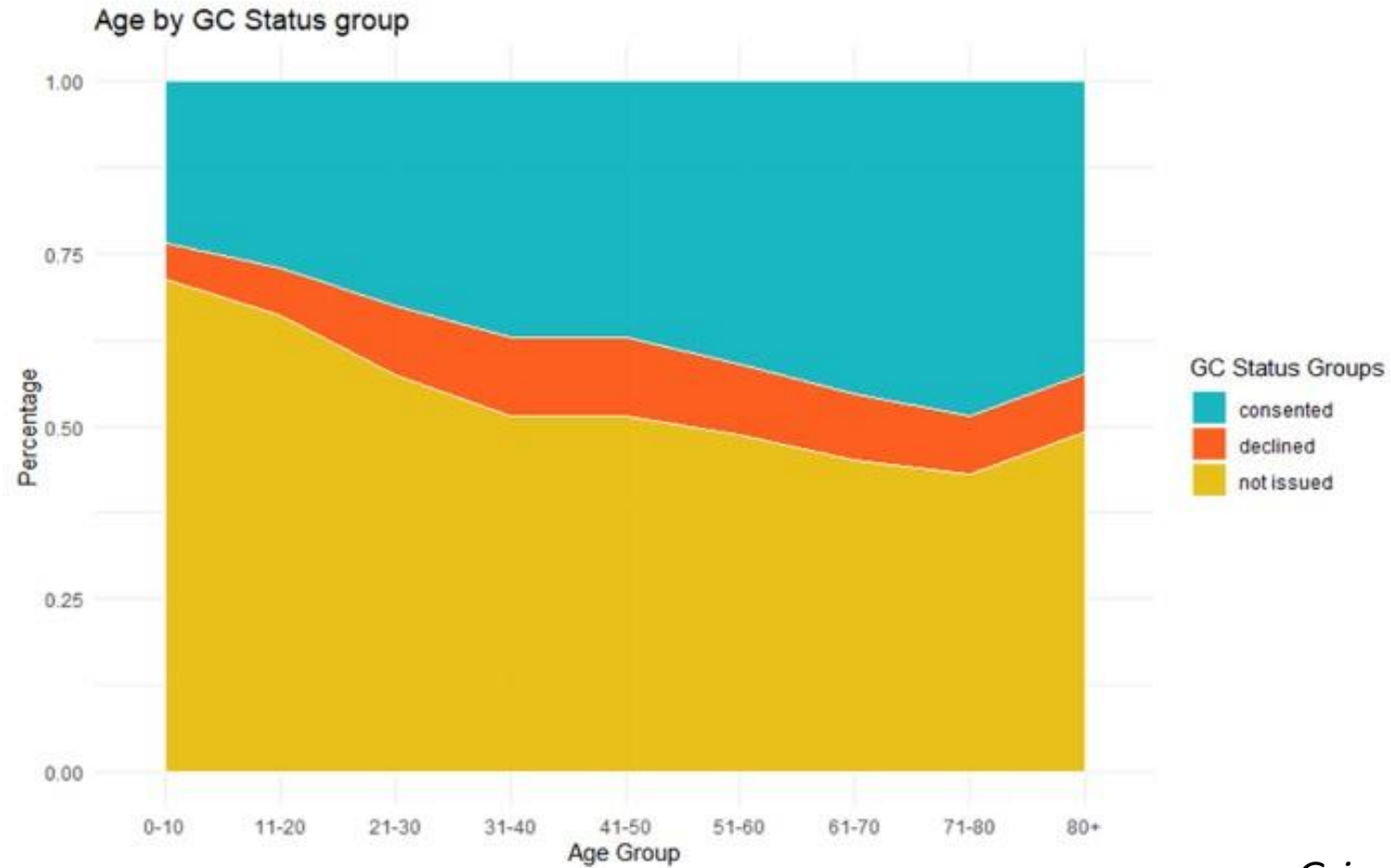
Reference group: "declined"

CI = confidence interval; OR = odds ratio of positive General Consent choice (consented)

Grissbach et al. 2022

REPRESENT Switzerland: Zurich

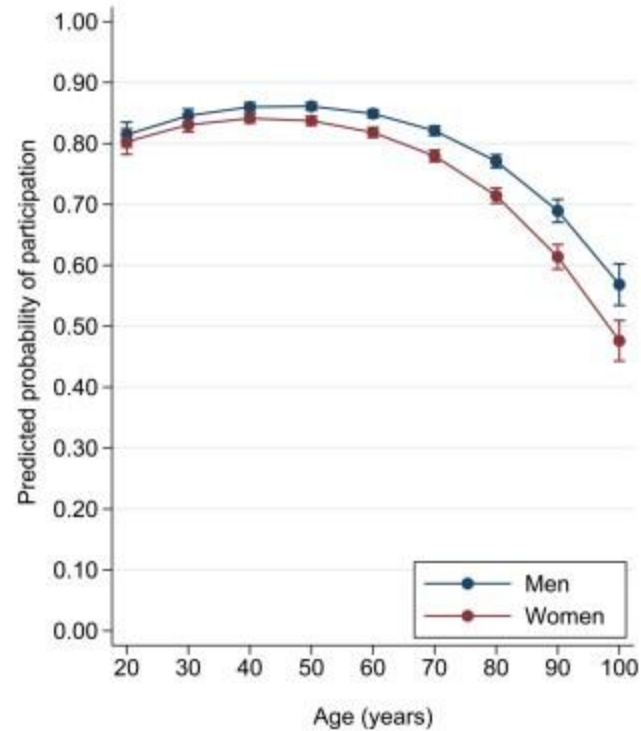
Figure 3: General Consent status distribution in age categories.



Griessbach et al. 2022

REPRESENT Switzerland: Lausanne

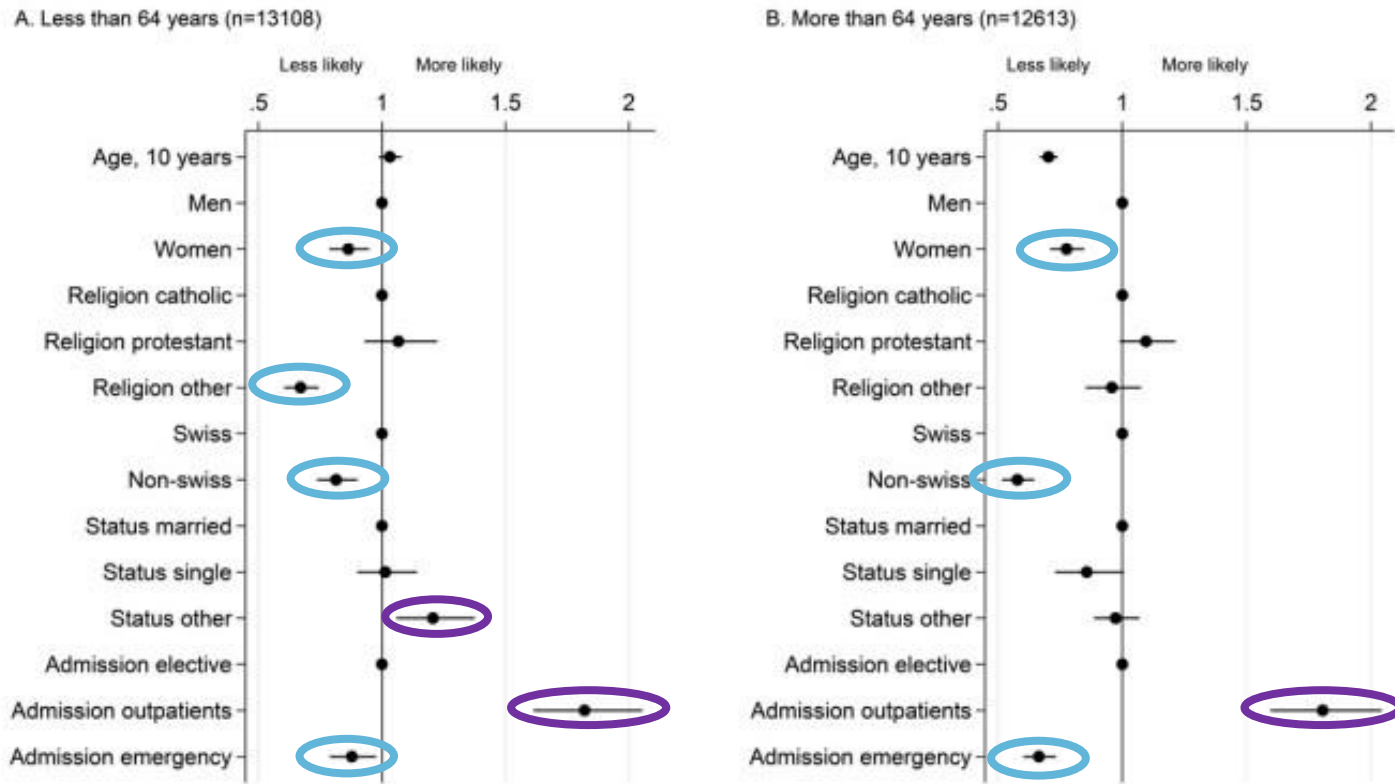
Figure 1: Predicted probability of participation by sex at specific age levels. Dots represent the predicted probability of participation by sex at specific age levels (20 years, 30 years, etc.) generated from a multiple logistic regression model in which the outcome was participation (code is 1 for a participant and 0 for a non-participant) and which included consent place, citizenship, religion and marital status as covariates. The whiskers represent 95% confidence intervals. The age-specific estimated probabilities of participation are depicted in blue for men and in red for women.



Bochud et al. 2017

REPRESENT Switzerland: Lausanne

Figure 2: Factors associated with willingness to participate among 25 721 patients. Dots represent odds ratios and bars 95% confidence intervals from a multivariable logistic model including willingness to participate as the dependent variable, run separately in the two age strata. The age cut off at 64 years was chosen as it is close to the median age and happens to closely match the retirement age in Switzerland. Patients aged <64 years are depicted in Panel A, and those aged 64 or older are shown in Panel B.

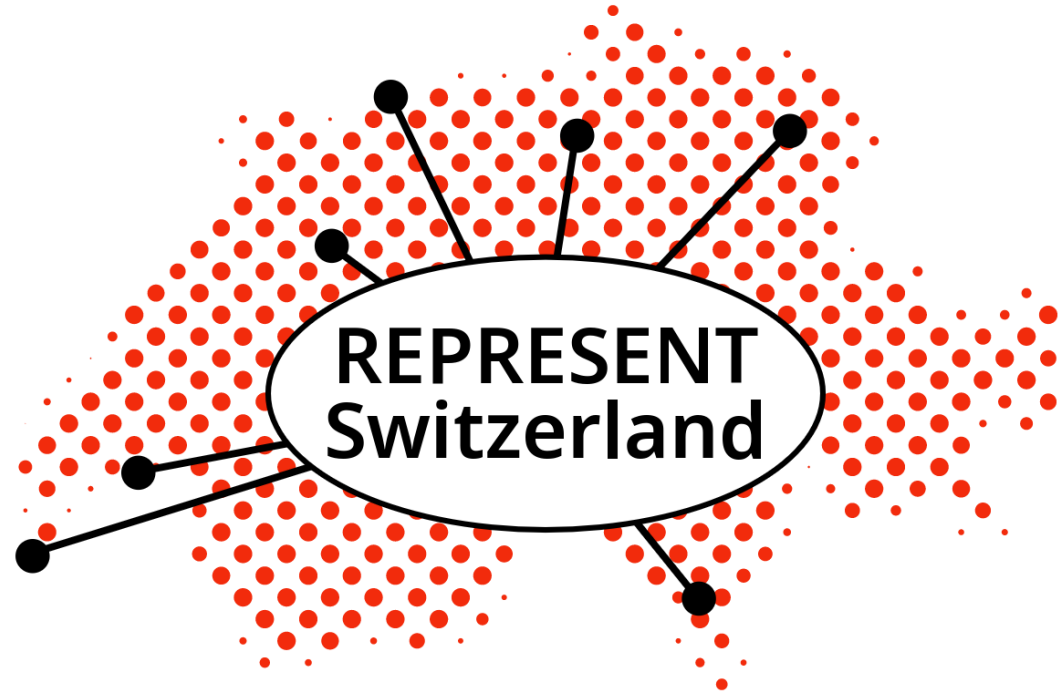


Taux d'accepteurs du CG: 79% (2017)

Taux de réponses au CG: 61% (non publié)

Bochud et al. 2017

REPRESENT: Switzerland

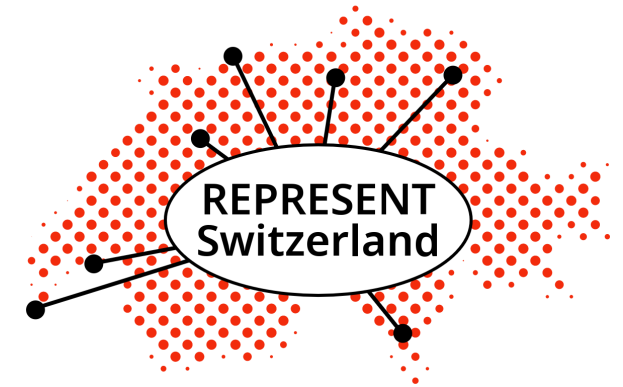


REPresentativeness of RESearch data obtained through the Swiss 'General Informed ConsENT'

REPRESENT Switzerland: consortium

Multicentrique

- Centre de Recherche Clinique - Genève
- Centre de Recherche Clinique - Lausanne
- Clinical Trials Center - Zürich
- Clinical Trials Unit - St.Gallen
- Clinical Trials Unit - Bern
- Departement Klinische Forschung Basel
- Clinical Trial Unit dell'Ente Ospedaliero
- Inselspital Universitätsspital Bern
- Universitäts-Kinderspital beider Basel
- Institute of Social and Preventive Medicine (ISPM)
- Swiss Personalized Health Network (SPHN)



REPRESENT Switzerland: nouveautés

Multicentrique

Consortium

Etude des refuseurs

Anonymisation

- dé-identification
- protection de ré-identification

REPRESENT Switzerland: anonymisation

LRH Art. 2 alinéa 2:

« Elle **ne s'applique pas** à la recherche pratiquée:

a. sur des embryons in vitro au sens de la loi fédérale du 19 décembre 2003 relative à la recherche sur les cellules souches embryonnaires;

b. sur du matériel biologique anonymisé;

c. sur des données liées à la santé qui ont été **collectées anonymement ou anonymisées.** »

REPRESENT Switzerland: anonymisation

LRH Art. 2 alinéa 2:

Elle **ne s'applique pas** à la recherche:

a. sur des embryons in vitro et sur les cellules souches embryonnaires; *décret fédéral du 19 décembre 2003*

b. sur du matériel biologique

c. sur des données liées à la recherche **collectées anonymement ou anonymisées.**



REPRESENT Switzerland: modalités de l'étude

Study design

Etude de cohorte rétrospective

REPRESENT Switzerland: modalités de l'étude

Study design

Etude de cohorte rétrospective

Study population & exposure

Tout patient ayant eu un contact avec un des hôpitaux en 2019 ou 2023, pas de critère d'exclusion.

- Non exposés au CG
- Non réponders au CG
- Accepteurs du CG
- Refuseurs du CG

REPRESENT Switzerland: modalités de l'étude

Study design

Etude de cohorte rétrospective

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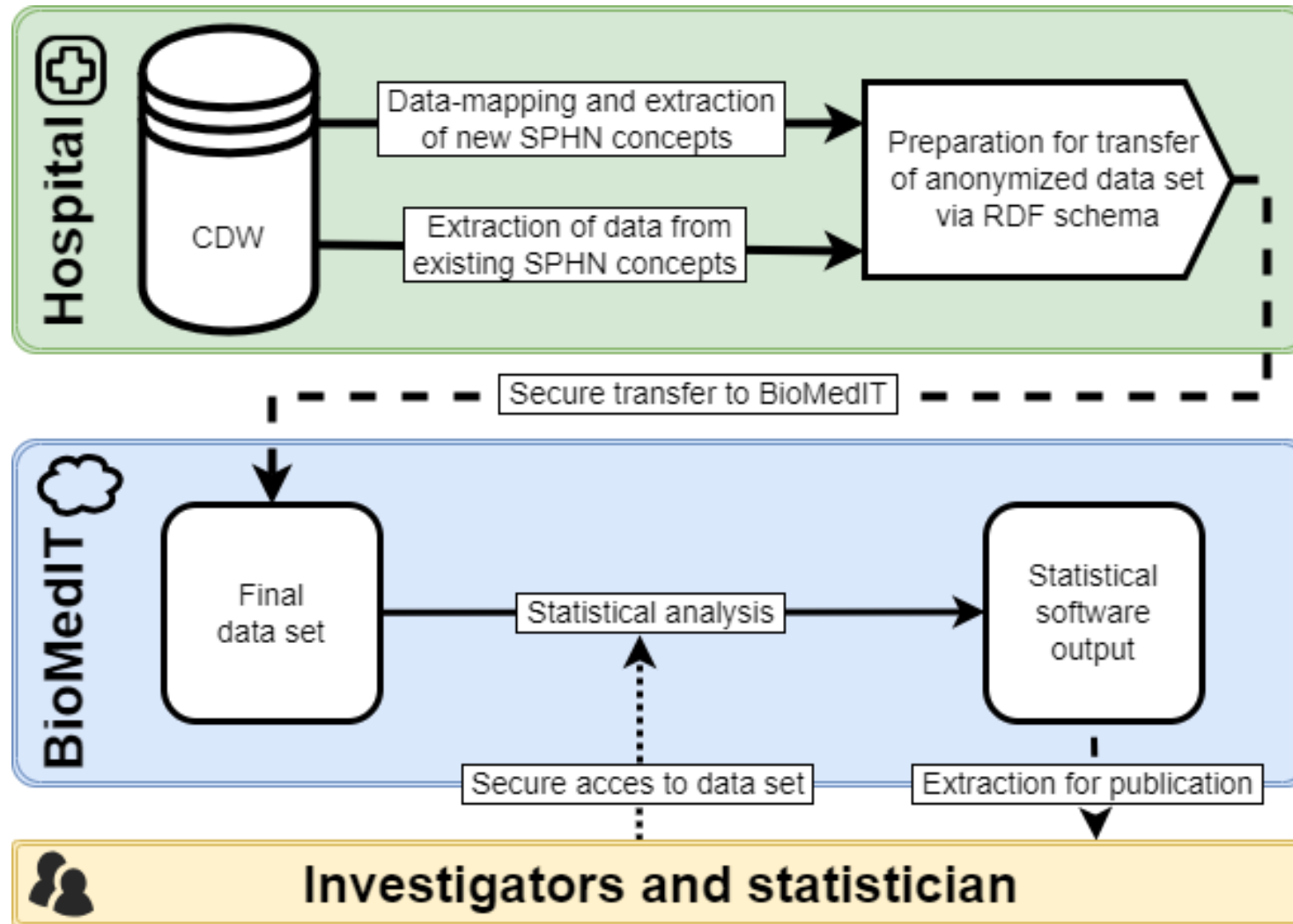
Objectif

Etablir et comparer les caractéristiques démographiques et cliniques des accepteurs, refuseurs, non-réponders et non-exposés au consentement général afin de déterminer la représentativité des accepteurs.

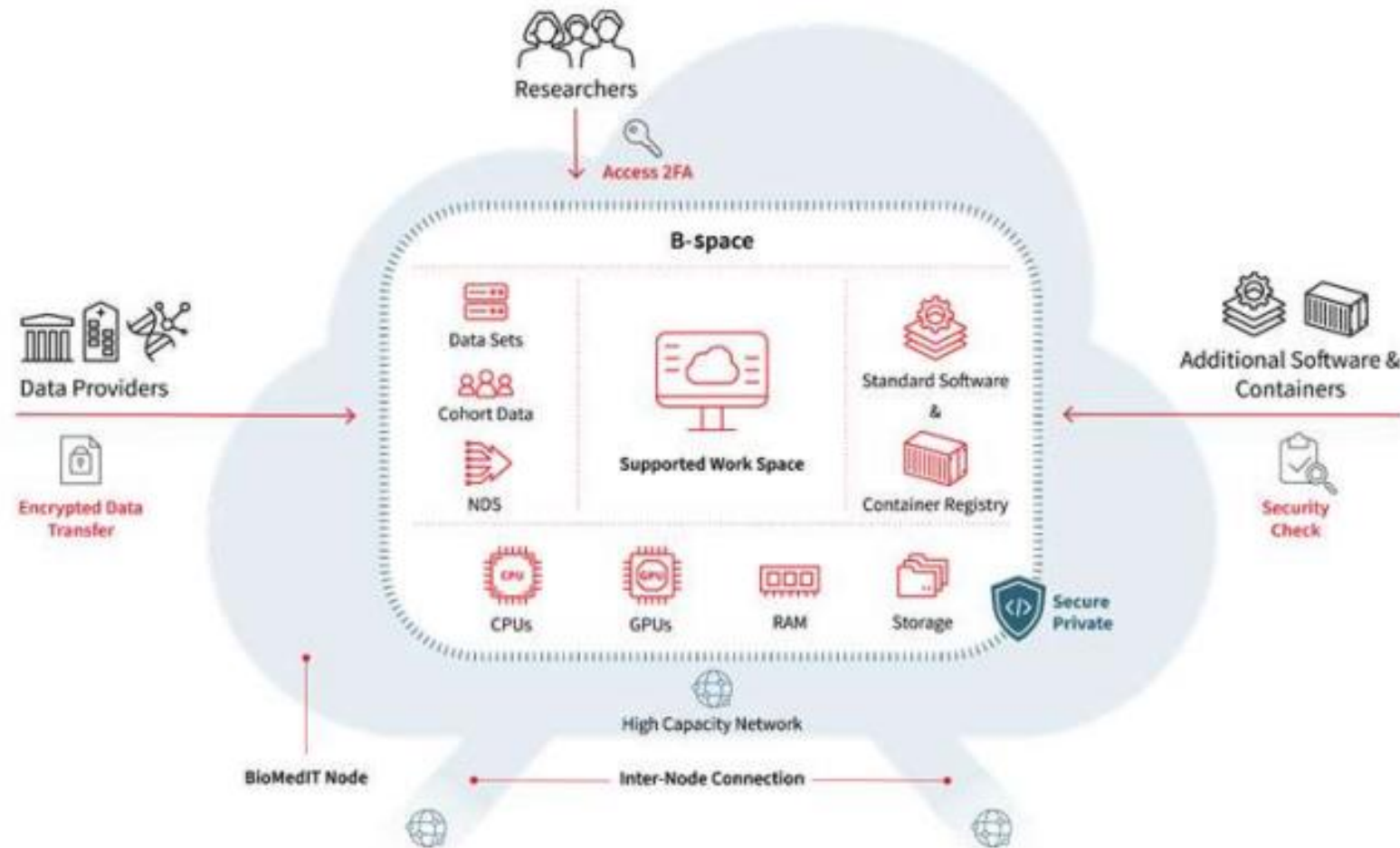
REPRESENT Switzerland: variables

Variables	Protection
GC status	n/a
Age	agrégation
Gender	n/a
Charlson score (from ICD-10 codes)	transformation et agrégation (score numérique)
Elixhauser score (from ICD-10 codes)	transformation et agrégation (score numérique)
Nationality	agrégation
Language	agrégation
Insurance status	n/a
Country of residence	agrégation
Hospital issuing GC	n/a
Mean imposable income (from ZIP code)	transformation et agrégation (score numérique)
Rural typology (from ZIP code)	transformation et agrégation (score numérique)

REPRESENT Switzerland: flux des données



REPRESENT Switzerland: flux des données



sphn.ch

Conclusion:

Le consentement général : une source de biais ?

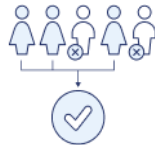
Types of selection bias

Bias due to factors related to the study's participants, such as the choice of population or sampling and recruitment methods.



Sampling bias

Occurs when some members of the intended population are less likely to be included than others



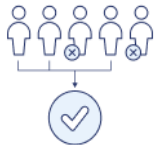
Attrition bias

Occurs when participants who drop out of a study systematically differ from the ones who remain.



Volunteer bias

People with specific characteristics are more likely to participate than others



Survivorship bias

Successful observations or people are more likely to be represented in the sample than unsuccessful ones



Non-response bias

People who refuse to participate or drop out systematically differ from those who take part.



Undercoverage bias

Some members of a population are inadequately represented in the sample



30-60% de répondeurs

Conclusion:

Le consentement général : une source de biais ?

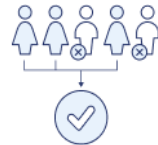
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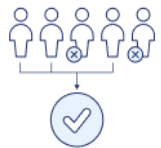
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20% refuseurs

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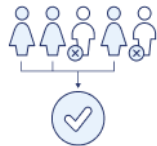
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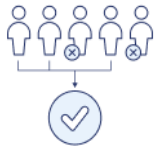
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âge, sexe, culture, nombre et type comorbidités ...

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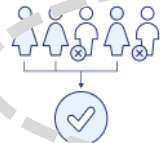
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Conclusion:

Le consentement général : une source de biais ?

Probablement:

- Plusieurs sources identifiées
- Plusieurs populations identifiées
- Différences démographiques et cliniques
- Résultats hétérogènes

→ Etude grande échelle nécessaire:

- Confirmation du biais, de ses sources et son étendue dans tous les centres utilisant le CG en 2023

→ Challenge:

- Multicentrique (!)
- Analyse des refuseurs: vraie anonymisation, choix de variables limités, structures de sécurité complexes, ...

Remerciements

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Dr. Reinhard Maier – KSSG

Dr. Katrin Cramerli - SPHN

Remerciements



Le consentement général : une source de biais ?

Discussion et questions