

En 2018, Quelle est la définition du concept de vulnérabilité dans la littérature médicale? Revue systématique

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Pour le

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Par

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In 2018, what is the definition of the concept of vulnerability for medical literature? A systematic review.

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Abbrevations

AIDS : Acquired Immune Deficiency Syndrome
COB : Centre Ouest Bretagne
ENT : Espace Numérique de Travail
GP: General Practitioner
RCT : Randomized Controlled Trial
HIV : Human Immonodeficiency Virus
ICCC: Innovative Care for Chronic Conditions
IMRAD: Introduction, Methods, Results and Discussion
LGBT : Lesbian, Gay, Bisexual and Transgender
PICO : Patient, Intervention, Comparison, Outcome
PRISMA: Preferred Reporting Items for Systematic reviews and Meta-Analyses
SPICES: Scaling up Packages of Interventions for Cardiovascular disease prevention in selected sites in Europe and sub-Saharan Africa

SSA: Sub-Saharan Africa

WONCA: World Organization of National Colleges Academies of General Practitioners

In 2018, what is the definition of the concept of vulnerability for medical literature? Systematic review.

Background: For the last ten years, "vulnerability" and "vulnerable populations" have been used in medical literature. SPICES (Scaling up Packages of Interventions for Cardiovascular disease prevention in selected sites in Europe and Sub-saharian africa) is an implementation study which will implement effective primary cardiovascular prevention interventions. It targets populations who are usually excluded from prevention. Those populations could fall within the definition of vulnerable populations.

Research question: What is the definition of vulnerability in the medical literature?

Methods: A systematic review was conducted on Cochrane, Medline, Pubmed and Google Scholar databases using the PRISMA methodology. Meta-analyzes, systematic reviews and randomized controlled trials were included if they followed the IMRAD format, were in English or French, addressed vulnerability or vulnerable populations and were published to January 2018. Definitions were compared and classified using the MesH terminology and a similarity software. A frequency of vulnerability factors among the definitions was calculated.

Results: Of the 588 eligible articles, 15 articles were initially included. Their bibliography was screened adding 13 articles. There was no consensual definition of vulnerability. The most frequent vulnerability factors were elderly (68%), race and ethnic minorities (64%), chronic conditions (64%), low income (57%), limited access to care and services (50%). Three studies used the EquiFrame framework, which promoted inclusion of vulnerable groups for health policies. Aday's definition referred to vulnerable subpopulations.

Discussion: The term of "vulnerable populations" did not fit to SPICES project. Aday's definition seemed the most appropriate for medical research. A consensual definition of vulnerability would be needed.

En 2018, Quelle est la définition du concept de vulnérabilité dans la littérature médicale ? Revue systématique.

Introduction : Depuis une dizaine d'année, les notions de « vulnérabilité » et de « populations vulnérables » ont été utilisées dans la littérature scientifique. Le projet SPICES est une étude d'implémentation visant à mettre en œuvre des interventions efficaces en prévention cardiovasculaire primaire. Elle cible les populations habituellement exclues des actions de prévention cardiovasculaire. Ces populations pourraient entrer dans la définition des populations vulnérables.

Question de recherche : Quelle est la définition du concept de vulnérabilité dans la littérature médicale ?

Matériel et Méthode : Une revue de littérature a été effectuée sur les bases de données Cochrane, Pubmed et Google Scholar selon la méthode PRISMA. Des méta-analyses, revues systématiques et essais contrôlés randomisés ont été inclus s'ils suivaient le format IMRAD, étaient rédigées en anglais ou en français, abordaient la vulnérabilité ou les populations vulnérables, et s'ils étaient publiés avant janvier 2018. Les définitions ont été classées selon la terminologie MeSH et comparées avec un logiciel de similarité. Une fréquence des différents facteurs de vulnérabilité parmi les définitions a été calculée.

Résultats : Parmi les 588 articles éligibles, 15 articles ont été initialement inclus. 13 articles supplémentaires ont été inclus après une rétrobibliographie. Il n'existait pas de définition consensuelle de la vulnérabilité. Les facteurs de vulnérabilité les plus cités étaient : les personnes âgées (68%), les minorités raciales et ethniques (64%), les maladies chroniques (64%), le faible revenu (57%), l'accès limité aux soins et services (50%). Trois études ont utilisé le cadre EquiFrame, facilitant l'inclusion des groupes vulnérables dans les politiques de santé. La définition d'Aday désignait les sous-populations vulnérables.

Discussion : Le terme de « populations vulnérables » n'étaient pas adaptées au projet SPICES. La définition d'Aday semblait la plus appropriée pour la recherche médicale. Une définition consensuelle de la vulnérabilité serait nécessaire.

1 Introduction

For a decade, the concept of vulnerability has been used in the scientific literature (1). The etymology of vulnerability derives from the latin word "*Vulnerare*" which means "*to hurt*".

Historically, the concept of vulnerability appeared for the first time in the Nuremberg Code in 1947. Medical research established the first ethical principles to protect individuals (2). In 1979, the Belmont Report raised for the first time the notion of vulnerable subjects from a research perspective (3).

Currently, the concept of vulnerability extends through several fields, such as sociology, anthropology, environmental sciences and health (4). In the Medline database, "vulnerable populations" are a MesH term and are defined as "a group of people whose range of options is severely limited, who are frequently coerced in their decision making, or whose decision may be compromised in their ability to give informed consent".

Many authors such as Aday, Luna, Hurst, Shi and Kipnis have explored the concept of vulnerability leading to different conclusions and propositions.

For Aday (5), vulnerability implied that everyone was potentially vulnerable or at risk. Her definition facilitated the identification of vulnerable populations, which presented a risk of poor physical, psychological and / or social health. This notion of risk factors was shared by several authors such as Shi (6), for whom vulnerability was an accumulation of individual and community risk factors.

On the other hand, Luna and VanderPoel explored vulnerability in identifiable subpopulations to conclude that vulnerability depended on the context (7). This was consistent with Kipnis's definition(2). Kipnis considered that vulnerability could be both a physical or psychic condition or depend on a situation. For that purpose, he proposed a taxonomic classification of vulnerability.

These different propositions seemed conflicting and did not allow to easily identify vulnerable populations for medical research. (8).

This research work is part of the SPICES project (Scaling up Packages of Interventions for Cardiovascular disease prevention in selected sites in Europe

and sub-Saharan Africa). SPICES is a five-year international research program funded by the European Union, including France (University of Brest), United Kingdom (University of Manchester and Nottingham Trent), Belgium (University of Antwerp), Uganda (Makerere University) and South Africa (Limpopo University). SPICES is inspired by the progress in addressing HIV / AIDS in sub-Saharan Africa (SSA) and in chronic disease management through the WHO Innovative Care for Chronic Conditions (ICCC Framework) plan. Its aim is to implement interventions for European and Sub-Saharan people who experienced difficulties with primary cardiovascular prevention and people who were not reached by current programs of cardiovascular primary prevention (See Appendix 3: SPICES Project: Situational Analysis Work Package.). In France, the study will be conducted in Central West Brittany (COB). This territory has a low medical demography with 8.5 general practitioners per 10,000 inhabitants with 10.4 for the national average. It is also a low-income area with a high prevalence of CVD(9). Its population seemed to be a potential target of this project. The research team questioned whether the term vulnerable populations, used in medical research, could encompass those populations that are difficult to reach through primary cardiovascular prevention.

The research question was: In 2018, what is the definition of the concept of vulnerability for medical literature?

2 <u>Method</u>

2.1 Research question following the PICO Model:

The PICO model (P: population, I: intervention, C: comparison, O: Outcomes) was used to define the search question of the review (10):

- P: Studies experimenting on vulnerable populations
- I: Literature review
- C: None
- O: Definition of vulnerability and factors of vulnerability.
- Research question: In 2018, what is the definition of the concept of vulnerability in the medical literature?

2.2 Protocol and registration

No literature review protocol was completed for this study.

All bibliographic references and search equations are available in the <u>Appendix</u> $\underline{4}$.

2.3 Eligibility Criteria

To be included, articles should respect the following criteria:

- Population: focus on human populations.
- Type of studies: meta-analyzes, systematic reviews, randomized controlled trials.
- Topic: the concept of vulnerability and vulnerable populations.
- Structure: IMRAD structure.
- Language: articles in English and French.
- Date of publication: Origins of the databases to January 2018.

2.4 Information sources

A systematic review of the scientific literature was conducted on MEDLINE databases, Pubmed, the Cochrane library, Google Scholar according to the Preferred Reporting Items for Systematic reviews and Meta-analyses (Prisma) methodology (11). One researcher drived the literature review with the help of a research group composed of 3 senior researchers.

	Pubmed	Cochrane	Google Scholar
	(vulnerable populations [MeSH Terms]) AND ((definition) OR concept)	Vulnerable populations	Vulnerability definition
Included			Vulnerability concept
			Vulnerable populations concept
			Vulnerable population definition
	(vulnerable populations [MeSH Terms])	Vulnerability	Vulnerability meaning
	(vulnerable populations [MeSH Terms]) AND (((definition) OR meaning) OR concept)	Vulnerability concept	Vulnerable population meaning
	(vulnerable populations [MeSH Terms]) AND ((definition) OR concept)	Vulnerability meaning	
	(vulnerable populations [MeSH Terms]) AND ((definition) OR meaning)	Vulnerability definition	
	(vulnerability)	Vulnerable population definition	
	(vulnerability) AND (definition)	Vulnerable population meaning	
	(vulnerability) AND (((definition) OR meaning) OR concept)	Vulnerable population concept	
	(vulnerability) AND (((definition) OR meaning) OR concept)	Sensitive population	
Excluded	(underserved populations) AND definition	Frailty population	
	(underserved populations) AND (definition) OR meaning)	Underserved populations	
	(underserved populations) AND (((definition) OR concept) OR meaning)		
	(frailty population)		
	(frailty population) AND definition		
	(frailty population) AND (((definition) OR meaning) OR concept)		
	(sensitive population) AND (definition)		
	(sensitive population) AND (((definition) OR		

2.5 Search Strategy with research equations

(sensitive population) AND (((definition) OR meaning) OR concept)

2.6 Study selection

The selection of articles was organized in 4 phases: identification, screening, eligibility and inclusion.

During the screening phase, articles were selected after reading their title and abstract. 15 articles were selected.

During the eligibility phase, an evaluation of the bibliographic references of the 15 articles selected previously was carried out. The bibliographic references were selected on their titles and their summary, according to the same criteria of inclusion and exclusion. A full reading was subsequently performed for the 28 articles included in the literature review.

Studies were excluded according to the following criteria:

- Population: focus on specific populations (as AIDS populations, geriatric populations, pediatric populations).
- Type of studies: no meta-analyzes, no systematic reviews, no randomized controlled trials.
- Topic: Not addressing the concept of vulnerability or vulnerable populations.
- Structure: no fulfilment of the IMRAD structure.
- Language: no English or French.
- Unavailable on the ENT of the Brest faculty of Medicine, of the UBODOC website.
- Outcomes: No definition of vulnerable populations or vulnerability.

2.7 Summary measures

To summarize results of the study, a classification of the sub-topics following MesH terms was conducted and similarity around the definitions was calculated. The similarity software Outils-seo was used. This software is available on:

http://outils-seo.alwaysdata.net/outils-contenu-editorial/calcul-similaritecontenu/ Similarity rate was calculated using the following formula:

(number of words in the "tested definition" found in the "28 proposed definitions" divided by the total number of words "of the 28 proposed definitions" corresponding to the percentage of similarity.)

The similarity threshold set by the software was 70%. Above this rate, the content could be considered as similar. The similarity software used the Jaccard index to estimate the similarity.

(See Appendix 1: Calculation method similarity rate)

MesH terminology was used to classify every single factor of vulnerabilities found in the individual studies:

- MesH socio-economic factors were "Social and economic factors that characterize the individual or group within the social structure". They included family characteristics, social class, social conditions, employment, educational level, poverty, occupation, income, social conditions.
- MesH demographic factors were "Statistical interpretation and description of a population with reference to distribution, composition, or structure". They included age, family characteristics, health status, dynamic distribution, sex distribution.
- MesH poor medical access or healthcare disparities were "Differences in access to or availability of medical facilities and services".
- MesH disease or illness were "A definite pathologic process with a characteristic set of signs and symptoms. It might affect the whole body or any of its parts, and its etiology, pathology, and prognosis might be known or unknown".

After reading and analyzing the included articles, biases were systematically evaluated. A first evaluation of biases was made by identifying self-reported biases. In a second phase, a search on biases on a full text reading of the article was conducted. Biases were defined as in the reference *« Identifying and Avoiding Bias in Research »* (12): selection biases (including recruitment bias, sampling bias, volunteering bias, admission bias, transfer bias, attrition bias), information biases (including monitoring bias, subjectivity bias, nonresponse bias, recall bias), as ranking biases and confusion biases. (12)

3 <u>Results</u>

3.1 Study selection

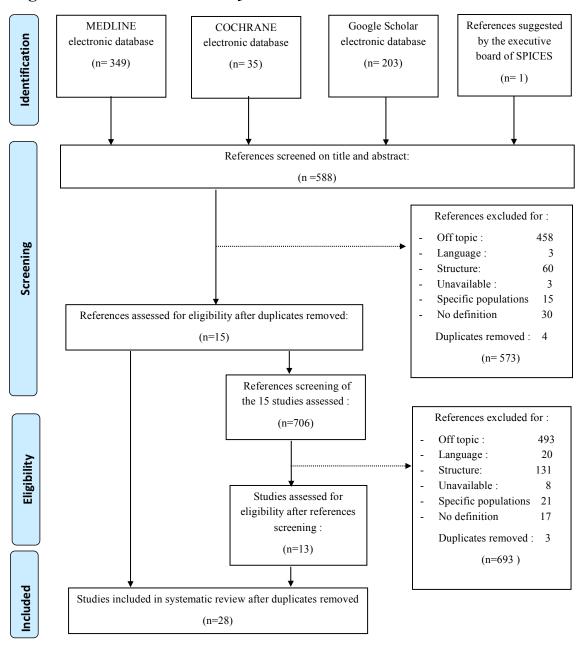


Figure 1: Flow chart of the systematic review

During the identification phase, 588 articles from Pubmed, Cochrane and Google scholar databases were identified. An article was added, suggested by the executive board of the SPICES research group.

Of the 588 articles, 576 articles were excluded because of exclusion criteria: offtopic (n = 458), language (n = 3), no IMRAD (n = 60), unavailability (n = 3), specific populations (n = 15), lack of definition (n = 30). 4 duplicates were excluded. 15 articles were selected.

706 bibliographic references were evaluated on their title and abstract. 693 articles were excluded because of exclusion criteria: off-topic (n = 493), language (n = 20), no IMRAD (n = 131), unavailability (n = 8), specific population (n = 21), without definition (n = 17). A total of 28 studies were finally included in the systematic review.

3.2 Study characteristics

Study characterictics	Papers included
Туре	
Reviews	19
RCT	9
Language	
English	28
Paper origin	
United States	9
Switzerland	2
Canada	5
UK	5
South Korea	1
South Africa	2
Namibia	1
China	1
Brazil	2
Year of publication	
< 2000	0
2000 - 2009	8
2010 - 2015	15
2016-2018	5

Table 1: Details of publications included in the review

3.3 Data extraction

	Study title	Vulnerability concepts	Vul	nerability factors	Rationale of choice
			Demographic	Children The elderly	
			Economic	Low income individuals	
			Social	Ethnic minority	
	Are Sexual and	Populations with a		People with HIV	
	Reproductive	higher risk of poor	Illness	People with disabilities	
1	Health Policies	health outcomes and		Migrants, asylum seekers and	Consensus after
	Designed for	healthcare	Poor medical access	refugees	review
	All? (13)	discrepancies in		Rural populations	
	~ /	access to healthcare		Sex workers	
			Sexually	LGBT	
			transmitted diseases	Victims of sexual abuse, gender	
			exposed	violence, and human trafficking	
			Demographic	The elderly	
	Community			Homeless	
	Based		Social	Veterans	
	Cardiovascular	Multidimensional		Uninsured	
	Health	construct, resulting	Economic	Low income	
2	Interventions in	from numerous		People living with disabilities	Consensus after
-	Vulnerable	individuals as well	Illness	Chronic disease	review
	Populations: A	as community level	Cultural	Racial and ethnic minorities	
	Systematic Review (14)	factors.	Poor medical access	Rural population	
				Limitation of primary care	-
				service	
	Contributions of	oncept of erability to fessionalindividuals or communities become more susceptible to	Demographic	Children	
	the concept of vulnerability to professional nursing practice: integrated review			The elderly	
				Women	
3				People living with HIV	Consensus after
5			Illness	Tuberculosis	review
				Chronic diseases	
			Poor medical access	Victims of violence	
	()		Demographic	Children	
			Demographie	Homeless	
				Incarcerated people	
			Socio economic	Unemployed	
				Low income	
				People with disabilities	
	How ethical is			Decisional impairment	
	ethical research?	Impairment of the	Illness	Mental health disease	
	Recruiting	person's capacity to	1111035	Substance abuse	
4	marginalized,	exercise autonomy		Chronic disease	Consensus
	vulnerable	and true ability to		Limitation of primary care	Consensus
	groups into	protect their own	Poor medical access	service	
	health services research (16)	interests.	Sexually		
			transmitted diseases	Sex workers	
			Institutionalization	Emergency situation	

Table 2: Vulnerability concepts and factors identified in the systematic review

			Demographic	Children	
	Identifying the			The elderly	
	'Vulnerables' in	When some or all of	Gender	Pregnant women	
	Biomedical	the subjects are	Socio economic	Low education level	
	Research: the	likely to be		Low income	
5	vox populis from	vulnerable to		People with disabilities	Choice of the author
		coercion or undue	Illness	Mental health disease	
	the Tuskegee	influence	mness	People with HIV	
	Legacy Project	influence		Chronic disease	
	(17)			Refugees and immigrants	
			Cultural	Racial and ethnic minorities	
				Children	
			Demographic	The elderly	
				Homeless	
				Incarcerated people	
				Widowed status	
			Socio economic	Unemployment	
				Uninsured	
	Mapping the			Low education level	
	concept of	Potential risk of		Low income	
	vulnerability	developing certain			C
6	related to health	diseases or suffering		People with disabilities	Consensus after
	care disparities: a	from environmental	T11	Mental health disease	review
	scoping review	hazards.	Illness	Cognitive impairment	
	(4)			People living with HIV	
				Chronic disease	
			D 1 1	Racial and ethnic minorities	
			Poor medical access	Refugees and immigrants	
				Rural population	
			Limitation of primary care service	Underserved people.	
			Institutionalization	Emergency situation	
			D 1.	Neonates / Children	
			Demographic	The elderly	
	New			Homeless	
	perspectives on	Use to identify	Socio economic	Incarcerated people	
	vulnerability	individuals and		Economically disavantaged	
7	using emic and	groups at risk of		Mental health disease	Choice of the author
	etic approaches	harm	Illness	People with disabilities	
	(18)	IIaIIII		Chronic disease	
	(10)		Poor medical access	Racial and ethnic minorities	
			1 001 medical access	Refugees and immigrants	
			Domographia	Children with special health care needs	
			Demographic	The elderly	
	Organizational		<u> </u>		
	interventions		Socio commin	Incarcerated people Uninsured	
	improving		Socio economic		
8	access to	Concern patients		Low income	
	community-	with chronic		People with disabilities	C.
	based primary	conditions and		Congenital conditions	Consensus
-	health care for	socioeconomically	Illness	Mental disease	after review
	vulnerable	disadvantaged		People living with HIV	
	populations: a	people		Substance abuse	
	scoping review			Chronic disease	
	(19)		Poor medical access	Racial and ethnic minorities	
				Refugees and immigrants	
			Limitation of	Underserved people.	
			primary care service	1 1	

9 Prevalence of instability sind population (20) Included those who have less access to have have a decreased risk of hams, because they have a decreased risk of have a decreased risk of have a decreased to have access to have a decreased				Socio economic	Low income	
9 inductor inductor with access in the inductor induct		Prevalence of				
9 Synthwise and inferences and set of the sources in needed to handle primary care service independences in the sources independence in the source in the						
10 risk level in a population (20) needed to handle risks to health Limitation of primary care service Underserved people. 11 Reconsidering vulnerability in population (20) Increased risk of harms, because they have a decrussor. A critical poposal for this expanding health Increased risk of harms, because they have a decrussor. A critical proposal for the expanding health proposal for the proposal for the expanding health Increased risk of harms, because they have a decrussor. A critical proposal for the expanding health Neonates / children Consensus after review 11 Increased risk of harms, because they proposal for the concerpt (21) Increased risk of harms, because they have a decrussor. Safeguard their own interests Increased Poor medical access Consensent Mental health disease (Consensus after review 11 Strategies for expanding health populations (22) Poor medical access Consensus after review 11 Strategies for expanding health populations (22) Poor medical access Institutionalization free primary care service Institutionalized people Subordinate members of hierarchies 11 Strategies for expanding health populations (22) People most in need of protection Demographic Increased risk of hear and the resulting dovid concomic Informal sector workers 112 Vulnerability in the perioperative patient: a concerpt analysis (23) Increased risk of harm and the resulting dovid population Informal sector workers 112 Vulnerability in the periopera				Poor medical access	Racial and ethnic minorities	
10 Reconsidering values bijs and proposal for the case of the authors of this concept (21) Increased risk of harms, because they are a decreased equacity, for whatever reason, to softguard their own interests Increased risk of harms, because they are a decreased equacity, for whatever reason, to softguard their own interests Increased risk of harms, because they are a decreased equacity, for whatever reason, to softguard their own interests Increased risk of harms, because they are a decreased equacity, for whatever reason, to softguard their own interests Increased risk of harms, because they are a decreased equacity, for whatever reason, to softguard their own interests Interest decreased reason to softguard their own interests Chronic disease Consensus after review 11 Strategies for coverage in vulnerable populations (22) People most in need of primary care service Institutionalized people Institutionalized people Chronic diseases 11 Strategies for coverage in vulnerable populations (22) People most in need of protection Demographic Institutionalized people Chronic diseases Chronic diseases 12 Vulnerability in the perioperative potentiation (23) Increased risk of harm and the resulting development of potential and a cruat problemities Demographic The elderly Choice of the authors 12 Vulnerability in the perioperative potential and cruat problemities Increased risk of harm and the resulting development of potential and acruat problemities	9	risk level in a vulnerable	needed to handle		Underserved people.	Choice of the author
10 Reconsidering values bijs and proposal for the case of the authors of this concept (21) Increased risk of harms, because they are a decreased equacity, for whatever reason, to softguard their own interests Increased risk of harms, because they are a decreased equacity, for whatever reason, to softguard their own interests Increased risk of harms, because they are a decreased equacity, for whatever reason, to softguard their own interests Increased risk of harms, because they are a decreased equacity, for whatever reason, to softguard their own interests Increased risk of harms, because they are a decreased equacity, for whatever reason, to softguard their own interests Interest decreased reason to softguard their own interests Chronic disease Consensus after review 11 Strategies for coverage in vulnerable populations (22) People most in need of primary care service Institutionalized people Institutionalized people Chronic diseases 11 Strategies for coverage in vulnerable populations (22) People most in need of protection Demographic Institutionalized people Chronic diseases Chronic diseases 12 Vulnerability in the perioperative potentiation (23) Increased risk of harm and the resulting development of potential and a cruat problemities Demographic The elderly Choice of the authors 12 Vulnerability in the perioperative potential and cruat problemities Increased risk of harm and the resulting development of potential and acruat problemities					Neonates / children	
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				women	
				Women	
				Homeless	
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			Socio economic	Economically disadvantaged	
				people	
				Low education level	
				People with disabilities	
				Adult with learning	
	The concept of			difficulties	
	'vulnerability' in	An increased		Patients in terminal care	
13	research ethics:	likelihood of being	T11		Consensus after
	an in-depth	wronged or of	Illness	Mental health disease	review
	analysis of	incurring harm		Incapacity for self determination	
	policies and	<i>8 8 8</i>		Limited capacity to consent	
	guidelines (3)			Very sick people	
	8			Chronic disease	
				Racial and ethnic minorities	
				Nomads	
			Poor medical access	Refugees and immigrants	
				Rural population / underserved	
				area	
			limitation of	Limitation of primary care	
			primary care service	service	
			<u> </u>	Institutionalized	
				Subordinate members of	
			Institutionalization	hierarchies	
				Emergency settings	
			Demographic	The elderly	
			Demographic	Social exclusion	
	Vulnerability as				
	a heuristic	~	Socio economic	Precarious people	
	concept for	Shapes the		Divorce	Consensus after
14	interdisciplinary	probability of an		Unemployed	review
	research: a	event or hazard	Illness	Depression	
	scoping			Refugees and immigrants	
	review (1)		Poor medical access	Limitation of primary care	
				service	
			Socio economic	Economically disadvantaged	
	Vulnerability in	Referring to		people	
	palliative care	individuals with		~	
15	research:	limited cognitive	Medical	Patients in terminal care	Choice of the authors
15	findings from a	abilities or		Cancer	Choice of the authors
	qualitative study	diminished	Institutional	Under authority	
	(24)	autonomy	Communicative	Lack capacity to communicate	
		-	Deferencial	Subject to the informal	
			Deterencial	authority	
	Accessing			The elderly	
	vulnerable		Age	Children	
	research	Who is or may be		People with disabilities	
	populations: an	unable to protect		Terminal care	
16	experience with	him or herself		Mental disease	Choice of the authors
	gatekeepers	against significant	Illness	Decisional impairment	
	of ethical	harm or exploitation	1111055		
	approval (25)			Chronic disease	
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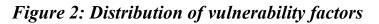
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			Damagna	Children with special needs	
	Core concepts of		Demographic	The elderly	
	human rights and		Qui i	Women Headed Household	
	inclusion of	experience limited	Socio economic	Limited resources	
	vulnerable	resources and		People with disabilities	
17	groups in the	consequent high	Illness	Mental disease	Choice of the author
17	mental health	relative risk for	miess	People with HIV	choice of the dution
	policies of	morbidity and		Chronic illness	
	Malawi,	premature mortality		Racial and ethnic minorities	
	Namibia, and	promutate mortanty	Poor medical access	Living away from service	
	Sudan (26)			Displaced populations	
			Institutionalization	Emergency settings	
				Children with special health care	
				needs	
	Core Concepts of		Demographic	The elderly	
	Human Rights	Social groups who		Women	
	and Inclusion of	experience limited	Socio economic	Limited resources	
	Vulnerable	resources and		People with disabilities	
18	Groups in the	consequent high	Illness	Chronic disease	Choice of the authors
	Namibian Policy	relative risk for		Racial and ethnic minorities	
	on Orthopaedic	morbidity and		Rural population	
	Technical	premature mortality.	Poor medical access	Limitation of primary care	
	Services (27)		r oor medical access	service	
				Displaced populations	
				Neonates	
			Demographic	Women / Pregnant women	
		archers and populations fine with a wide range of vulnerability tions in characteristics and /AIDS require special al Trials protection.	Socio economic	Incarcerated people	
	How			Homeless	
	Researchers				
	Define Vulnerable Populations in HIV/AIDS Clinical Trials			Economically disadvantaged	
19				people	Choice of the author
				Low education level	
				Decisional impairment	
				People with HIV	
	(28)			Substance abuse	
			D	Chronic disease	
			Poor medical access	Racial and ethnic minorities	
				Orphans and children with	
			Demographic	special health care needs	
	Inclusion of	Social groups who		The elderly	
	vulnerable	experience limited		Women headed household	
	groups in health	resources and	Socio economic	Economically disadvantaged	
20	policies:	consequent high		persons	Consensus after
	Regional policies	relative risk for	Illness	People with disabilities	review
	on health	morbidity and		Chronic disease	
	priorites in	premature mortality		Racial and ethnic minorities	
	Africa (29)		Poor medical access	Limitation of primary care	
				service	
				Displaced populations	
			Cognitive	Mentally handicapped	
	Research		20511110	Low education level	
	vulnerability : an	Those who are	Social	Sex workers	
	illustrative case	relatively or		Migrant	
21	study from the	absolutely incapable	Allocational	Low outcomes	Choice of the author
	south african		Medical	People with disabilities	Choice of the author
	mining industry	1 0	Medical	People with HIV	
		own interests.	Infrasturucture	Lack of ressources	-
	(30)		Juridic	Incarcereted people	
			Deferential	Subordinate members	
	•			-	

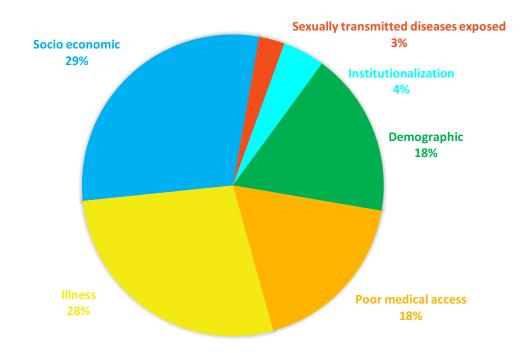
22	Social and Medical Vulnerability Factors of Emergency Department Frequent Users in a Universal Health Insurance System (31)	An accumulation of specific social and medical factors.	Socio economic Illness Poor medical access Institutionalization	Homeless People under gardianship Widowed Divorced Unemployment Uninsured Low income Psychiatric disease Substance abuse Chronic disease Limitation of primary care service Asylum seeker Institutionalized people	Choice of the authors
23	Social stability and HIV risk behavior : evaluating the role of accumulated vulnerability (32)	Accumulated disadvantage in one's social circumstances	Socio economic Limitation of primary care service Illness	Homeless Incarcerated people Unemployment Low income Limitation of primary care service People with HIV Substance abuse	Choice of the authors
24	The use of the "vulnerability" concept in the nursing area (33)	Group of people whose possibility of choice is severely limited, frequently subject to coercion in their decision.	Demographic socio economic Illness Poor medical access	Children The elderly Pregnant women Homeless Unemployment Low education level Low income People with disabilities People with HIV Racial and ethnic minorities	Consensus after review
25	Using human rights for sexual and reproductive health: improving legal and regulatory frameworks (34)	Social group limited in his right to make a decision concerning reproduction free of discrimination, coercion and violence.	Demographic Socio economic Poor medical access Sexually transmitted diseases exposed	Children Women Low income Racial and ethnic minorities Rural populations Victims of sexual abuse, gender violence.	Choice of the author
26	Vulnerability and the Patient : Practitioner Relationship: The Roles of Gatekeeping and Primary Care Performance(35)	Vulnerability can be measured by predisposing, enabling, and need characteristics.	Demographic Socio economic Illness Poor medical access	The elderly Homeless Unemployment Low education level Uninsured Low income Substance abuse Chronic disease Racial and ethnic minorities Refugees and immigrants Limitation of primary care service	Choice of the author

	Vulnerability and the Receipt		Socio economic	Low education level Uninsured Low income	
27	of Recommended Preventive Services: The Influence of Multiple Risk Factors (36)	Vulnerability can be operationalized as a profiles of multiple risk factors	Poor medical access	Racial and ethnic minorities Limitation of primary care service	Choice of the author
			Demographic	The elderly	
				Homeless	
	Vulnerability	e	Socio economic	Uninsured	
28	and Unmet	for poor health		Low income	Choice of the author
	Health Care	Health Carestatus and healthNeeds (6)care access.	Illness	People with HIV	
	meeds (6)			Racial and ethnic minorities	1
			Poor medical access	Limitation of primary care	
				service	

3.4 Additional analysis

Vulnerability factors that were gathered belonged to categories of demographic factors, socioeconomic, medical, cultural factors, and accessibility to care and services.





Socioeconomic factors and medical conditions including HIV were quoted in more than 90% of articles.

Vulnerability factors mentioned in more than 50% of the studies were:

- limited access to care and services (50%),
- low income (57%),
- people with disabilities (61%),
- chronic conditions (64%),
- race and ethnic minorities (64%),
- the elderly (68%).

Vulnerability factors mentioned in more than 25% of the studies were:

- pregnant and lactating women (25%),
- rural population (25%),
- substance abusers (25%),
- female gender (29%),
- unemployed persons (29%),
- institutionalized individuals (29%),
- uninsured (29%),
- incarcerated (32%),
- people with mental health conditions (36%),
- refugees and immigrants (39%).
- pediatric population (43%),
- people living with HIV (43%),
- homeless (46%).

Factors that were the least mentioned in the selected studies were:

- social exclusion (4%),
- persons under guardianship (4%),
- LGBT people (4%),
- people with tuberculosis (4%),
- lack of communication (4%),
- nomadic people (7%),
- displaced populations (11%),
- sex workers (11%),
- people in emergencies (18%).

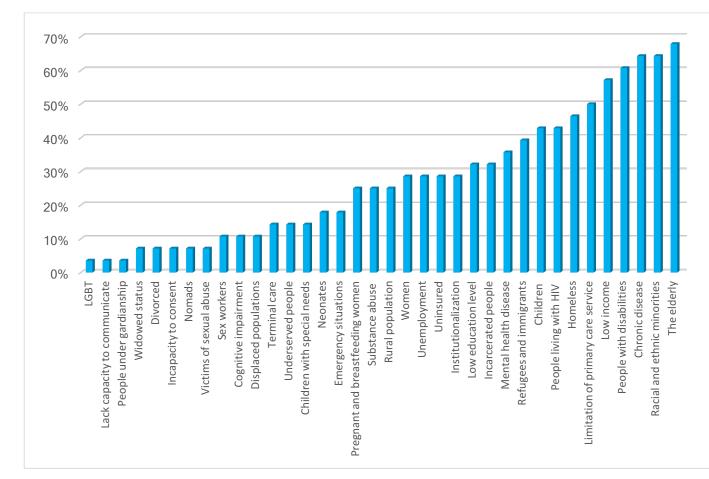


Figure 3: Frequency of the vulnerability factors

Legend: HIV: Human Immunodeficiency Virus ; LGBT: Lesbian, Gay, Bisexual and Transgender

The analysis of the global definitions of vulnerability by the similarity software found a similarity rate between from 10 to 8%, corresponding to a lack of a consensual definition (See <u>Appendix 1: Calculation method similarity rate</u>).

Three of the included studies (13)(27)(26) explored vulnerable populations using the Equiframe scale. This evaluation tool was designed to promote the inclusion of vulnerable groups and fundamental human rights concepts in health policies. It evaluated 21 basic concepts of human rights and 12 vulnerable groups mentioned in health policies including: limited resources, increased relative risk for morbidity, mother child mortality, women headed household, children (with special needs), older age, youth, ethnic minorities, displaced populations, living away from services, suffering from chronic illness, disabled. Equiframe was developed by research organizations and non-governmental organizations, to identify key themes around human rights, the right to health and vulnerability, which were of relevance across a variety of health, delivery contexts and particular health equity challenges. The Draft Framework was presented at consultation workshops conducted in Sudan, Malawi, Namibia and South Africa and attended by over a hundred participants drawn from relevant clinicians and practitioners, civil servants, elected government representatives, non-governmental organizations (NGOs), independent consultants, researchers and academics, including members of different vulnerable groups. Feedback was incorporated into a revised Framework. Its aim was to contribute to enhancing equity in healthcare.

Included studies had mainly selection biases. Some studies also reported information bias (17)(25), recall bias(32), recruitment bias (24), attrition bias (24), confusion bias (28)(35)(36) (See <u>Appendix 2</u>).

Biases were defined as in the reference *« Identifying and Avoiding Bias in Research »* (12): selection biases (including recruitment bias, sampling bias, volunteering bias, admission bias, transfer bias, attrition bias), information biases (including monitoring bias, subjectivity bias, nonresponse bias, recall bias), ranking biases and confusion biases. (12).

Among the main biases found in studies, we have noted of several selection biases such as:

- Sampling bias which was an error due to a non-random sample of a population, causing some members of the population to be less likely to be included than others.
- Attrition bias which was a selection bias caused by loss of participants.
- Recruitment bias which appeared whenever the probability that subjects enter the study is related to one factor studied.
- Admission bias referred to a situation where the chance of exposed cases being admitted to the study were different to exposed controls.
- Volunteering bias appeared when the volunteer subjects to participate in a research project were different from the general population.
- Recall bias was an error caused by differences in the accuracy of the recollections retrieved by study participants regarding events or experiences from the past.

3.5 Main authors definitions

Considering the prevalence of the authors, 3 teams were dominant. Shi, Mannan and Dearbhail Bracken-Roche had each three studies included. Several studies echoed Aday's concept of vulnerable populations.

Mannan defined vulnerable populations as "social groups who experience limited resources and consequent high relative risk for morbidity and premature mortality. This may include children, the aged, ethnic minorities, displaced populations, people suffering from chronic illnesses and persons with disabilities"(26).

In his articles, Shi considered vulnerable populations as "those at greater risk for poor health status and health care access. Many efforts have been made to characterize vulnerable groups, including by diseases, age groups (e.g., the elderly), and demo- graphics (e.g., homeless individuals), racial and ethnic minorities, low SES populations"(6).

According to Dearbhail Bracken-Roche, vulnerability was "an increased likelihood of being wronged or of incurring harm. Vulnerability can stem from a lack of capacity or from one's health status, but also from social pressures that may impact one's ability to make a free and informed decision, consistent with some scholarly perspectives. Groups most frequently identified are children, minors or young people, prisoners, as well as persons with mental health issues, patients in emergency settings, and certain ethnocultural, racial or ethnic minority groups" (3).

Aday considered that everyone was potentially vulnerable: "The notion of risk underlying the concept of vulnerability implies that everyone is potentially vulnerable (or at risk), that is, there is always a chance of developing health problems. The risk is, however, greater for those with the least social status(age, gender, race and ethnicity), social capital (family structure, marital status, voluntary organizations, socials networks) and human capital (schools, jobs, income, housing) resources to either prevent or ameliorate the origins and consequences of poor physical, psychological, or social health like high-risk mothers and infants; chronically ill and disabled; persons with AIDS; mentally ill and disabled; alcohol or substance abusers; suicide or homicide prone; abusing families; the homeless; and immigrants and refugees "(5)

4 **Discussion**

This literature review confirmed that no consensual definition of vulnerability existed in 2018.

4.1 Limits and biases:

Among the possible biases of this study, there may be a selection bias due to the limitation of searches to the Pubmed, Cochrane and Google scholar databases. However, our aim was to focus on the high-level medical literature. The research team selected these databases to limit literature review to the medical field. Other databases such as Scopus, Cairn, Psychinfo could be included for a next literature review to capture the medico-social, economic or psychological aspect of vulnerability.

The research team selected articles showing high scientific accuracy by using the IMRAD structure. On the 343 on-topic articles, this strategy excluded 191 references. 45% only of the articles of interest followed the IMRAD structure. This was less than expected, as this structure was widely adopted in the 1970s and is the only pattern for original papers in major journals (37).

A selection and information bias may have occurred in the review by the presence of a single researcher. The selection bias has been controlled by following the PRISMA procedure, doing retro bibliography and adding papers identified by the executive board of the research team. The information bias was offset by the completion of the research groups and the availability of the SPICES research team.

4.2 Strenghs of the study :

Our weighting of vulnerability factors facilitated the comparison of studies, and provided a more precise analysis of the current trends about the vulnerability concept. The similarity rate among the definitions objectified by the similarity software was only 10.8% (See Appendix). There is no definition correlated with current research data and an absence of similarities between the different versions.

The Equiframe tool provide specific questions to include vulnerable populations without providing a consensual definition. Aday's concept had the specificity of identifying vulnerable subpopulations facilitating an implementation in medical research. There were some correlations between the Equiframe tool and Aday's concept, given the similarity of factors such as social status (age, gender, race and ethnicity), human resources (income), and morbidity (chronic illness, disabled). The particularity of Aday's definition was to detail each specific vulnerable group. For example, the item "limited resources" mentioned by the Equiframe tools was detailed in Aday's definition of "employment, income, housing". The "chronic diseases" cited by Equiframe were detailed in the definition of Aday by specifying the inclusion of mental pathologies and HIV. The definition of Aday seemed more complete and more adapted to both research, teaching and clinical medical practice.

4.3 Comparison to the literature

A previous literature review in 2013(4) explored the concept of vulnerability in the area of health disparity. This literature review was based on the Inverse Care Law (ICL), which states that people with the greatest need for health care receive the least amount of health care services. It addressed the concept of multi-vulnerability with a weighting of different factors, illustrating the dynamic relationship between health services received, needs and level of vulnerability. Among the main factors were: "poverty (90%), racial / ethnic minority (78%), and the presence of chronic physical or mental illnesses (52%), lack of insurance (34%), old age (26%) ". Major factors of vulnerability were identical to our study, but there was a difference in the factors' frequency. Comparatively, our study graded the elderly (68%), chronic conditions (64%), race and ethnic minorities (64%), people with disabilities (61%), low income (57%), limited access to care and services (50%). This could be explained by the bottom-up approach, a different selection of items, oriented towards the disparity of health care. A consensual definition of vulnerability would be necessary to include the different current data in the literature, and to allow better reproducibility.

A study published by a Brest team in 2013 (38) explored the concept of multimorbidity and found the following definition: "Multimorbidity is defined as any combination of chronic disease with at least one other disease (acute or chronic) or biopsychosocial factor (associated or not) or somatic risk factor. Any biopsychosocial factor, any risk factor, the social network, the burden of diseases, the health care consumption, and the patient's coping strategies may function as modifiers (of the effects of multimorbidity). Multimorbidity may modify the health outcomes and lead to an increased disability or a decreased quality of life or frailty."

There were identical factors between multimorbidity and vulnerability such as chronic disease and biopsychosocial factor. Both multimorbidity and vulnerability are combinations of biopsychosocial factors that exacerbate health determinants. They seem in any case to be closely related. They are both challenging concepts for general practice (GP). The World Organization of National Colleges, Academies and Academic Associations of General Practitioners/Family Physicians (WONCA) defined internationally general practice in 2002 (39) as: "*a person-centered orientated to the individual, family and community dimensions, responding to health problems in their physical, psychological, social and cultural dimensions and existential*"(39).

This definition focused on biopsychosocial factors integrated to the general practice for a better understanding of the cultural dimension of our patients. It focused on global and holistic care to help to develop our relationship and on a person-centered approach to integrate specific disabilities or vulnerability factors to care. At present, the socio-economic context also obliges us to integrate some factors of vulnerability into our daily practice, and to reflect at the community level.

One of the goals of national health policies is to reduce health discrepancies within the population. One step is to set up appropriate actions to protect vulnerable populations because vulnerability underlines the need of protection and the right to health. According to the WHO: "*priority must be given to vulnerable groups because equity-based health care contributes to empowerment and social inclusion*" (13).

4.4 **Prospects for Research, Teaching and practice:**

In the future, further studies could be conducted to find a consensual definition of vulnerability in medical research. A qualitative methodology such as a Delphi round would be interesting for such research. An update of the MESH terminology on vulnerability and vulnerable populations would be desirable, based on current literature data.

In the teaching field, araising the awareness of students on the factors of vulnerability would be interesting. Learning to recognize a vulnerable person could lead to specific care. This could help students and seniors to put in place concrete actions centered on the person to reduce health discrepancies at the office level.

An easy detection of vulnerability could lead to the development of prevention strategies at the community level to act directly on specific determinants of health and health discrepancies. Realization of screening tools for clinical practice would also necessary for teaching, caring and health prevention development.

5 <u>Conclusion</u>

This literature review confirmed that there was no consensual definition of vulnerability in 2018.

Among the results of the study, 36 vulnerability factors were found, the more frequent factors were elderly (68%), chronic conditions (64%), race and ethnic minorities (64%), people with disabilities (61%), low income (57%), limited access to care and services (50%). The similarity rate between the different definitions was 10.8%. Of all the existing concepts, the Aday's definition had the distinction of identifying vulnerable sub-populations with a potential application to medical research. The Equiframe scale, designed to promote the inclusion of vulnerable groups in health policies, had been used in several studies but does not provide a specific definition.

For the SPICES project, it was inappropriate to use the term "vulnerable populations" to describe high-risk cardiovascular populations in COB countries with limited access to care.

In the literature, there were similarities between the factors defining multi morbidity and vulnerability. the elderly (68%), chronic conditions (64%), race and ethnic minorities (64%), people with disabilities (61%), low income (57%), limited access to care and services (50%).

In the future, prevention of the factors of vulnerability would be interesting at the community level. Screening tools would be of interest for clinical practice. Further research would be interesting to provide a consensual definition of the vulnerability, as an update of the MesH terminology.

6 <u>Appendix</u>

6.1 Appendix 1: Calculation method similarity rate on outils-seo.com

http://outils-seo.alwaysdata.net/outils-contenu-editorial/calcul-similarite-contenu/#result

	Definitions of vulnerability	Percentage of similarity
1	Populations with a higher risk of poor health outcomes and healthcare discrepancies in access to healthcare	19.8 % (75 words in common)
2	Multidimensional construct, resulting from numerous individual as well as community level factors.	1.0 % (4 words in common)
3	Opportunity for individuals or communities become more susceptible to diseases or disabilities	8.6 % (33 words in common)
4	Impairment of the person's capacity to exercise autonomy and true ability to protect their own interests.	16.1 % (61 words in common)
5	When some or all of the subjects are likely to be vulnerable to coercion or undue influence	13.5 % (words in common)
6	Potential risk of developing certain diseases or suffering from environmental hazards.	10.7 % (41 words in common)
7	Use to identify individuals and groups at risk of harm	17.5 % (67 words in common)
8	Concern patients with chronic conditions and socioeconomically disadvantaged people	5.5 % (21 words in common)
9	Included those who have less access to the resources needed to handle risks to health	7.7 % (29 words in common)
10	Increased risk of harms, because they have a decreased capacity, for whatever reason, to safeguard their own interests	15.7 % (59 words in common)
11	People most in need of protection	6.4 % (words in common)
12	Increased risk of harm and the resulting development of potential and actual problems	13.4 % (51 words in common)
13	An increased likelihood of being wronged or of incurring harm	10.4 % (words in common)
14	Shapes the probability of an event or hazard	8.5 % (33 words in common)
15	Referring to individuals with limited cognitive abilities or diminished autonomy	9.6 % (37 words in common)
16	Who is or may be unable to protect him or herself against significant harm or exploitation	9.0 % (34 words in common)
17	Social groups who experience limited resources and consequent high relative risk for morbidity and premature mortality	16.1 % (61 words in common)
18	Social groups who experience limited resources and consequent high relative risk for morbidity and premature mortality.	16.2 % (61 words in common)
19	Includes individuals and populations with a wide range of vulnerability characteristics and require special protection.	12.2 % (46 words in common)
20	Social groups who experience limited resources and consequent high relative risk for morbidity and premature mortality	16.2 % (61 words in common)
21	Those who are relatively or absolutely incapable of protecting their own interests.	10.8 % (41 words in common)
22	An accumulation of specific social and medical factors.	10.4 % (40 words in common)
23	Accumulated disadvantage in one's social circumstances	1.8 % (7 words in common)
24	Group of people whose possibility of choice is severely limited, frequently subject to coercion in their decision.	13.1 % (49 words in common)
25	Social group limited in his right to make a decision concerning reproduction free of discrimination, coercion and violence.	18.3 % (68 words in common)
26	Vulnerability can be measured by predisposing, enabling, and need characteristics.	6.7 % (24 words in common)
27	Vulnerability can be operationalized as a profiles of multiple risk factors	10.1 % (39 words in common)
28	Those at greater risk for poor health status and health care access.	9.6 % (37 words in common)
	Percentage of similarity :	10,875%

6.2 Appendix 2: Limitation of included studies.

	Title of studies	Limitations	Argumentations
1	Are Sexual and Reproductive Health Policies Designed for All? (14)	Selection bias	"Methodologically, this study relied primarily on health policy analysis and key informant interviews and has a range of limitations that have to be taken into account. "
2	Community Based Cardiovascular Health Interventions in Vulnerable Populations: A Systematic Review (15)	Selection bias	Inclusion of term: vulnerable populations OR healthcare disparities. "Our review was also limited by the selection of studies published in English as well as possible publication bias. Further, the heterogeneity of the studies prevented us from conducting a meta-analysis"
3	Contributions of the concept of vulnerability to professional nursing practice: integrated review (16)	Selection bias	Limitations of period of publication from 2006 to 2010. Limitation of database ILACS, MEDLINE and SCIELO. Not define number of researchers.
4	How ethical is ethical research? Recruiting marginalized, vulnerable (16)	Selection bias	"All women also reported positive experiences of the SHV service, indicating a potential selection bias"
5	Identifying the 'Vulnerables' in Biomedical Research: the vox populis from the Tuskegee Legacy Project (21)	Selection bias and information	Via RDD telephone interviews, "As the first study to present direct data on the vox populis as to who constitutes the vulnerables in biomedical research, one major inherent limitation in interpreting these findings is the inevitable uncertainty as to generalizability of these findings in the absence of prior similar studies", "response rates to random-digit dial telephone surveys in recent years which typically yield response rates in the range of 45-60% for surveys conducted by professional, high quality national survey companies"
6	Mapping the concept of vulnerability related to health care disparities: a scoping review (4)	Selection bias	"Our review revealed that despite its substantial additions, the existing literature has both important theoretical and empirical limitations. For instance, the vast majority of papers is mostly heuristic and lacks a solid theoretical basis."

7	New perspectives on vulnerability using emic and etic approaches (19)	Selection bias	Limitation to 3 databases: Medline, CINAHL and Psychlit. Using the keyword `vulnerability' (truncated) and `nursing', which are not mesh terms. No details on selection of articles: reading titles? Reading summary? One researcher
8	Organizational interventions improving access to community- based primary health care for vulnerable populations: a scoping (19)	Selection bias	Limitation to 3 databases. "While only one 'dimension-outcome' pattern was found in this review, the limited number of included studies on patients in situation of vulnerability and the theory- driven approach may have precluded finding others",
9	Prevalence of metabolic syndrome and cardiovascular risk level in a vulnerable population (20)	Selection bias and recruitment bias	"Study limitations should be taken into consideration when interpreting the findings of this study. This study population was recruited from only urban areas using convenience sampling. Future studies including populations in rural areas would provide more information about vulnerable populations in general"
10	Reconsidering 'vulnerability' in research ethics: A critical analysis and proposal for the refinement of this concept (21)	Selection bias	One researcher, "limitations of social scientific research, such as the possibility of the researchers' subjective input into the study design, questions, and data analysis. "
11	Strategies for expanding health insurance coverage in vulnerable populations (22)	Selection bias and attribution bias	"These special contexts in the studies conducted in the US probably limit the applicability of the evidence to other countries with different insurance schemes. Other key explanatory factors such as the characteristics of different kinds of vulnerable populations and health insurance schemes "

12	Vulnerability in the perioperative patient: a concept analysis (23)	Selection bias	Search terms were restricted to 'concept analysis', 'vulnerability', 'perioperative', 'patient' and 'perioperative patient'. Not MESH TERM, no details of criteria of inclusion.
13	The concept of 'vulnerability' in research ethics: an in-depth analysis of policies and guidelines (3)	Selection bias	:"The perspectives of researchers and REBs, but also of research participants, who seem to have been largely left out of the development of research ethics guidelines, could be investigated. At the same time, there are conceptual gaps within individual guidelines and policies that require the attention of those charged with their development. This lack of clarity could diminish the usability of the guidance put forth in policies and therefore undermine its impact on research practices."
14	Vulnerability as a heuristic concept for interdisciplinary research: a scoping review (1)	Selection bias	"Note that excluding the medical and epidemiological studies is a thematic choice for assessing vulnerability as an interdisciplinary heuristic in the social sciences. Unlike including the vast amount of medical and epidemiological research, concentrating on sub - disciplines within our primary field of interest — the social sciences."
15	Vulnerability in palliative care research: findings from a qualitative study (24)	Selection bias, recruitment bias, and admission bias	"While we acknowledge that this is potentially a difficult area to predict on all fronts, since the interviews were not experienced consistently among participants"
16	Accessing vulnerable research populations: an experience with gatekeepers of ethical approval (29)	Recruitment bias, selection bias, information bias	"Population of the same place in a Hospice", "However, gatekeepers can potentially be paternalistic and tokenistic, preventing potential participants from speaking for themselves or exercising agency in their own right.", "The terminology used to discuss end-of-life issues can also be problematic: euphemisms for death are often employed, e.g. the phrase 'place of care' is sometimes used by health professionals as a substitute for the phrase 'place of death'", "That the principal researcher was known to the hospice professionally as a former member of staff with professional expertise in dealing with vulnerable hospice patients and sensitive subjects also carried weight"
17	Core concepts of human rights and inclusion of vulnerable groups in the mental health policies of Malawi, Namibia, and Sudan(26)	Selection bias	It is important to note that since this framework was used to perform what was inherently a content analysis, it is bound by the limitations of using such a methodology, including expertise required to perform this type of analysis.
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18	Core Concepts of Human Rights and Inclusion of Vulnerable Groups in the Namibian Policy on Orthopaedic Technical Services (27)	Selection bias	"This framework was used to perform what was inherently a content analysis, it is bound by the limitations of using such a methodology, including the expertise required to perform this type of analysis. Further, the framework requires the use of two independent raters, to generate some scope for divergent interpretations of the material analysed"
19	How Researchers Define Vulnerable Populations in HIV/AIDS Clinical Trials (28)	Confusion bais	"This study has two main limitations. For the investigator, the response rate of 42% at the site level was low even though all 65 were asked to participate. Given that we were unsuccessful in interviewing. Second, the conceptual framework for vulnerable populations in HIV/AIDS clinical trials is missing the perspectives coming from HIV/AIDS clinical trial enrollees with respect to how they consider themselves vulnerable"
20	Inclusion of vulnerable groups in health policies: Regional policies on health priorities in Africa (29)	Selection bias	"Very few implementation plans or monitoring and evaluation suggestions were made. While guidelines for these latter components should be provided in regional policies, the detail would be the domain of the individual country policies. The lack of further specifications in the 'access to universal and equitable health care' may lead to lack of implementation in a context. This lack, furthermore, may reflect poor or no knowledge of the required specifications and/or the human rights implications of not addressing specific needs ".

21	Research vulnerability : an illustrative case study from the south african mining industry (30)	Selection bias, recruitment bias	One researcher, specific population on Mineworkers on South Africa, not reproductive study.
22	Social and Medical Vulnerability Factors of Emergency Department Frequent Users in a Universal Health Insurance System (31)	Confusion bias	"Several potential methodologic limitations should be considered. Using medical charts to extract outcome data constrains the scope of measurable vulnerability factors. We cannot exclude that other determinants that were not collected could also be good indicators of ED frequent use. Another major limitation is conducting the research at a single location. This is one of the most frequent methodologic problems found in ED research on frequent users "
23	Social stability and HIV risk behavior : evaluating the role of accumulated vulnerability (32)	Selection bias, recall bias recruitment bias.	"There are several limitations to this study. Data were cross- sectional and thus causal associations cannot be inferred. Participants may have been reticent to disclose personal information or offered more socially desirable responses. Responses may have been subject to recall bias. The minimal remuneration for study participation may also have provided incentive for individuals with greater financial need to participate in the study. There is some risk of sampling bias due to recruitment time periods and locations. "
24	The use of the "vulnerability" concept in the nursing area (33)	Selection bias	The literature review was performed in Medline and CINAHIL. The keywords vulnerability and vulnerable were used, associated to nursing ",Not Mesh term. "An important consideration about the literature research is that several publications, such as books, journals, theses and others, are not indexed in these databases. Therefore, the scientific production about vulnerability addressed in this literature review should not be considered as the existent totality. "

25	Using human rights for sexual and reproductive health: improving legal and regulatory frameworks (34)	Selection bias	"The analysis is carried out through examining the legal/policy and public health data alongside the country's human rights commitments. The latter consist of international and regional human rights treaties ratified, the relevant general comments to those treaties and country-specific concluding observations of the treaty monitoring bodies, as well as States' own national constitutions and human rights laws. The analysis almost always reveals discrepancies and gaps that need addressing."
26	Vulnerability and the Patient : Practitioner Relationship: The Roles of Gatekeeping and Primary Care Performance	Confusion bias	"Several limitations should be considered. First, the analyses presented reflect statistical association rather than causality. Causal relationships between gatekeeping arrangements, primary care experiences, and PPRs are difficult to ascertain due to the cross- sectional nature of the data set. Second, limitations in the data source prevented us from studying a broad array of vulnerable characteristics", "The validity of these responses is unclear. In general, studies on consumers' knowledge of their health plan benefits indicate that they have incomplete knowledge, particularly if they have not used many services."
27	Vulnerability and the Receipt of Recommended Preventive Services: The Influence of Multiple Risk Factors (36)	Confusion bias.	There are several limitations to this study. First, the risk factors included are not exhaustive; other combinations of risk factors (e.g., language, marital status) may produce different results. Second, this study was not able to examine the periodicity of preventive services in accord with USPSTF recommendations.
28	Vulnerability and Unmet Health Care Needs (6)	Selection bias	There are several limitations to this study. First, the risk factors included in the vulnerability profiles were meant to be illustrative and not exhaustive. Other studies might consider combining additional or different risk factors to examine the robustness of these findings. Second, the measures of unmet needs assess delayed or missed care due to costs but do not assess delayed. Third, the study was not able to account for managed care insurance type. Managed care plans are constantly studied for their influence on access to care,

6.3 Appendix 3: SPICES Project: Situational Analysis Work Package.

<u>Background</u>: Combination prevention of risk factors for CVD; implementation of medical screening for individuals at risk; and provision of effective and affordable treatment to those who require it prevent disability and death and improve quality of life. The burden of CVDs can be significantly reduced if cost-effective preventive and curative actions, along with interventions for prevention and control of CVDs already available, are implemented in an effective and balanced manner (Gaziano, Galea et al. 2007) (40). The total cost of implementing a combination of very cost-effective population-wide and individual interventions, in terms of current health spending, amounts to 4% of GDP in low-income countries, 2% in lower middle-income countries and less than 1% in upper middle income and high-income countries.

To contribute to efforts towards reducing the burden of CVD in low-middle and high income countries and to foster reciprocal learning, a consortium of six (6) Universities - University of Antwerp, University of Manchester, Makerere University, Brest University, Limpopo University and the Nottingham Trent University received funding from the European Commission through the Horizon 2020 research and innovation action to implement and evaluate a comprehensive CVD prevention program in five settings: a rural & semi-urban community in a low-income country (Uganda), middle income (South Africa) and vulnerable groups in three high-income countries (Belgium, France and United Kingdom). The five-year project (code named SPICES) aims to replicate and implement a comprehensive set of proven, effective, efficient people & family-centered interventions (as demonstrated by the HIV response and the Innovative Chronic Care Conditions (ICCC) framework) to strengthen the capacity of health systems to deal with CVD risk factors focusing on four key intervention areas - health promotion, CVD profiling, care & management as well as follow-up and self-management. Facilitators and barriers to scaling-up the interventions, including context-specific factors and differing social and health systems environments will be evaluated.

At the inception of the project, a situational analysis is proposed to document opportunities, resources, challenges and barriers in order to benchmark the proposed interventions. The situational analysis will entail conducting reviews of relevant literature, mapping health systems and CVD prevention and care services as well as formative and baseline assessments to document healthcare practices, lifestyle practices, barriers, and facilitators to CVD prevention and care in selected localities in high, middle and low income settings. The situation analysis will be done based on the four key intervention areas of health promotion, CVD profiling, care & management as well as follow-up and self-management.

<u>Situational Analysis Objectives:</u> The main objective of the situational analysis is to generate crucial information and a realistic picture of the opportunities, resources, challenges and barriers in relation to the interventions for CVD prevention and management in all project sites. The specific objectives are to document:

- 1. The burden of CVDs and CVD risk factors at the country level or (selected communities depending on contextual feasibility)
- 2. The current policies and practices in CVD prevention specifically in relation to implementation of the four key SPICES interventions
- 3. The successes and challenges to implementation of current interventions in the four SPICES intervention areas (CVD profiling, Health promotion, Care and management & self-management and follow-up)
- 4. The readiness to implement the four SPICES intervention areas, desired modifications and change process to facilitate their implementation

Situational analysis implementation approach

- 1. The situational analysis will be done through mixed methods approach in order to quantify the relative importance of key potential facilitators and barriers as well as in-depth experiences of critical stakeholders, and mechanisms for operationalising the proposed interventions.
- 2. The process will start with a mapping and/or documentation of stakeholders in CVD prevention and management at the national and subnational levels in order to identify the appropriate respondents for the situational analysis questions, stakeholder engagement plan, and eventual dissemination and knowledge translation.
- 3. Note: In some countries, the information required for the situational analysis is better organised and easily available whereas in others there could be major evidence gaps in basic information—the situational analysis focus may thus vary across sites.
- 4. Even in countries with better documentation, it will be necessary to assemble information in critical baseline parameters.

- a. This will provide a better understanding of the contextual differences and similarities across partner countries, to consortium members and other stakeholders in order to situate and appropriately interpret the findings—effectiveness of the planned models.
- b. It will also enable participating teams within the consortium to clearly appreciate the differences across the countries, potential facilitators, and barriers and inform the joint decision on appropriate interventions and methodologies.
- 5. Approach for the situational analysis may differ in some aspects—some countries may require more in-depth assessments to generate critical baseline data
- 6. Primary health care facility guides will be administered face-to-face or through other approaches e.g. telephone or Skype calls, etc. to relevant heads of units/department at Primary healthcare level. This could be a health center or hospital for Uganda and South Africa, or could be the GP, nurses or other relevant persons for UK/France/Belgium.

6.4 Appendix 4: Link to annex documents

Link to annex documents included:

- List of eligible articles Google Scholar
- List of eligible PubMed articles
- List of Eligible Items Cochrane
- Selection of articles and justifications of the arts on databases PubMed,
- Cochrane and Google Scholar.
- Retro bibliography
- Flow Chart.

https://drive.google.com/open?id=1UMqNf_-AY8GIwrNRvWMtaSafCigy8ksR

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SERMENT D'HIPPOCRATE

Au moment d'être admis(e) à exercer la médecine, je promets et je jure d'être fidèle aux lois de l'honneur et de la probité.

Mon premier souci sera de rétablir, de préserver ou de promouvoir la santé dans tous ses éléments, physiques et mentaux, individuels et sociaux.

Je respecterai toutes les personnes, leur autonomie et leur volonté, sans aucune discrimination selon leur état ou leurs convictions. J'interviendrai pour les protéger si elles sont affaiblies, vulnérables ou menacées dans leur intégrité ou leur dignité. Même sous la contrainte, je ne ferai pas usage de mes connaissances contre les lois de l'humanité.

J'informerai les patients des décisions envisagées, de leurs raisons et de leurs conséquences. Je ne tromperai jamais leur confiance et n'exploiterai pas le pouvoir hérité des circonstances pour forcer les consciences.

Je donnerai mes soins à l'indigent et à quiconque me le demandera. Je ne me laisserai pas influencer par la soif du gain ou la recherche de la gloire.

Admis (e) dans l'intimité des personnes, je tairai les secrets qui me seront confiés. Reçu (e) à l'intérieur des maisons, je respecterai les secrets des foyers et ma conduite ne servira pas à corrompre les mœurs.

Je ferai tout pour soulager les souffrances. Je ne prolongerai pas abusivement les agonies. Je ne provoquerai jamais la mort délibérément.

Je préserverai l'indépendance nécessaire à l'accomplissement de ma mission. Je n'entreprendrai rien qui dépasse mes compétences. Je les entretiendrai et les perfectionnerai pour assurer au mieux les services qui me seront demandés.

J'apporterai mon aide à mes confrères ainsi qu'à leurs familles dans l'adversité.

Que les hommes et mes confrères m'accordent leur estime si je suis fidèle à mes promesses ; que je sois déshonoré (e) et méprisé (e) si j'y manque. »

Serment prononcé par le Docteur.....

Le

Pour l'Ordre national des médecins, Le médecin





THESE DE DOCTORAT EN MEDECINE

INTERNE

Madame / Monsieur Inscrit-e en DES de EVEN Ludovic Médecine générale

Titre définitif de la thèse soutenue : In 2018, what is the definition of the concept of vulnerability for the medical literature? A systematic review.

ACCORD	DU PRESIDENT DU JURY DE THESE SUR L'IMPRESSION DE LA THESE
OUI :	

La présente autorisation d'imprimer sa thèse est délivrée à l'interne susmentionné.

Brest, le 02 09 2018.

Le directeur de l'UFR de médecine et des sciences de la santé de Brest Le président du jury de thèse

C. BERTHOU

EVEN Ludovic : In 2018, what is the definition of the concept of vulnerability in the medical literature? Revue systématique. Th. : Méd. : Brest 2018

<u>RESUME</u> :

Introduction : Depuis une dizaine d'année, les notions de « vulnérabilité » et de « populations vulnérables » ont été utilisées dans la littérature scientifique. Le projet SPICES est une étude d'implémentation visant à mettre en œuvre des interventions efficaces en prévention cardiovasculaire primaire. Elle cible les populations habituellement exclues des actions de prévention cardiovasculaire. Ces populations pourraient entrer dans la définition des populations vulnérables.

Question de recherche : Quelle est la définition du concept de vulnérabilité dans la littérature médicale ?

Matériel et Méthode : Une revue de littérature a été effectuée sur les bases de données Cochrane, Pubmed et Google Scholar selon la méthode PRISMA. Des méta-analyses, revues systématiques et essais contrôlés randomisés ont été inclus s'ils suivaient le format IMRAD, étaient rédigées en anglais ou en français, abordaient la vulnérabilité ou les populations vulnérables, et s'ils étaient publiés avant janvier 2018. Les définitions ont été classées selon la terminologie MeSH et comparées avec un logiciel de similarité. Une fréquence des différents facteurs de vulnérabilité parmi les définitions a été calculée.

Résultats : Parmi les 588 articles éligibles, 15 articles ont été initialement inclus. 13 articles supplémentaires ont été inclus après une rétrobibliographie. Il n'existait pas de définition consensuelle de la vulnérabilité. Les facteurs de vulnérabilité les plus cités étaient : les personnes âgées (68%), les minorités raciales et ethniques (64%), les maladies chroniques (64%), le faible revenu (57%), l'accès limité aux soins et services (50%). Trois études ont utilisé le cadre EquiFrame, facilitant l'inclusion des groupes vulnérables dans les politiques de santé. La définition d'Aday désignait les sous-populations vulnérables.

Discussion : Le terme de « populations vulnérables » n'étaient pas adaptées au projet SPICES. La définition d'Aday semblait la plus appropriée pour la recherche médicale. Une définition consensuelle de la vulnérabilité serait nécessaire.

MOTS CLES :

LITERATURE REVIEW ; VULNERABLE POPULATIONS ; VULNERABILITY

<u>JURY</u>: Président : Pr Jean Yves Le Reste Membres : Pr Michel Botbol <u>Dr Delphine Le Goff</u> Dr Patrice Nabbe

DATE DE SOUTENANCE : 13 septembre 2018

ADRESSE DE L'AUTEUR : 1 straed Le Gall de Kerdu, 22300 Lannion.

EVEN Ludovic: In 2018, what is the definition of the concept of vulnerability for medical literature? A systematic Review. Th. : Méd. : Brest 2018

SUMMARY:

Background: For the last ten years, "vulnerability" and "vulnerable populations" have been used in medical literature. SPICES (Scaling up Packages of Interventions for Cardiovascular disease prevention in selected sites in Europe and Sub-saharian africa) is an implementation study which will implement effective primary cardiovascular prevention interventions. It targets populations who are usually excluded from prevention. Those populations could fall within the definition of vulnerable populations.

Research question: What is the definition of vulnerability in the medical literature?

Methods: A systematic review was conducted on Cochrane, Medline, Pubmed and Google Scholar databases using the PRISMA methodology. Meta-analyzes, systematic reviews and randomized controlled trials were included if they followed the IMRAD format, were in English or French, addressed vulnerability or vulnerable populations and were published to January 2018. Definitions were compared and classified using the MesH terminology and a similarity software. A frequency of vulnerability factors among the definitions was calculated.

Results: Of the 588 eligible articles, 15 articles were initially included. Their bibliography was screened adding 13 articles. There was no consensual definition of vulnerability. The most frequent vulnerability factors were elderly (68%), race and ethnic minorities (64%), chronic conditions (64%), low income (57%), limited access to care and services (50%). Three studies used the EquiFrame framework, which promoted inclusion of vulnerable groups for health policies. Aday's definition referred to vulnerable subpopulations.

Discussion: The term of "vulnerable populations" did not fit to the SPICES project. Aday's definition seemed the most appropriate for medical research. A consensual definition of vulnerability would be needed.

<u>MOTS CLES</u> : LITERATURE REVIEW ; VULNERABLE POPULATIONS ; VULNERABILITY

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