Mémoire, y compris stage professionnalisant[BR]- Séminaires méthodologiques intégratifs[BR]- ???

Auteur : Vanhaelen, Alix
Promoteur(s) : Belche, Jean; Ethgen, Olivier
Faculté : Faculté de Médecine
Diplôme : Master en sciences de la santé publique, à finalité spécialisée en épidémiologie et économie de la santé
Année académique : 2019-2020
URI/URL : http://hdl.handle.net/2268.2/9257

IX. Annexes

Annexe I : Équations de recherche

Scopus:

(TITLE (no-show* OR "no show*" OR non-attendance OR "non attendance" OR "missing appointment*" OR "missed appointment*") AND TITLE-ABS-KEY (reason* OR predict* OR investigation* OR factor*) AND TITLE-ABS-KEY (primary AND care* OR "primary health care center*" OR outpatient* OR out-patient* OR "community-health center*" OR "health service*" OR physiotherap* OR nurs* OR gp OR "General practitioner*" OR "general practice"))

PubMed :

(((no-show*[Title]) OR (“no show*”[Title]) OR (non-attendance[Title]) OR (“non attendance”[Title]) OR (“missing appointment*”[Title]) OR (“missed appointment*”[Title])) AND ((reason*[Title/Abstract]) OR (predict*[Title/Abstract]) OR (investigation* [Title/Abstract]) OR (factor*[Title/Abstract])) AND ((“primary care*”[Title/Abstract]) OR (“primary health care center*”[Title/Abstract]) OR (outpatient*[Title/Abstract]) OR (out-patient*[Title/Abstract]) OR (“community-health center*”[Title/Abstract]) OR (“health service*”[Title/Abstract]) OR (physiotherap*[Title/Abstract]) OR (nurs*[Title/Abstract]) OR (GP[Title/Abstract]) OR (“General practitioner*”[Title/Abstract]) OR (“general practice”[Title/Abstract])))

PEDro :
Title : appointment
Title : no show

Lilacs :

(ti:(no-show* OR "no show*" OR non-attendance OR "non attendance" OR "missing appointment*" OR "missed appointment*")) AND (tw:(reason* OR predict* OR investigation* OR factor*)) AND (tw:(“primary care*” OR "primary health care center*" OR outpatient* OR out-patient* OR "community-health center*" OR "health service*" OR physiotherap* OR nurs* OR gp OR "General practitioner*" OR "general practice"))

Science Direct :

Title:
("non-attendance") OR (“missing appointment*”) OR (“missed appointment*”)

Titre/Abstract/Keywords :
(reason OR reasons OR predict OR predictors OR "to predict" OR investigation OR factors)

Cochrane:

((no-show*) OR (“no show*”) OR (non-attendance) OR (“non attendance”) OR (“missing appointment*”) OR (“missed appointment*”)) in Record Title AND ((reason*) OR (predict*) OR (investigation*) OR (factor*)) in Title Abstract Keyword AND ((“primary care*”) OR (“primary health care center*”) OR (outpatient*) OR (out-patient*) OR (“community-health center*”) OR (“health service*”) Or (physiotherap*) OR (Nurs*) OR (GP) OR (“General practitioner*”) OR (“general practice”)) in Title Abstract Keyword - (Word variations have been searched)

Remarques :
- **Science Direct** ne permet que 8 booléens par recherche, deux recherches simultanées ont donc été effectuéees. Les mots clés type « no-show », « non-attendance » n’ont pas été utilisés, car le système de recherche renvoie plus de 3200 articles comprenant « no » ou « non ».
- **PEDro** ne permet pas de combiner les termes. Deux recherches séparées ont donc été réalisées.

Annexe 2. Évaluation de la qualité des études incluses dans la revue systématique

JBI	Bickler (1985)	Hamilton, Luthra et al. (2002)	Hamilton, Round et al. (2002)	Lasser et al. (2005)	Neal et al. (2005)	Kaplan-Lewis et al. (2013)	Norris et al. (2014)	Ellis et al. (2017)	McQueenie et al. (2019)	Lenzi et al. (2019)
Item 1	cas-témoin	transversale	cohorte	cohorte	cas-témoin	cohorte	cohorte	cohorte	cohorte	cohorte
Item 2	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes
Item 3	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Item 4	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Item 5	Yes	Not App	No	No	Yes	Unclear	No	Yes	Yes	Yes
Item 6	Yes	Unclear	No	No	Yes	No	No	Unclear	Unclear	Unclear
Item 7	No	Unclear	Yes	No	No	Yes	Yes	Yes	Yes	Yes
Item 8	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes
Item 9	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Item 10	Yes	/	Not App	Not App	No	No	Not App	Yes	Not App	Not App
Item 11	/	/	Yes	No	/	Yes	Yes	Yes	Yes	Yes
Nombre Yes	6	4	8	7	6	7	7	10	9	9
Qualité	faible	moyenne	bonne	moyenne	faible	moyenne	moyenne	bonne	bonne	bonne

Not App = not applicable

Annexe 3. Références des articles de la revue systématique

Bickler CB. Defaulted appointments in general practice. 1985;(January):19–22.

Hamilton W, Round A, Sharp D. Patient, hospital, and general practitioner characteristics associated with non-attendance: a cohort study. Br J Gen Pract. 2002 Apr;52(477):317–9.

Hamilton W, Luthra M, Smith T, Evans P. Non-attendance in general practice: A questionnaire survey. Prim Heal Care Res Dev. 2002;3(4):226–30.

Neal RD, Hussain-Gambles M, Allgar VL, Lawlor DA, Dempsey O. Reasons for and consequences of missed appointments in general practice in the UK: Questionnaire survey and prospective review of medical records. Vol. 6, BMC Family Practice. 2005.

Lasser KE, Mintzer IL, Lambert A, Cabral H, Bor DH. Missed appointment rates in primary care: The importance of site of care. Free Clin Local Responses to Heal Care Needs. 2013;9781421408(3):132–43.

Kaplan-Lewis E, Percac-Lima S. No-show to primary care appointments: Why patients do not come. J Prim Care Community Heal. 2013;4(4):251–5.

Norris JB, Kumar C, Chand S, Moskowitz H, Shade SA, Willis DR. An empirical investigation into factors affecting patient cancellations and no-shows at outpatient clinics. Decis Support Syst, 2014;57(1):428–43, http://dx.doi.org/10.1016/j.dss.2012.10.048

Ellis DA, McQueenie R, McConnachie A, Wilson P, Williamson AE. Demographic and practice factors predicting repeated non-attendance in primary care: a national retrospective cohort analysis. Lancet Public Heal, 2017;2(12):e551–9, http://dx.doi.org/10.1016/S2468-2667(17)30217-7

Lenzi H, Ben ÂJ, Stein AT. Development and validation of a patient no-show predictive model at a primary care setting in Southern Brazil. PLoS One. 2019 Apr 1;14(4).

McQueenie R, Ellis DA, McConnachie A, Wilson P, Williamson AE. Morbidity, mortality and missed appointments in healthcare: A national retrospective data linkage study. BMC Med. 2019 Jan 11;17(1).

Annexe 4. Résultats détaillés de la revue systématique

Auteurs (année)	Méthode		Caractéristiques de la population			
	Design de l'étude	Durée	Taille de l'échantillon	Origine des données	Discipline	Paiement par le patient
Bickler (1985)	Étude cas témoin	2 mois	100 paires des patients (200 patients)	West Granton Medical Group, Écosse, UK	Médecine générale	Non : NHS financé par l'impôt
Hamilton, Round et al. (2002)	Étude de cohorte prospective	5 mois	2 078 patients	36 médecins de 13 centres de médecine générale à Exeter, UK	Médecine générale	Non : NHS financé par l'impôt
Hamilton, Luthra et al. (2002)	Étude transversale	3 mois	174 absentéistes	5 centres de médecine générale à Exeter, Devon, UK	Médecine générale	Non : NHS financé par l'impôt
Neal et al. (2005)	Étude cas témoin	12 mois	27 paires de patients (54 patients)	7 centres de médecine générale, Yorkshire, UK	Médecine générale	Non : NHS financé par l'impôt
Lasser et al. (2005)	Étude de cohorte	1 an	74 120 rendez-vous 13 882 patients	58 soignants, Cambridge, UK	Médecine générale	Non : NHS financé par l'impôt
Kaplan-Lewis et al. (2013)	Étude de cohorte	5 mois	5604 rendez-vous	1 centre de santé communautaire à Chelsea, USA	Soins de santé primaires	Selon le cas : détails dans les résultats
Norris et al. (2014)	Étude de cohorte	5 ans	88 345 patients 858 579 rendez-vous	9 cliniques universitaires privées, Indiana, USA	Soins de santé primaire	Selon le cas : détails dans les résultats
Ellis et al. (2017)	Étude de cohorte	3 ans	550 083 patients 9 177 054 rendez-vous	11 centres de médecine générale, Ecosse , UK	Médecine générale	Non : NHS financé par l'impôt
Lenzi et al. (2019)	Étude de cohorte	2 ans et 5 mois	57 586 rendez-vous	Centre hospitalier Conceição, Brésil	Soins de santé primaire	Non : Sistema Unico de Saude avec accès gratuit aux soins dans les centres conventionnés
McQueenie et al. (2019)	Étude de cohorte	3 ans	824 374 patients	136 centres de médecine générale, Ecosse, UK	Médecine générale	Non : NHS financé par l'impôt

	Critères de jugement		
Auteurs (année)	**Outil de collecte des données**	**Paramètres étudiés**	**Facteurs prédictifs**
Bickler (1985)	Données des centres de santé	P : âge, sexe, résident temporaire, nombre de médecins vus l'année précédente, addiction aux drogues, inscrit dans le centre de santé depuis moins d'un an O : jour, personne qui a proposé le rdv, personne ayant pris le rdv, façon de prendre le rdv, délais	P : 16-35 ans, peu de rdv l'année précédente O : lundi, prise de rdv en face à face (pas par téléphone), courts délais
Hamilton, Round et al. (2002)	Données des centres de santé	P: âge, sexe, indicateur socio-économique de la zone (score de Jarman) O : discipline consultée, délais, nombre d'années de pratique du GP, taux de demandes de consultations du GP	P : jeune, homme, zone avec faible statut socio-économique (haut score de Jarman) O : longs délais, GP fortement demandé
Hamilton, Luthra et al. (2002)	Questionnaire	P : âge, sexe O : type de rdv, transport, façon de prendre le rdv, raison du rdv Autre : opinion pour diminuer les rdv manqués	Pas de résultat significatif
Neal et al. (2005)	Questionnaire	P : âge, sexe, antécédents de rdv manqués, nombre de rdv l'année précédente, statut psychiatrique (GHQ-12 score), raison d'avoir raté le rdv (pour les patients ayant raté un rdv) / raison possible de rdv manqué (pour les patients présents au rdv) O : raison du rdv, raison d'avoir raté le rdv	P : jeune, homme, probable atteinte psychique (haut score GHQ-12)
Lasser et al. (2005)	Questionnaire	P : race, âge, sexe, type d'assurance, langue, ancienneté du patient O : délais Autre : soignant : race, sexe, ethnicité, langue(s), nombre de consultations par semaine, nombre d'années de pratique, rapidité pour avoir un rdv	P : jeune, avec assurance publique, parlant créole haïtien, qui ne parle pas la même langue que le soignant, qui n'est pas de la même race que le soignant O : longs délais
Kaplan-Lewis et al. (2013)	Données des centres de santé	P : âge, sexe, race, ethnicité, langue, assurance, raison du rdv manqué O : raison du rdv manqué	P : jeune, noir ou hispanique, assuré par Medicaid ou sans assurance
Norris et al. (2014)	Données des centres de santé	P : âge, antécédents de rdv manqués, type d'assurance O : délais, jour, heure, météo	P : enfant âgé (=<21) ou adulte jeune (22-75), antécédents de rdv manqués, assuré par Medicaid ou sans assurance O : longs délais, lundi, matin, neige
Ellis et al. (2017)	Données des centres de santé	P : âge, sexe, statut socio-économique (SIMD = scottish index of multiple deprivation), ethnicité (exclue en post hoc) O : délais, nombre moyen de rdv par patient par centre de santé, durée moyenne de rdv par patient, urbain/rural	P : 76 ans et plus, femme, faible statut socio-économique O : longs délais, nombre moyen élevé de rdv par patient, zone urbaine
Lenzi et al. (2019)	Données des centres de santé	P : âge, sexe, ethnicité, nombre de rdv précédents O : date, jour, heure, date et heure de la prise de rdv, type de soignant, type de rdv, délais, temps d'attente	P : antécédents de rdv manqués, femme, non caucasien O : rdv qui n'est pas pris le jour même
McQueenie et al. (2019)	Données des centres de santé	P : nombre de pathologies chroniques, type de pathologies chroniques, prescription, mortalité toutes causes confondues O : statut socio-économique moyen du centre de santé, rural/urbain	P : nombre élevé de pathologies chroniques, pathologies chroniques physiques, abus d'alcool et de substances psychoactives

rdv : rendez-vous, P : facteurs au niveau du patient, O : facteurs organisationnels, GP = general practitioner

			Risque de biais			
Auteurs (année)	**Financement**	**Conflit d'intérêt**	**Biais de sélection**	**Biais d'information**	**Biais de confusion**	**Qualité**
Bickler (1985)	Pas d'information	Pas d'information	Les patient contrôle est le patient qui suit directement un rdv manqué	Possibles erreurs d'encodage	Pas de statistiques descriptives des deux groupes	Faible 6 Yes
Hamilton, Round et al. (2002)	National R&D Programme Primary/Secondary Care Interface du NHS.	Pas d'information	non	Possibles erreurs d'encodage	Pas d'information sur la profession, le niveau d'éducation, les revenus, le motif de visite	Bonne 8 Yes
Hamilton, Luthra et al. (2002)	Research and Development General Practices de 2 cabinets participants sur les 5	Pas d'information	-Choix des sujets par les centres de santé - 35% de questionnaires complétés	Désirabilité sociale	Pas d'information sur la profession, le niveau d'éducation, les revenus, le motif de visite	Moyenne 4 Yes
Neal et al. (2005)	NHS Northern and Yorkshire R&D Directorate	Pas de conflit d'intérêt déclaré	Les patient contrôle est le patient qui suit directement un rdv manqué	Questionnaire différent dans les 2 groupes	Pas de statistiques descriptives des deux groupes	Faible 6 Yes
Lasser et al. (2005)	Pas d'information	Pas d'information	non	Identification visuelle de l'origine du patient par le soignant	Pas d'information sur la profession, le niveau d'éducation, les revenus, le motif de visite	Moyenne 7 Yes
Kaplan-Lewis et al. (2013)	Harvard Medical School Center for Primary Care Academic Innovations Collaborative Grant	Pas de conflit d'intérêt déclaré	37% des rdv manqués ont répondu pour la raison de rdv manqué	Possibles erreurs d'encodage	Pas d'information sur la profession, le niveau d'éducation, les revenus, le motif de visite	Moyenne 7 Yes
Norris et al. (2014)	Pas d'information	Pas d'information	non	Possibles erreurs d'encodage	Pas d'information sur la profession, le niveau d'éducation, les revenus, le motif de visite	Moyenne 7 Yes
Ellis et al. (2017)	Scottish Governement Chief Scientist Office	Pas de conflit d'intérêt déclaré	non	Possibles erreurs d'encodage	Pas d'information sur la profession, le motif de visite	Bonne 10 Yes
Lenzi et al. (2019)	Non financé	Pas de conflit d'intérêt déclaré	non	Possibles erreurs d'encodage	Pas d'information sur la profession, le niveau d'éducation, les revenus, le motif de visite	Bonne 9 Yes
McQueenie et al. (2019)	Scottish Governement Chief Scientist Office	Pas de conflit d'intérêt déclaré	non	Possibles erreurs d'encodage, Toutes les causes de rdv manqués ne sont pas établies	Pas d'information sur la profession, le niveau d'éducation, les revenus, le motif de visite	Bonne 9 Yes

Annexe 5. Guide d'entretien

Remarques préalables

Avant l'entretien, il convient d'arriver bien avant l'heure prévue pour s'installer, préparer le matériel et le local. La première tâche est ensuite de noter le lieu et la date de la rencontre dans le journal de bord. Lorsque le participant arrive, il ne faut pas oublier de fermer la porte pour éviter toute perturbation, l'inviter cordialement à s'installer et lui proposer une boisson pour qu'il se sente à l'aise.

Pendant l'entretien, en cas de sous-entendu, il est pertinent de demander à la personne de préciser les informations latentes. Concernant les informations floues, peu claires ou confuses, il est aussi utile de demander au participant de préciser son point de vue.
Le texte ci-dessous est un exemple de ce qui serait dit. Il ne sera pas étudié, ni récité. L'expérimentateur aura simplement une feuille avec quelques mots-clés afin de ne pas oublier d'aborder tous les points d'intérêt.

Après l'entretien, il est aussi important de noter dans le journal de bord ce qui s'est éventuellement dit hors enregistrement.

Introduction

Étudiante à l'Université de Liège en master en Santé Publique à finalité Épidémiologie et Économie de la Santé, je réalise un mémoire sur les rendez-vous manqués en maisons médicales à Liège.

Cette étude se déroule en deux parties. La première partie est déjà réalisée : il s'agissait d'établir un état des lieux de la situation par une étude quantitative sur les facteurs prédictifs de rendez-vous manqués en maison médicale à Liège. La deuxième partie est celle à laquelle vous êtes invité à participer. Il s'agit d'une étude quantitative ayant pour objectif de fournir des pistes de réflexion à propos des rendez-vous en maisons médicales à Liège.

Principes éthiques

Je vous donne le document de consentement à lire. Vous pouvez me poser des questions après lecture de celui-ci. Suite à cela, l'interview sera enregistrée à l'aide d'un dictaphone ; elle sera ensuite entièrement retranscrite sur Word. Aucun nom ne sera cité, tout sera traité de façon anonyme.

Si vous êtes d'accord de participer à l'étude, d'être enregistré par dictaphone et que votre témoignage soit utilisé, je vous demande de signer le document en deux exemplaires, l'un que vous garderez et l'autre que je vais conserver. Sachez que les données seront traitées et présentées de façon confidentielle et que vous avez le droit de retirer votre consentement à tout moment de l'étude. Avez-vous des questions ?

Questions

En premier lieu, j'aimerais savoir si vous avez un avis sur le sujet.

- À votre avis, les rendez-vous manqués sont-ils un réel problème ?
- Que faites-vous quand cela vous arrive ?

- Quelle est votre profession au sein de la maison médicale ?
- Êtes-vous titulaire, remplaçant, assistant, en arrêt de travail ou autre ?
- Depuis combien d'années exercez-vous en maison médicale ?

- Selon vous, pourquoi constate-t-on une différence au niveau de … ? (à adapter selon les résultats obtenus, autant de questions que de points soulevés par la partie quantitative)

- Pensez-vous qu'il soit possible de diminuer le nombre de rendez-vous manqués ?
    - à votre niveau personnellement ?
    - au niveau de votre secteur ?
    - au niveau de l'organisation ?
    - au niveau du patient ?

Il existe plusieurs moyens de diminuer les rendez-vous manqués. Par exemple, une étude a montré que la mise en place d'un système de rendez-vous par internet a permis la diminution des taux de rendez-vous manqués allant d'une baisse de 3% (41) jusqu'à une baisse gigantesque de 42% (42). D'autres études se sont intéressées aux systèmes de rappel par courrier, téléphone ou SMS. Par courrier, les chercheurs ont observé une modification du taux de rendez-vous manqués de 18 à 17% (20), par téléphone de 29 à 23 % (43) et par SMS une étude constate 14% de diminution du taux de rendez-vous manqués (27).

- Selon vous, pourquoi cela n'a pas été mis en place auparavant ? Quelles seraient les difficultés à cette mise en place ? (Éventuellement, reprendre pour aider)

L’entretien arrive à son terme.

- Avez-vous des choses à ajouter ?

Conclusion

Je vous remercie grandement pour votre participation. Avez-vous des questions ?
Après retranscription, vous pourrez relire votre interview afin de vérifier que vos propos ne sont pas déformés. Si vous le désirez, les conclusions de l’étude vous seront communiquées après analyse des données.

Annexe 6. Réponse du Collège des Enseignants

Zimbra **alix.vanhaelen@student.uliege.be**

RE: Demande d'avis au collège des enseignants - mémoire Santé Publique

De : Master en Sciences de la Santé publique - ULiège <mssp@uliege.be> ven., 13 mars 2020 11:50

Objet : RE: Demande d'avis au collège des enseignants - mémoire Santé Publique

À : alix vanhaelen <alix.vanhaelen@student.uliege.be>

Bonjour,

Votre dossier est en ordre en ce qui concerne votre demande d'avis éthique.

Bonne continuation dans votre projet de recherche.

Bien à vous,

Le Collège restreint des Enseignants

Annexe 7. Formulaire de consentement pour l'utilisation de données à caractère personnel dans le cadre d'un travail de fin d'étude

.

Université de Liège

Formulaire de consentement pour l'utilisation de données à caractère personnel dans le cadre d'un travail de fin d'étude

Rendez-vous manqués en maison médicale à Liège : état des lieux et pistes de réflexion

Ce mémoire s'intéresse aux rendez-vous manqués en maisons médicales à Liège. Il se déroule en deux parties. La première partie est déjà réalisée : il s'agissait de réaliser un état des lieux de la situation par une étude quantitative sur les facteurs prédictifs de rendez-vous manqués en maison médicale à Liège. La deuxième partie est celle à laquelle vous êtes invité à participer. Il s'agit d'une étude quantitative ayant pour objectif de fournir des pistes de réflexion à propos des rendez-vous en maisons médicales à Liège.

Ce document a pour but de vous fournir toutes les informations nécessaires afin que vous puissiez donner votre accord de participation à cette étude en toute connaissance de cause.

Pour participer à ce projet de recherche, vous devrez signer le consentement à la fin de ce document et nous vous en remettrons une copie signée et datée. Vous serez totalement libre, après avoir donné votre consentement, de vous retirer de l'étude.

Responsable(s) du projet de recherche

Le promoteur et le co-promoteur de ce travail de fin d'étude sont : Jean-Luc Belche, jlbelche@uliege.be et Olivier Ethgen, O.Ethgen@uliege.be

L'étudiant réalisant ce travail de fin d'étude est : Alix Vanhaelen, alix.vanhaelen@student.uliege.be

Description de l'étude

Cette étude a pour but de déterminer les facteurs influençant les rendez-vous manqués en maison médicale à Liège et de proposer des pistes de réflexion sur le sujet. Elle sera menée, sauf prolongation, jusqu'à la fin de l'année académique 2019-2020.

Protection des données à caractère personnel

Le ou les responsables du projet prendront toutes les mesures nécessaires pour protéger la confidentialité et la sécurité de vos données à caractère personnel, conformément au *Règlement général sur la protection des données* (RGPD – UE 2016/679) et à la loi du 30 juillet 2018 relative à la protection des personnes physiques à l'égard des traitements de données à caractère personnel

1. *Qui est le responsable du traitement ?*

Le Responsable du Traitement est l'Université de Liège, dont le siège est établi Place du 20-Août, 7, B- 4000 Liège, Belgique.

2. *Quelles seront les données collectées ?*

Les données récoltées sont : profession au sein de la maison médicale, statut au sein de la maison médicale, nombre d'années d'ancienneté, opinion personnelle à propos des résultats de l'étude quantitative, opinion personnelle pour diminuer le nombre de rendez-vous manqués (au niveau personnel, du secteur, de l'organisation et du patient), opinion sur la mise en place un système de gestion des rendez-vous manqués.

3. À quelle(s) fin(s) ces données seront-elles récoltées ?

Les données à caractère personnel récoltées dans le cadre de cette étude serviront à la réalisation du travail de fin d'étude présenté ci-dessus. Elles pourraient, éventuellement, aussi servir à la publication de ce travail de fin d'étude ou d'articles issus de cette recherche, à la présentation de conférences ou de cours en lien avec cette recherche, et à la réalisation de toute activité permettant la diffusion des résultats scientifique de cette recherche. Sauf mention contraire, ces données seront rendues anonymes dans les résultats de cette étude.

4. Combien de temps et par qui ces données seront-elles conservées ?

Les données à caractère personnel récoltées seront conservées jusqu'à la réalisation et la validation par le jury du travail de fin d'étude présenté ci-dessus. Le cas échéant, la conservation de ces données pourrait être allongée de quelques mois afin de permettre les autres finalités exposées au point 3.

Ces données seront exclusivement conservées par l'étudiant réalisant ce travail de fin d'étude, sous la direction de son promoteur.

5. Comment les données seront-elles collectées et protégées durant l'étude ?

Les données seront récoltées lors d'entretiens individuels et enregistrées sur un dictaphone. Les données sont stockées sous fichier crypté.

Ensuite, les enregistrements seront retranscrits sur Word. Les enregistrements audio seront supprimés. Les participants pourront relire leur retranscription.

Ensuite, les retranscriptions seront anonymisées. Les données de contact seront stockées sous forme de code dans un autre fichier au cas où la personne souhaiterait se retirer de l'étude. Il sera maintenant impossible de déterminer l'identité des personnes interviewées et dont on parle dans les entretiens.

Ensuite, la rédaction du mémoire commencera avec des réponses anonymes.

Finalement, la base de données sera détruite après la publication du mémoire.

6. Ces données seront-elles rendues anonymes ou pseudo-anonymes ?

Les données seront anonymisées et il ne sera pas possible de lier des identités aux données.

7. Qui pourra consulter et utiliser ces données ?

Seuls l'étudiant réalisant le travail de fin d'étude présenté plus haut, son promoteur et les membres du jury de mémoire (pour validation de la démarche scientifique) auront accès à ces données à caractère personnel.

8. Ces données seront-elles transférées hors de l'Université ?

Non, ces données ne feront l'objet d'aucun transfert ni traitement auprès de tiers.

9. Sur quelle base légale ces données seront-elles récoltées et traitées ?

La collecte et l'utilisation de vos données à caractère personnel reposent sur votre consentement écrit. En consentant à participer à l'étude, vous acceptez que les données personnelles exposées au point 2 puissent être recueillies et traitées aux fins de recherche exposées au point 3.

10. Quels sont les droits dont dispose la personne dont les données sont utilisées ?

Comme le prévoit le RGPD (Art. 15 à 23), chaque personne concernée par le traitement de données peut, en justifiant de son identité, exercer une série de droits :

- obtenir, sans frais, une copie des données à caractère personnel la concernant faisant l'objet d'un traitement dans le cadre de la présente étude et, le cas échéant, toute information disponible sur leur finalité, leur origine et leur destination;
- obtenir, sans frais, la rectification de toute donnée à caractère personnel inexacte la concernant ainsi que d'obtenir que les données incomplètes soient complétées ;
- obtenir, sous réserve des conditions prévues par la réglementation et sans frais, l'effacement de données à caractère personnel la concernant;
- obtenir, sous réserve des conditions prévues par la réglementation et sans frais, la limitation du traitement de données à caractère personnel la concernant;
- obtenir, sans frais, la portabilité des données à caractère personnel la concernant et qu'elle a fournies à l'Université, c'est - à - dire de recevoir, sans frais, les données dans un format structuré couramment utilisé, à la condition que le traitement soit fondé sur le consentement ou sur un contrat et qu'il soit effectué à l'aide de procédés automatisés ;
- retirer, sans qu'aucune justification ne soit nécessaire, son consentement. Ce retrait entraine automatiquement la destruction, par le chercheur, des données à caractère personnel collectées ;
- introduire une réclamation auprès de l'Autorité de protection des données (https://www.autoriteprotectiondonnees.be, contact@apd-gba.be).

11. Comment exercer ces droits ?

Pour exercer ces droits, vous pouvez vous adresser au Délégué à la protection des données de l'Université, soit par courrier électronique (dpo@uliege.be), soit par lettre datée et signée à l'adresse suivante :

Université de Liège
M. le Délégué à la protection des données,
Bât. B9 Cellule "GDPR",
Quartier Village 3,
Boulevard de Colonster 2,
4000 Liège, Belgique.

Coûts, rémunération et dédommagements

Aucun frais direct lié à votre participation à l'étude ne peut vous être imputé. De même, aucune rémunération ou compensation financière, sous quelle que forme que ce soit, ne vous sera octroyée en échange de votre participation à cette étude.

Retrait du consentement

Si vous souhaitez mettre un terme à votre participation à ce projet de recherche, veuillez en informer l'étudiant réalisant le travail de fin d'étude, dont les coordonnées sont reprises ci-dessus. Ce retrait peut se faire à tout moment, sans qu'une justification ne doive être fournie. Sachez néanmoins que les traitements déjà réalisés sur la base de vos données personnelles ne seront pas remis en cause. Par ailleurs, les données déjà collectées ne seront pas effacées si cette suppression rendait impossible ou entravait sérieusement la réalisation du projet de recherche. Vous en seriez alors averti.

Questions sur le projet de recherche

Toutes les questions relatives à cette recherche peuvent être adressées à l'étudiant réalisant le travail de fin d'étude, dont les coordonnées sont reprises ci-dessus.

Je déclare avoir lu et compris les 4 pages de ce présent formulaire et j'en ai reçu un exemplaire signé par les personnes responsables du projet. Je comprends la nature et le motif de ma participation au projet et ai eu l'occasion de poser des questions auxquelles j'ai reçu une réponse satisfaisante. Par la présente, j'accepte librement de participer au projet.

Nom et prénom :

Date :

Signature :

Nous déclarons être responsables du déroulement du présent projet de recherche. Nous nous engageons à respecter les obligations énoncées dans ce document et également à vous informer de tout élément qui serait susceptible de modifier la nature de votre consentement.

Nom et prénom du Promoteur : Belche Jean-Luc

Date :

Signature :

Nom et prénom de l'étudiant réalisant le travail de fin d'étude : Vanhaelen Alix

Date :

Signature :

Annexe 8. Document de consentement de la Fédération des maisons médicales

FÉDÉRATION
MAISONS
MÉDICALES
santé et solidarité

Document de consentement pour l'utilisation de données de votre dossier santé

« La maison médicale ....s'engage à respecter la réglementation en vigueur applicable au traitement de données à caractère personnel et, en particulier, le règlement européen 2016/679 entré en vigueur le 25 mai 2018. Cela signifie que la maison médicale..... s'engage à vous informer quant à l'utilisation de vos données personnelles et à respecter vos droits. D'autre part, la Fédération des maisons médicales, sous-traitant de votre maison médicale sur certaines questions de statistiques, s'engage également à respecter vos droits, en accord avec le Règlement Générale de Protection des Données. »

La Fédération des maisons médicales récolte et analyse des données prélevées dans les dossiers de santé informatisés des patients de l'ensemble des maisons médicales membre de la fédération. Mais cela ne sera jamais fait sans votre accord !

Votre maison médicale enverra vos données à la fédération uniquement si vous avez donné votre consentement.

Lisez attentivement les explications ci-dessous et posez toutes questions nécessaires à votre maison médicale avant de remplir ce document.

Qu'est-ce que la fédération ?

Il y a des maisons médicales et des associations de santé intégrée un peu partout en Belgique. Elles se rencontrent, elles discutent ensemble de leur travail, et elles se sont regroupées en une fédération, la Fédération des maisons médicales. La Fédération des maisons médicales regroupe plus de 110 maisons médicales comme la vôtre localisées à Bruxelles et en Wallonie.

Quelles données sont collectées ?

Une partie de vos données administratives et de santé seront collectées à l'exception de l'ensemble des données permettant une identification directe (nom, prénom, numéro de téléphone, adresse, date de naissance). Ceci dans le but de conserver votre anonymat.

Quelle est la finalité de cette collecte de données ?

Le but est de nous aider à objectiver les problématiques rencontrées en maison médicale, améliorer les pratiques dans les équipes, fournir des informations sur les soins de première ligne et obtenir des éléments concrets pour défendre le modèle des maisons médicales.

- *Pour mieux connaitre l'état de santé des personnes qui fréquentent les maisons médicales et les associations de santé intégrée ; essayer de savoir si elles ont des caractéristiques particulières ; voir quels sont les résultats de certains programmes que nous menons (par exemple la campagne de vaccination contre la grippe, le suivi des patients diabétiques, ...).*
- *Pour pouvoir évaluer rapidement et efficacement la qualité des soins que vous recevez.*
- *Pour chercher des systèmes d'organisation, de payement, de coordination qui donnent les meilleurs résultats.*

FÉDÉRATION DES MAISONS MÉDICALES et des collectifs de santé francophones asbl
boulevard du Midi 25/5 - 1000 Bruxelles ■ 02 514 40 14 ■ fmm@fmm.be ■ www.maisonmedicale.org

FÉDÉRATION
MAISONS
MÉDICALES
santé et solidarité

Qui aura accès à mes données ?

Uniquement les personnes qui travaillent au service d'études de la Fédération.
Des mesures sont prises pour empêcher l'accès de ces données à des personnes extérieures. Vos données seront conservées dans un environnement sécurisé.
De plus, la Fédération des maisons médicales s'engage à ne pas vendre, échanger, transférer ou donner vos données à une autre association.

Puis-je refuser que mes données soient transmises à la fédération ?

Le formulaire ci-dessous vous donne la possibilité de refuser le transfert de vos données. Ce refus n'aura aucun impact sur votre prise en charge au sein de la maison médicale.

Puis-je retirer mon consentement ?

Oui. A tout moment, vous pouvez demander à votre maison médicale le retrait de votre consentement. Celui-ci aura un effet immédiat.

Pour pouvoir envoyer vos données à la Fédération des maisons médicales, nous vous demandons votre accord :

Je, soussigné

Mr/Mme/Mlle* .....

autorise / n'autorise pas (barrez la mention inutile)

la maison médicale / l'association de santé intégrée à transmettre à la Fédération des maisons médicales, des données de mon dossier de santé /du dossier de santé de mon enfant ..... (barrez la mention inutile et complétez le nom de l'enfant si nécessaire).

Date et signature

* à partir de 16 ans

FÉDÉRATION DES MAISONS MÉDICALES et des collectifs de santé francophones asbl
boulevard du Midi 25/5 - 1000 Bruxelles ■ 02 514 40 14 ■ fmm@fmm.be ■ www.maisonmedicale.org

Annexe 9. Illustration statistique

Introduction

Comme la collecte des données n'a pu avoir lieu, il n'est pas possible d'avoir de résultats préliminaires.
Pour illustrer ce qui aurait été fait, des données sur les rendez-vous manqués en libre accès sur le site Kaggle ont été utilisées (disponibles au lien suivant : https://www.kaggle.com/joniarroba/noshowappointments). Il s'agirait de données de soins primaires venant du Brésil. L'origine et la fiabilité des données sont à prendre avec beaucoup de prudence. L'objectif est ici d'illustrer ce qui aurait été fait.

Matériel et méthodes

La méthode utilisée est décrite dans le point 3.6.
Malheureusement, ces données ne permettent d'analyser que trois des variables sélectionnées pour l'étude, à savoir : l'âge, le sexe et les délais de rendez-vous.
La base de données contient 110.527 observations.
Il n'y a pas de données manquantes, les modèles et analyses statistiques sont donc réalisés sur la totalité des observations.
Les résultats significatifs sont en italique dans les tableaux. Le seuil de significativité est de 0,05 pour toutes les analyses.

Résultats

La prévalence de rendez-vous manqués est de 20,2% dans l'échantillon.
L'investigation de la normalité des variables *Âge* et *Délais* montre que la variable continue *Âge* suit une distribution normale tandis que la variable continue *Délais* ne le fait pas.

Les statistiques descriptives sont présentées en détail dans la table 1.

L'**âge** est en moyenne de 37,1 ans dans l'échantillon total, de 37,8 ans parmi les personnes qui n'ont pas manqué de rendez-vous et de 34,3 ans parmi celles qui ont raté un rendez-vous.

Les **délais** sont en moyenne de 11,2 jours, avec 16,8 jours parmi les rendez-vous manqués et 9,7 jours parmi les rendez-vous prestés.

Concernant le **sexe**, 35% de l'échantillon est masculin et 65% féminin. Parmi les 35% d'hommes, 7% ont manqué un rendez-vous et 28% n'en ont pas manqué. Alors que chez les 65% de femmes, 13,2% en ont manqué un tandis que 51,8% non.

Les analyses ne concluent pas à une association significative entre le sexe et le fait que le rendez-vous soit manqué ou non (p=0,17). Par contre, il existe une association significative entre le fait de manquer un rendez-vous et les variables « âge » (p<0,01) et « délais » (p<0,01).

Table 1. Caractéristiques de l'échantillon total, dans les deux groupes et p-valeur associée

		Rendez-vous manqué		
	Total	**Non**	**Oui**	**p-valeur***
Total (%)		88.208 (79,81)	22.319 (20,19)	
Âge (années) (moyenne +- SD)	37,09 +- 23,11	37,79 +- 23,34	34,32 +- 21,97	*< 0,01*
Délais (jours)	11,18	9,7	16,8	*< 0,01*
(moyenne p25-p75)	(1,00–16,00)	(1,00–13,00)	(5,00–24,00)	
Sexe (n,%)				0,17
Masculin	38.687 (35,00)	30.962 (28,01)	7.725 (6,99)	
Féminin	71.840 (65,00)	57.246 (51,79)	14.594 (13,20)	

**p-valeur via test t de Student pour l'âge, Mann-Withney pour les délais, Chi Carré pour le sexe*

En table 2, les résultats des différents modèles sont présentés sous forme d'Odd ratio avec l'intervalle de confiance à 95% correspondant. Le modèle de sélection manuelle ne retient que les deux variables significatives lors de la régression univariée : l'âge et les délais. Tandis que les trois méthodes de sélection systématique (backward, forward et stepwise) retiennent les trois variables.

Vu le nombre élevé d'observations, les odd ratio sont les mêmes dans les différents modèles réalisés. Dans tous les modèles, l'âge est significativement associé à la probabilité de manquer un rendez-vous. En effet, pour chaque année supplémentaire, le sujet a 1% de risque en moins de rater le rendez-vous (OR 0,99 (0,99-0,99)). Dans tous les modèles, les délais sont associés

significativement à la probabilité de manquer un rendez-vous. Pour chaque jour supplémentaire entre la prise de rendez-vous et le rendez-vous, la personne présente 3% de risque supplémentaire de manquer le rendez-vous (OR 1,03 (1,03-1,03)). Dans les trois modèles de sélection systématique, le sexe est significativement associé à la probabilité de rater un rendez-vous. En comparaison aux femmes, les hommes ont 4% de risque en moins de rater un rendez-vous (OR 0,96 (0,93-0,99). Les intervalles de confiance sont très étroits, ceci est dû au grand nombre d'observations (N=110.527) qui augmente la puissance de l'étude et la précision de l'estimation des Odd ratio.

Table 2. Régressions logistiques binaires univariées et multivariées à propos de la probabilité de manquer un rendez-vous : Odd ratio et intervalle de confiance à 95%

	Univariée	**Multivariée**	
		Sélection manuelle	**Backward / Forward / Stepwise**
	OR (IC 95%)	**OR (IC 95%)**	**OR (IC 95%)**
Âge	*0,99 (0,99-0,99)*	*0,99 (0,99-0,99)*	*0,99 (0,99-0,99)*
Délais	*1,03 (1,03-1,03)*	*1,03 (1,03-1,03)*	*1,03 (1,03-1,03)*
Sexe			
Homme VS Femme	0,98 (0,95-1,01)		*0,96 (0,93-0,99)*

Table 3. Caractéristiques des modèles

	Sélection manuelle	**Sélection automatique**
AIC	107.333	107.329
Taux de concordance	65,8	65,8
Taux de discordance	34,1	34,1
Indice C Hosmer - Lemeshow	1.303	1.296

Les caractéristiques des modèles sont présentées en table 3. Suite au grand nombre d'observations (N = 110.527), le taux de concordance de 65,8 et celui de discordance de 34,1 sont les mêmes dans les différents modèles. La valeur d'AIC est légèrement inférieure et donc meilleure parmi les modèles de sélection automatique (107.329) que par sélection manuelle (107.333). L'indice C d'Hosmer et Lemeshow est meilleur dans le cas des sélections automatiques (1.296) que dans le cas de la sélection manuelle (1.303). Les valeurs d'AIC et de l'indice C d'Hosmer – Lemeshow sont assez proches.

Discussion

Comme il n'y a pas de données manquantes et que les modèles sont construits selon la même combinaison de variables, les OR présentent les mêmes valeurs dans les différents modèles. Par ailleurs, les taux de concordance et discordance sont les mêmes dans tous les modèles. Les valeurs d'AIC et de l'indice C d'Hosmer – Lemeshow sont proches entre les modèles par sélection automatique et manuelle.

La procédure de sélection automatique *Backward* est adaptée pour les grands échantillons comme dans notre étude (N=110.527). Le choix du modèle se base également sur ce qui a déjà été montré dans la littérature. La différence entre les modèles est de l'intégration de la variable *Sexe* par sélection automatique. Dans la littérature, l'association de cette variable avec la probabilité de manquer un rendez-vous est controversée. En effet, comme décrit dans la revue systématique de ce mémoire, les études arrivent à des conclusions opposées. Vu que les données utilisées pour ces analyses statistiques ne correspondent pas au contexte spécifique de la patientèle des maisons médicales en Belgique, il parait plus pertinent de ne pas retenir la variable *Sexe* et donc de privilégier le modèle par sélection manuelle.

Selon ce modèle, les rendez-vous sont plus susceptibles d'être manqués suite à de longs délais de rendez-vous et par un patient jeune.

Conclusion

Les rendez-vous sont plus susceptibles d'être manqués suite à de longs délais de rendez-vous et par un patient jeune. Pour diminuer le nombre de rendez-vous manqués, l'organisation pourrait envisager de réduire les délais de prise de rendez-vous et cibler une conscientisation de la patientèle plus jeune.

Nous insistons sur le fait que les données retenues ici ne servent qu'à illustrer ce qui aurait été fait et que ces conclusions ne sont pas généralisables au contexte particulier de notre question de recherche en maison médicale en Belgique.

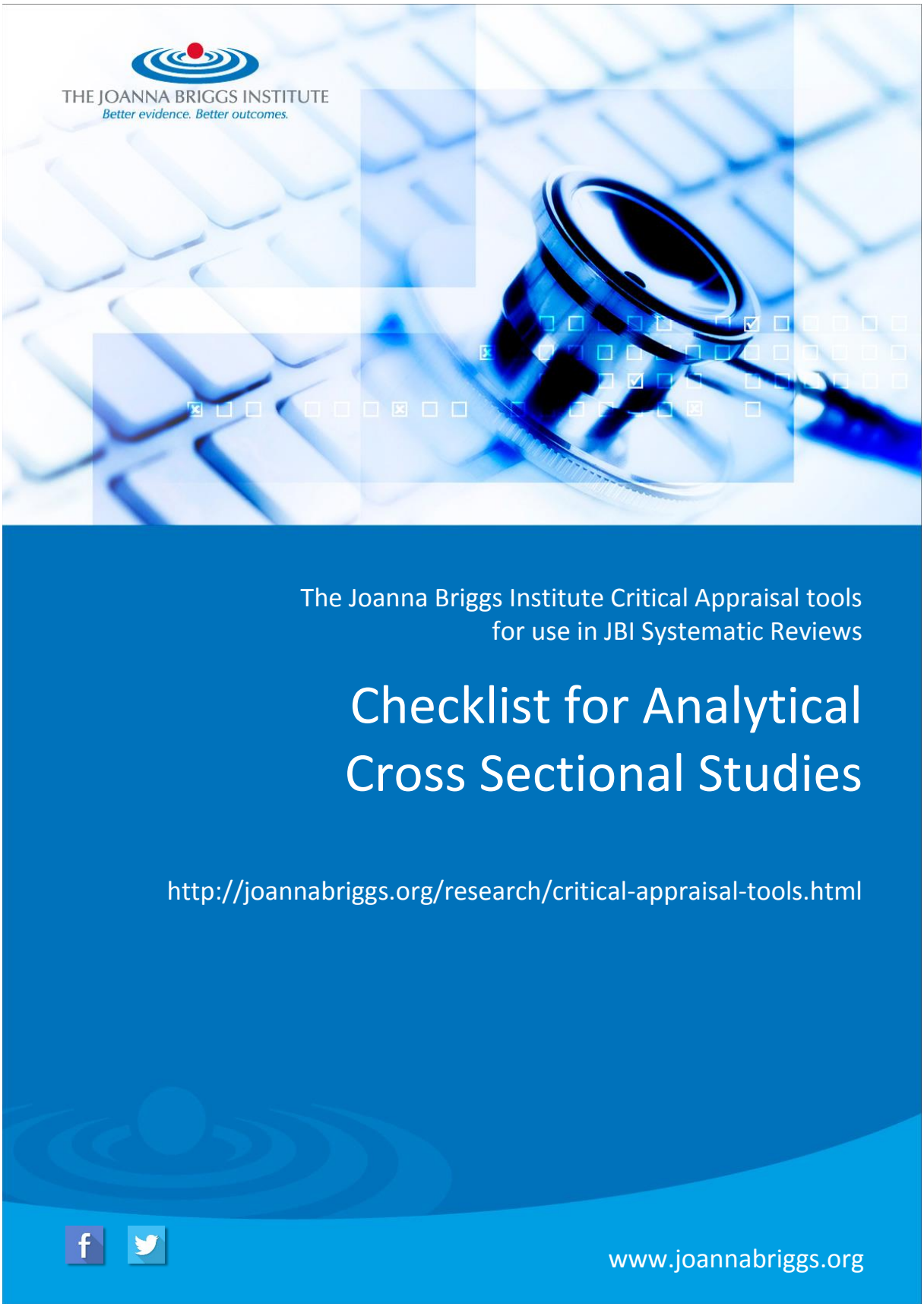
Annexe 10. Évaluation de la qualité de la partie quantitative, qualitative et de la revue systématique

	partie quantitative	*partie qualitative*	*revue systématique*
JBI	transversale	qualitative	Revue systématique
Item 1	Yes	Yes	Yes
Item 2	Yes	Yes	Yes
Item 3	Yes	Yes	Yes
Item 4	Not App	Not App	Yes
Item 5	Unclear	Not App	Yes
Item 6	Unclear	No	No
Item 7	Yes	No	No
Item 8	Yes	Yes	Unclear
Item 9	/	Yes	No
Item 10	/	Not App	Yes
Item 11	/	/	Yes
Nombre Yes	5	5	7
Qualité	moyenne	moyenne	moyenne

Annexe 11. Évaluation du risque de biais de la revue systématique (ROBIS)

Domain 1 : study eligibility criteria	1.1	Yes
	1.2	Yes
	1.3	Yes
	1.4	No
	1.5	Yes
Concerns		**Low**
Domain 2: Identification and selection of studies	2.1	Yes
	2.2	Yes
	2.3	Probably yes
	2.4	Yes
	2.5	Probably yes
Concerns		**Low**
Domain 3: data collection and study appraisal	3.1	No
	3.2	Yes
	3.3	Yes
	3.4	Yes
	3.5	No
Concerns		**Unclear**
Domain 4: Synthesis and findings	4.1	Yes
	4.2	No
	4.3	Probably yes
	4.4	Probably yes
	4.5	No
	4.6	Yes
Concerns		**Unclear**
Risk of bias in the review	A	Probably yes
	B	Yes
	C	Yes
Risk of bias in the review		**Low**

Annexe 12. Échelles utilisées



THE JOANNA BRIGGS INSTITUTE

The Joanna Briggs Institute

Introduction

The Joanna Briggs Institute (JBI) is an international, membership based research and development organization within the Faculty of Health Sciences at the University of Adelaide. The Institute specializes in promoting and supporting evidence-based healthcare by providing access to resources for professionals in nursing, midwifery, medicine, and allied health. With over 80 collaborating centres and entities, servicing over 90 countries, the Institute is a recognized global leader in evidence-based healthcare.

JBI Systematic Reviews

The core of evidence synthesis is the systematic review of literature of a particular intervention, condition or issue. The systematic review is essentially an analysis of the available literature (that is, evidence) and a judgment of the effectiveness or otherwise of a practice, involving a series of complex steps. The JBI takes a particular view on what counts as evidence and the methods utilized to synthesize those different types of evidence. In line with this broader view of evidence, the Institute has developed theories, methodologies and rigorous processes for the critical appraisal and synthesis of these diverse forms of evidence in order to aid in clinical decision-making in health care. There now exists JBI guidance for conducting reviews of effectiveness research, qualitative research, prevalence/incidence, etiology/risk, economic evaluations, text/opinion, diagnostic test accuracy, mixed-methods, umbrella reviews and scoping reviews. Further information regarding JBI systematic reviews can be found in the JBI Reviewer's Manual on our website.

JBI Critical Appraisal Tools

All systematic reviews incorporate a process of critique or appraisal of the research evidence. The purpose of this appraisal is to assess the methodological quality of a study and to determine the extent to which a study has addressed the possibility of bias in its design, conduct and analysis. All papers selected for inclusion in the systematic review (that is – those that meet the inclusion criteria described in the protocol) need to be subjected to rigorous appraisal by two critical appraisers. The results of this appraisal can then be used to inform synthesis and interpretation of the results of the study. JBI Critical appraisal tools have been developed by the JBI and collaborators and approved by the JBI Scientific Committee following extensive peer review. Although designed for use in systematic reviews, JBI critical appraisal tools can also be used when creating Critically Appraised Topics (CAT), in journal clubs and as an educational tool.

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JBI Critical Appraisal Checklist for Analytical Cross Sectional Studies

Reviewer_____Date_____

Author _____Year_____Record Number_____.

	Yes	No	Unclear	Not applicable
1. Were the criteria for inclusion in the sample clearly defined?	☐	☐	☐	☐
2. Were the study subjects and the setting described in detail?	☐	☐	☐	☐
3. Was the exposure measured in a valid and reliable way?	☐	☐	☐	☐
4. Were objective, standard criteria used for measurement of the condition?	☐	☐	☐	☐
5. Were confounding factors identified?	☐	☐	☐	☐
6. Were strategies to deal with confounding factors stated?	☐	☐	☐	☐
7. Were the outcomes measured in a valid and reliable way?	☐	☐	☐	☐
8. Was appropriate statistical analysis used?	☐	☐	☐	☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info ☐

Comments (Including reason for exclusion)

_____

_____

_____

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Explanation of analytical cross sectional studies critical appraisal

How to cite: Moola S, Munn Z, Tufanaru C, Aromataris E, Sears K, Sfetcu R, Currie M, Qureshi R, Mattis P, Lisy K, Mu P-F. Chapter 7: Systematic reviews of etiology and risk . In: Aromataris E, Munn Z (Editors). *Joanna Briggs Institute Reviewer's Manual.* The Joanna Briggs Institute, 2017. Available from https://reviewersmanual.joannabriggs.org/

Analytical cross sectional studies Critical Appraisal Tool

Answers: Yes, No, Unclear or Not/Applicable

1. **Were the criteria for inclusion in the sample clearly defined?**

   The authors should provide clear inclusion and exclusion criteria that they developed prior to recruitment of the study participants. The inclusion/exclusion criteria should be specified (e.g., risk, stage of disease progression) with sufficient detail and all the necessary information critical to the study.

2. **Were the study subjects and the setting described in detail?**

   The study sample should be described in sufficient detail so that other researchers can determine if it is comparable to the population of interest to them. The authors should provide a clear description of the population from which the study participants were selected or recruited, including demographics, location, and time period.

3. **Was the exposure measured in a valid and reliable way?**

   The study should clearly describe the method of measurement of exposure. Assessing validity requires that a 'gold standard' is available to which the measure can be compared. The validity of exposure measurement usually relates to whether a current measure is appropriate or whether a measure of past exposure is needed.
   Reliability refers to the processes included in an epidemiological study to check repeatability of measurements of the exposures. These usually include intra-observer reliability and inter-observer reliability.

4. **Were objective, standard criteria used for measurement of the condition?**

   It is useful to determine if patients were included in the study based on either a specified diagnosis or definition. This is more likely to decrease the risk of bias. Characteristics are another useful approach to matching groups, and studies that did not use specified diagnostic methods or definitions should provide evidence on matching by key characteristics.

5. Were confounding factors identified?

Confounding has occurred where the estimated intervention exposure effect is biased by the presence of some difference between the comparison groups (apart from the exposure investigated/of interest). Typical confounders include baseline characteristics, prognostic factors, or concomitant exposures (e.g. smoking). A confounder is a difference between the comparison groups and it influences the direction of the study results. A high quality study at the level of cohort design will identify the potential confounders and measure them (where possible). This is difficult for studies where behavioral, attitudinal or lifestyle factors may impact on the results.

6. Were strategies to deal with confounding factors stated?

Strategies to deal with effects of confounding factors may be dealt within the study design or in data analysis. By matching or stratifying sampling of participants, effects of confounding factors can be adjusted for. When dealing with adjustment in data analysis, assess the statistics used in the study. Most will be some form of multivariate regression analysis to account for the confounding factors measured.

7. Were the outcomes measured in a valid and reliable way?

Read the methods section of the paper. If for e.g. lung cancer is assessed based on existing definitions or diagnostic criteria, then the answer to this question is likely to be yes. If lung cancer is assessed using observer reported, or self-reported scales, the risk of over- or under-reporting is increased, and objectivity is compromised. Importantly, determine if the measurement tools used were validated instruments as this has a significant impact on outcome assessment validity.
Having established the objectivity of the outcome measurement (e.g. lung cancer) instrument, it's important to establish how the measurement was conducted. Were those involved in collecting data trained or educated in the use of the instrument/s? (e.g. radiographers). If there was more than one data collector, were they similar in terms of level of education, clinical or research experience, or level of responsibility in the piece of research being appraised?

8. Was appropriate statistical analysis used?

As with any consideration of statistical analysis, consideration should be given to whether there was a more appropriate alternate statistical method that could have been used. The methods section should be detailed enough for reviewers to identify which analytical techniques were used (in particular, regression or stratification) and how specific confounders were measured.

For studies utilizing regression analysis, it is useful to identify if the study identified which variables were included and how they related to the outcome. If stratification was the analytical approach used, were the strata of analysis defined by the specified variables? Additionally, it is also important to assess the appropriateness of the analytical strategy in terms of the assumptions associated with the approach as differing methods of analysis are based on differing assumptions about the data and how it will respond.

The Joanna Briggs Institute Critical Appraisal tools
for use in JBI Systematic Reviews

Checklist for Cohort Studies

http://joannabriggs.org/research/critical-appraisal-tools.html

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Introduction

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JBI Critical Appraisal Checklist for Cohort Studies

Reviewer_____Date_____

Author _____Year_____Record Number_____

	Yes	No	Unclear	Not applicable
1. Were the two groups similar and recruited from the same population?	☐	☐	☐	☐
2. Were the exposures measured similarly to assign people to both exposed and unexposed groups?	☐	☐	☐	☐
3. Was the exposure measured in a valid and reliable way?	☐	☐	☐	☐
4. Were confounding factors identified?	☐	☐	☐	☐
5. Were strategies to deal with confounding factors stated?	☐	☐	☐	☐
6. Were the groups/participants free of the outcome at the start of the study (or at the moment of exposure)?	☐	☐	☐	☐
7. Were the outcomes measured in a valid and reliable way?	☐	☐	☐	☐
8. Was the follow up time reported and sufficient to be long enough for outcomes to occur?	☐	☐	☐	☐
9. Was follow up complete, and if not, were the reasons to loss to follow up described and explored?	☐	☐	☐	☐
10. Were strategies to address incomplete follow up utilized?	☐	☐	☐	☐
11. Was appropriate statistical analysis used?	☐	☐	☐	☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info ☐

Comments (Including reason for exclusion)

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Explanation of cohort studies critical appraisal

Moola S, Munn Z, Tufanaru C, Aromataris E, Sears K, Sfetcu R, Currie M, Qureshi R, Mattis P, Lisy K, Mu P-F. Chapter 7: Systematic reviews of etiology and risk . In: Aromataris E, Munn Z (Editors). *Joanna Briggs Institute Reviewer's Manual.* The Joanna Briggs Institute, 2017. Available from https://reviewersmanual.joannabriggs.org/

Cohort studies Critical Appraisal Tool

Answers: Yes, No, Unclear or Not/Applicable

1. **Were the two groups similar and recruited from the same population?**

   Check the paper carefully for descriptions of participants to determine if patients within and across groups have similar characteristics in relation to exposure (e.g. risk factor under investigation). The two groups selected for comparison should be as similar as possible in all characteristics except for their exposure status, relevant to the study in question. The authors should provide clear inclusion and exclusion criteria that they developed prior to recruitment of the study participants.

2. **Were the exposures measured similarly to assign people to both exposed and unexposed groups?**

   A high quality study at the level of cohort design should mention or describe how the exposures were measured. The exposure measures should be clearly defined and described in detail. This will enable reviewers to assess whether or not the participants received the exposure of interest.

3. **Was the exposure measured in a valid and reliable way?**

   The study should clearly describe the method of measurement of exposure. Assessing validity requires that a 'gold standard' is available to which the measure can be compared. The validity of exposure measurement usually relates to whether a current measure is appropriate or whether a measure of past exposure is needed.

   Reliability refers to the processes included in an epidemiological study to check repeatability of measurements of the exposures. These usually include intra-observer reliability and inter-observer reliability.

4. **Were confounding factors identified?**

   Confounding has occurred where the estimated intervention exposure effect is biased by the presence of some difference between the comparison groups (apart from the exposure investigated/of interest). Typical confounders include baseline characteristics, prognostic

factors, or concomitant exposures (e.g. smoking). A confounder is a difference between the comparison groups and it influences the direction of the study results. A high quality study at the level of cohort design will identify the potential confounders and measure them (where possible). This is difficult for studies where behavioral, attitudinal or lifestyle factors may impact on the results.

5. **Were strategies to deal with confounding factors stated?**

   Strategies to deal with effects of confounding factors may be dealt within the study design or in data analysis. By matching or stratifying sampling of participants, effects of confounding factors can be adjusted for. When dealing with adjustment in data analysis, assess the statistics used in the study. Most will be some form of multivariate regression analysis to account for the confounding factors measured. Look out for a description of statistical methods as regression methods such as logistic regression are usually employed to deal with confounding factors/variables of interest.

6. **Were the groups/participants free of the outcome at the start of the study (or at the moment of exposure)?**

   The participants should be free of the outcomes of interest at the start of the study. Refer to the 'methods' section in the paper for this information, which is usually found in descriptions of participant/sample recruitment, definitions of variables, and/or inclusion/exclusion criteria.

7. **Were the outcomes measured in a valid and reliable way?**

   Read the methods section of the paper. If for e.g. lung cancer is assessed based on existing definitions or diagnostic criteria, then the answer to this question is likely to be yes. If lung cancer is assessed using observer reported, or self-reported scales, the risk of over- or under-reporting is increased, and objectivity is compromised. Importantly, determine if the measurement tools used were validated instruments as this has a significant impact on outcome assessment validity.

   Having established the objectivity of the outcome measurement (e.g. lung cancer) instrument, it's important to establish how the measurement was conducted. Were those involved in collecting data trained or educated in the use of the instrument/s? (e.g. radiographers). If there was more than one data collector, were they similar in terms of level of education, clinical or research experience, or level of responsibility in the piece of research being appraised?

8. **Was the follow up time reported and sufficient to be long enough for outcomes to occur?**

   The appropriate length of time for follow up will vary with the nature and characteristics of the population of interest and/or the intervention, disease or exposure. To estimate an appropriate duration of follow up, read across multiple papers and take note of the range for duration of follow up. The opinions of experts in clinical practice or clinical research may also assist in determining an appropriate duration of follow up. For example, a longer timeframe may be needed to examine the association between occupational exposure to asbestos and the risk of lung cancer. It is important, particularly in cohort studies that follow up is long enough to enable the outcomes. However, it should be remembered that the research question and outcomes being examined would probably dictate the follow up time.

9. **Was follow up complete, and if not, were the reasons to loss to follow up described and explored?**

   It is important in a cohort study that a greater percentage of people are followed up. As a general guideline, at least 80% of patients should be followed up. Generally a dropout rate of 5% or less is considered insignificant. A rate of 20% or greater is considered to significantly impact on the validity of the study. However, in observational studies conducted over a lengthy period of time a higher dropout rate is to be expected. A decision on whether to include or exclude a study because of a high dropout rate is a matter of judgement based on the reasons why people dropped out, and whether dropout rates were comparable in the exposed and unexposed groups.

   Reporting of efforts to follow up participants that dropped out may be regarded as an indicator of a well conducted study. Look for clear and justifiable description of why people were left out, excluded, dropped out etc. If there is no clear description or a statement in this regards, this will be a 'No'.

10. **Were strategies to address incomplete follow up utilized?**

    Some people may withdraw due to change in employment or some may die; however, it is important that their outcomes are assessed. Selection bias may occur as a result of incomplete follow up. Therefore, participants with unequal follow up periods must be taken into account in the analysis, which should be adjusted to allow for differences in length of follow up periods. This is usually done by calculating rates which use person-years at risk, i.e. considering time in the denominator.

11. Was appropriate statistical analysis used?

As with any consideration of statistical analysis, consideration should be given to whether there was a more appropriate alternate statistical method that could have been used. The methods section of cohort studies should be detailed enough for reviewers to identify which analytical techniques were used (in particular, regression or stratification) and how specific confounders were measured.

For studies utilizing regression analysis, it is useful to identify if the study identified which variables were included and how they related to the outcome. If stratification was the analytical approach used, were the strata of analysis defined by the specified variables? Additionally, it is also important to assess the appropriateness of the analytical strategy in terms of the assumptions associated with the approach as differing methods of analysis are based on differing assumptions about the data and how it will respond.

The Joanna Briggs Institute Critical Appraisal tools
for use in JBI Systematic Reviews

Checklist for Case Control Studies

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Reviewer_____Date_____

Author _____Year_____Record Number_____

	Yes	No	Unclear	Not applicable
1. Were the groups comparable other than the presence of disease in cases or the absence of disease in controls?	☐	☐	☐	☐
2. Were cases and controls matched appropriately?	☐	☐	☐	☐
3. Were the same criteria used for identification of cases and controls?	☐	☐	☐	☐
4. Was exposure measured in a standard, valid and reliable way?	☐	☐	☐	☐
5. Was exposure measured in the same way for cases and controls?	☐	☐	☐	☐
6. Were confounding factors identified?	☐	☐	☐	☐
7. Were strategies to deal with confounding factors stated?	☐	☐	☐	☐
8. Were outcomes assessed in a standard, valid and reliable way for cases and controls?	☐	☐	☐	☐
9. Was the exposure period of interest long enough to be meaningful?	☐	☐	☐	☐
10. Was appropriate statistical analysis used?	☐	☐	☐	☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info ☐

Comments (Including reason for exclusion)

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Explanation of case control studies critical appraisal

How to cite: Moola S, Munn Z, Tufanaru C, Aromataris E, Sears K, Sfetcu R, Currie M, Qureshi R, Mattis P, Lisy K, Mu P-F. Chapter 7: Systematic reviews of etiology and risk . In: Aromataris E, Munn Z (Editors). *Joanna Briggs Institute Reviewer's Manual.* The Joanna Briggs Institute, 2017. Available from https://reviewersmanual.joannabriggs.org/

Case Control Studies Critical Appraisal Tool

Answers: Yes, No, Unclear or Not/Applicable

1. **Were the groups comparable other than presence of disease in cases or absence of disease in controls?**

The control group should be representative of the source population that produced the cases. This is usually done by individual matching; wherein controls are selected for each case on the basis of similarity with respect to certain characteristics other than the exposure of interest. Frequency or group matching is an alternative method. Selection bias may result if the groups are not comparable.

2. **Were cases and controls matched appropriately?**

As in item 1, the study should include clear definitions of the source population. Sources from which cases and controls were recruited should be carefully looked at. For example, cancer registries may be used to recruit participants in a study examining risk factors for lung cancer, which typify population-based case control studies. Study participants may be selected from the target population, the source population, or from a pool of eligible participants (such as in hospital-based case control studies).

3. **Were the same criteria used for identification of cases and controls?**

It is useful to determine if patients were included in the study based on either a specified diagnosis or definition. This is more likely to decrease the risk of bias. Characteristics are another useful approach to matching groups, and studies that did not use specified diagnostic methods or definitions should provide evidence on matching by key characteristics. A case should be defined clearly. It is also important that controls must fulfil all the eligibility criteria defined for the cases except for those relating to diagnosis of the disease.

4. **Was exposure measured in a standard, valid and reliable way?**

The study should clearly describe the method of measurement of exposure. Assessing validity requires that a 'gold standard' is available to which the measure can be compared. The validity

of exposure measurement usually relates to whether a current measure is appropriate or whether a measure of past exposure is needed.

Case control studies may investigate many different 'exposures' that may or may not be associated with the condition. In these cases, reviewers should use the main exposure of interest for their review to answer this question when using this tool at the study level.

Reliability refers to the processes included in an epidemiological study to check repeatability of measurements of the exposures. These usually include intra-observer reliability and inter-observer reliability.

5. Was exposure measured in the same way for cases and controls?

As in item 4, the study should clearly describe the method of measurement of exposure. The exposure measures should be clearly defined and described in detail. Assessment of exposure or risk factors should have been carried out according to same procedures or protocols for both cases and controls.

6. Were confounding factors identified?

Confounding has occurred where the estimated intervention exposure effect is biased by the presence of some difference between the comparison groups (apart from the exposure investigated/of interest). Typical confounders include baseline characteristics, prognostic factors, or concomitant exposures (e.g. smoking). A confounder is a difference between the comparison groups and it influences the direction of the study results. A high quality study at the level of case control design will identify the potential confounders and measure them (where possible). This is difficult for studies where behavioral, attitudinal or lifestyle factors may impact on the results.

7. Were strategies to deal with confounding factors stated?

Strategies to deal with effects of confounding factors may be dealt within the study design or in data analysis. By matching or stratifying sampling of participants, effects of confounding factors can be adjusted for. When dealing with adjustment in data analysis, assess the statistics used in the study. Most will be some form of multivariate regression analysis to account for the confounding factors measured. Look out for a description of statistical methods as regression methods such as logistic regression are usually employed to deal with confounding factors/ variables of interest.

8. Were outcomes assessed in a standard, valid and reliable way for cases and controls?

Read the methods section of the paper. If for e.g. lung cancer is assessed based on existing definitions or diagnostic criteria, then the answer to this question is likely to be yes. If lung cancer is assessed using observer reported, or self-reported scales, the risk of over- or under-

reporting is increased, and objectivity is compromised. Importantly, determine if the measurement tools used were validated instruments as this has a significant impact on outcome assessment validity.

Having established the objectivity of the outcome measurement (e.g. lung cancer) instrument, it's important to establish how the measurement was conducted. Were those involved in collecting data trained or educated in the use of the instrument/s? (e.g. radiographers). If there was more than one data collector, were they similar in terms of level of education, clinical or research experience, or level of responsibility in the piece of research being appraised?

9. Was the exposure period of interest long enough to be meaningful?

It is particularly important in a case control study that the exposure time was sufficient enough to show an association between the exposure and the outcome. It may be that the exposure period may be too short or too long to influence the outcome.

10. Was appropriate statistical analysis used?

As with any consideration of statistical analysis, consideration should be given to whether there was a more appropriate alternate statistical method that could have been used. The methods section should be detailed enough for reviewers to identify which analytical techniques were used (in particular, regression or stratification) and how specific confounders were measured.

For studies utilizing regression analysis, it is useful to identify if the study identified which variables were included and how they related to the outcome. If stratification was the analytical approach used, were the strata of analysis defined by the specified variables? Additionally, it is also important to assess the appropriateness of the analytical strategy in terms of the assumptions associated with the approach as differing methods of analysis are based on differing assumptions about the data and how it will respond.

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Better evidence. Better outcomes.

The Joanna Briggs Institute Critical Appraisal tools
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Checklist for Qualitative Research

http://joannabriggs.org/research/critical-appraisal-tools.html

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JBI Critical Appraisal Checklist for Qualitative Research

Reviewer_____Date_____

Author _____Year_____Record Number _____

		Yes	No	Unclear	Not applicable
1.	Is there congruity between the stated philosophical perspective and the research methodology?	☐	☐	☐	☐
2.	Is there congruity between the research methodology and the research question or objectives?	☐	☐	☐	☐
3.	Is there congruity between the research methodology and the methods used to collect data?	☐	☐	☐	☐
4.	Is there congruity between the research methodology and the representation and analysis of data?	☐	☐	☐	☐
5.	Is there congruity between the research methodology and the interpretation of results?	☐	☐	☐	☐
6.	Is there a statement locating the researcher culturally or theoretically?	☐	☐	☐	☐
7.	Is the influence of the researcher on the research, and vice- versa, addressed?	☐	☐	☐	☐
8.	Are participants, and their voices, adequately represented?	☐	☐	☐	☐
9.	Is the research ethical according to current criteria or, for recent studies, and is there evidence of ethical approval by an appropriate body?	☐	☐	☐	☐
10.	Do the conclusions drawn in the research report flow from the analysis, or interpretation, of the data?	☐	☐	☐	☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info ☐

Comments (Including reason for exclusion)

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Discussion of Critical Appraisal Criteria

How to cite: Lockwood C, Munn Z, Porritt K. Qualitative research synthesis: methodological guidance for systematic reviewers utilizing meta-aggregation. Int J Evid Based Healthc. 2015;13(3):179–187.

1. **Congruity between the stated philosophical perspective and the research methodology**

   Does the report clearly state the philosophical or theoretical premises on which the study is based? Does the report clearly state the methodological approach adopted on which the study is based? Is there congruence between the two? For example:

   A report may state that the study adopted a critical perspective and participatory action research methodology was followed. Here there is congruence between a critical view (focusing on knowledge arising out of critique, action and reflection) and action research (an approach that focuses on firstly working with groups to reflect on issues or practices, then considering how they could be different; then acting to create a change; and finally identifying new knowledge arising out of the action taken). However, a report may state that the study adopted an interpretive perspective and used survey methodology. Here there is incongruence between an interpretive view (focusing on knowledge arising out of studying what phenomena mean to individuals or groups) and surveys (an approach that focuses on asking standard questions to a defined study population); a report may state that the study was qualitative or used qualitative methodology (such statements do not demonstrate rigour in design) or make no statement on philosophical orientation or methodology.

2. **Congruity between the research methodology and the research question or objectives**

   Is the study methodology appropriate for addressing the research question? For example: A report may state that the research question was to seek understandings of the meaning of pain in a group of people with rheumatoid arthritis and that a phenomenological approach was taken. Here, there is congruity between this question and the methodology. A report may state that the research question was to establish the effects of counselling on the severity of pain experience and that an ethnographic approach was pursued. A question that tries to establish cause-and effect cannot be addressed by using an ethnographic approach (as ethnography sets out to develop understandings of cultural practices) and thus, this would be incongruent.

3. **Congruity between the research methodology and the methods used to collect data**

   Are the data collection methods appropriate to the methodology? For example:

   A report may state that the study pursued a phenomenological approach and data was collected through phenomenological interviews. There is congruence between the methodology and data collection; a report may state that the study pursued a phenomenological approach and data was collected through a postal questionnaire. There is incongruence between the methodology and data collection here as phenomenology seeks to elicit rich descriptions of the experience of a phenomena that cannot be achieved through seeking written responses to standardized questions.

4. **Congruity between the research methodology and the representation and analysis of data**

   Are the data analyzed and represented in ways that are congruent with the stated methodological position? For example:

   A report may state that the study pursued a phenomenological approach to explore people's experience of grief by asking participants to describe their experiences of grief. If the text generated from asking these questions is searched to establish the meaning of grief to participants, and the meanings of all participants are included in the report findings, then this represents congruity; the same report may, however, focus only on those meanings that were common to all participants and discard single reported meanings. This would not be appropriate in phenomenological work.

5. **There is congruence between the research methodology and the interpretation of results**

   Are the results interpreted in ways that are appropriate to the methodology? For example:

   A report may state that the study pursued a phenomenological approach to explore people's experience of facial disfigurement and the results are used to inform practitioners about accommodating individual differences in care. There is congruence between the methodology and this approach to interpretation; a report may state that the study pursued a phenomenological approach to explore people's experience of facial disfigurement and the results are used to generate practice checklists for assessment. There is incongruence between the methodology and this approach to interpretation as phenomenology seeks to understand the meaning of a phenomenon for the study participants and cannot be interpreted to suggest that this can be generalized to total populations to a degree where standardized assessments will have relevance across a population.

6. **Locating the researcher culturally or theoretically**

   Are the beliefs and values, and their potential influence on the study declared? For example:

   The researcher plays a substantial role in the qualitative research process and it is important, in appraising evidence that is generated in this way, to know the researcher's cultural and theoretical orientation. A high quality report will include a statement that clarifies this.

7. **Influence of the researcher on the research, and vice-versa, is addressed**

   Is the potential for the researcher to influence the study and for the potential of the research process itself to influence the researcher and her/his interpretations acknowledged and addressed? For example:

   Is the relationship between the researcher and the study participants addressed? Does the researcher critically examine her/his own role and potential influence during data collection? Is it reported how the researcher responded to events that arose during the study?

8. **Representation of participants and their voices**

   Generally, reports should provide illustrations from the data to show the basis of their conclusions and to ensure that participants are represented in the report.

9. **Ethical approval by an appropriate body**

   A statement on the ethical approval process followed should be in the report.

10. **Relationship of conclusions to analysis, or interpretation of the data**

    This criterion concerns the relationship between the findings reported and the views or words of study participants. In appraising a paper, appraisers seek to satisfy themselves that the conclusions drawn by the research are based on the data collected; data being the text generated through observation, interviews or other processes.

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Checklist for Systematic Reviews and Research Syntheses

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JBI Critical Appraisal Checklist for Systematic Reviews and Research Syntheses

Reviewer_____Date_____

Author _____Year_____Record Number_____

		Yes	No	Unclear	Not applicable
1.	Is the review question clearly and explicitly stated?	☐	☐	☐	☐
2.	Were the inclusion criteria appropriate for the review question?	☐	☐	☐	☐
3.	Was the search strategy appropriate?	☐	☐	☐	☐
4.	Were the sources and resources used to search for studies adequate?	☐	☐	☐	☐
5.	Were the criteria for appraising studies appropriate?	☐	☐	☐	☐
6.	Was critical appraisal conducted by two or more reviewers independently?	☐	☐	☐	☐
7.	Were there methods to minimize errors in data extraction?	☐	☐	☐	☐
8.	Were the methods used to combine studies appropriate?	☐	☐	☐	☐
9.	Was the likelihood of publication bias assessed?	☐	☐	☐	☐
10.	Were recommendations for policy and/or practice supported by the reported data?	☐	☐	☐	☐
11.	Were the specific directives for new research appropriate?	☐	☐	☐	☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info ☐

Comments (Including reason for exclusion)

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THE JOANNA BRIGGS INSTITUTE

JBI Critical Appraisal Checklist for Systematic Reviews and Research Syntheses

How to cite: Aromataris E, Fernandez R, Godfrey C, Holly C, Kahlil H, Tungpunkom P. Summarizing systematic reviews: methodological development, conduct and reporting of an Umbrella review approach. Int J Evid Based Healthc. 2015;13(3):132-40.

When conducting an umbrella review using the JBI method, the critical appraisal instrument for Systematic Reviews should be used.

The primary and secondary reviewer should discuss each item in the appraisal instrument for each study included in their review. In particular, discussions should focus on what is considered acceptable to the aims of the review in terms of the specific study characteristics. When appraising systematic reviews this discussion may include issues such as what represents an adequate search strategy or appropriate methods of synthesis. The reviewers should be clear on what constitutes acceptable levels of information to allocate a positive appraisal compared with a negative, or response of "unclear". This discussion should ideally take place before the reviewers independently conduct the appraisal.

Within umbrella reviews, quantitative or qualitative systematic reviews may be incorporated, as well as meta-analyses of existing research. There are 11 questions to guide the appraisal of systematic reviews or meta-analyses. Each question should be answered as "yes", "no", or "unclear". Not applicable "NA" is also provided as an option and may be appropriate in rare instances.

1. **Is the review question clearly and explicitly stated?**
   The review question is an essential step in the systematic review process. A well-articulated question defines the scope of the review and aids in the development of the search strategy to locate the relevant evidence. An explicitly stated question, formulated around its PICO (Population, Intervention, Comparator, Outcome) elements aids both the review team in the conduct of the review and the reader in determining if the review has achieved its objectives. Ideally the review question should be articulated in a published protocol; however this will not always be the case with many reviews that are located.

2. **Were the inclusion criteria appropriate for the review question?**
   The inclusion criteria should be identifiable from, and match the review question. The necessary elements of the PICO should be explicit and clearly defined. The inclusion criteria should be detailed and the included reviews should clearly be eligible when matched against the stated inclusion criteria. Appraisers of meta-analyses will find that inclusion criteria may include criteria around the ability to conduct statistical analyses which would not be the norm for a systematic review. The types of included studies should be relevant to the review question, for example, an umbrella review aiming to summarize a range of effective non-pharmacological interventions for aggressive behaviors amongst elderly patients with dementia will limit itself to including systematic reviews and meta-analyses that synthesize quantitative studies assessing the various interventions; qualitative or economic reviews would not be included.

3. **Was the search strategy appropriate?**
   A systematic review should provide evidence of the search strategy that has been used to locate the evidence. This may be found in the methods section of the review report in some cases, or as an appendix that may be provided as supplementary information to the review publication. A systematic review should present a clear search strategy that addresses each of the identifiable PICO components of the review question. Some reviews may also provide a description of the approach to searching and how the terms that were ultimately used were derived, though due to limits on word counts in journals this may be more the norm in online only publications. There should be evidence of logical and relevant keywords and terms and also evidence that Subject Headings and Indexing terms have been used in the conduct of the search. Limits on the search should also be considered and their potential impact; for example, if a date limit was used, was this appropriate and/or justified? If only English language studies were included, will such a language bias have an impact on the review? The response to these considerations will depend, in part, on the review question.

4. **Were the sources and resources used to search for studies adequate?**
   A systematic review should attempt to identify “all” the available evidence and as such there should be evidence of a comprehensive search strategy. Multiple electronic databases should be searched including major bibliographic citation databases such as MEDLINE and CINAHL. Ideally, other databases that are relevant to the review question should also be searched, for example, a systematic review with a question about a physical therapy intervention should also look to search the PEDro database, whilst a review focusing on an educational intervention should also search the ERIC. Reviews of effectiveness should aim to search trial registries. A comprehensive search is the ideal way to minimize publication bias, as a result, a well conducted systematic review should also attempt to search for grey literature, or “unpublished” studies; this may involve searching websites relevant to the review question, or thesis repositories.

5. **Were the criteria for appraising studies appropriate?**
   The systematic review should present a clear statement that critical appraisal was conducted and provide the details of the items that were used to assess the included studies. This may be presented in the methods of the review, as an appendix of supplementary information, or as a reference to a source that can be located. The tools or instruments used should be appropriate for the review question asked and the type of research conducted. For example, a systematic review of effectiveness should present a tool or instrument that addresses aspects of validity for experimental studies and randomized controlled trials such as randomization and blinding – if the review includes observational research to answer the same question a different tool would be more appropriate. Similarly, a review assessing diagnostic test accuracy may refer to the recognized QUADAS[1] tool.

6. **Was critical appraisal conducted by two or more reviewers independently?**
   Critical appraisal or some similar assessment of the quality of the literature included in a systematic review is essential. A key characteristic to minimize bias or systematic error in the conduct of a systematic review is to have the critical appraisal of the included studies completed independently and in duplicate by members of the review team. The systematic review should present a clear statement that critical appraisal was conducted by at least two reviewers working independently from each other and conferring where necessary to reach decision regarding study quality and eligibility on the basis of quality.

7. **Were there methods to minimize errors in data extraction?**
   Efforts made by review authors during data extraction can also minimize bias or systematic errors in the conduct of a systematic review. Strategies to minimize bias may include conducting all data extraction in duplicate and independently, using specific tools or instruments to guide data extraction and some evidence of piloting or training around their use.

8. **Were the methods used to combine studies appropriate?**
   A synthesis of the evidence is a key feature of a systematic review. The synthesis that is presented should be appropriate for the review question and the stated type of systematic review and evidence it refers to. If a meta-analysis has been conducted this needs to be reviewed carefully. Was it appropriate to combine the studies? Have the reviewers assessed heterogeneity statistically and provided some explanation for heterogeneity that may be present? Often, where heterogeneous studies are included in the systematic review, narrative synthesis will be an appropriate method for presenting the results of multiple studies. If a qualitative review, are the methods that have been used to synthesize findings congruent with the stated methodology of the review? Is there adequate descriptive and explanatory information to support the final synthesized findings that have been constructed from the findings sourced from the original research?

9. **Was the likelihood of publication bias assessed?**
   As mentioned, a comprehensive search strategy is the best means by which a review author may alleviate the impact of publication bias on the results of the review. Reviews may also present statistical tests such as Egger's test or funnel plots to also assess the potential presence of publication bias and its potential impact on the results of the review. This question will not be applicable to systematic reviews of qualitative evidence.

10. **Were recommendations for policy and/or practice supported by the reported data?**
    Whilst the first nine (9) questions specifically look to identify potential bias in the conduct of a systematic review, the final questions are more indictors of review quality rather than validity. Ideally a review should present recommendations for policy and practice. Where these recommendations are made there should be a clear link to the results of the review. Is there evidence that the strength of the findings and the quality of the research been considered in the formulation of review recommendations?

11. **Were the specific directives for new research appropriate?**
    The systematic review process is recognized for its ability to identify where gaps in the research, or knowledge base, around a particular topic exist. Most systematic review authors will provide some indication, often in the discussion section of the report, of where future research direction should lie. Where evidence is scarce or sample sizes that support overall estimates of effect are small and effect estimates are imprecise, repeating similar research to those identified by the review may be necessary and appropriate. In other instances, the case for new research questions to investigate the topic may be warranted.

References

1. Whiting P, Rutjes AWS, Reitsma JB, Bossuyt PMM, Kleijnen J. The development of QUADAS: a tool for the quality assessment of studies of diagnostic accuracy included in systematic reviews. BMC Medical Research Methodology. 2003;3:25 doi:10.1186/1471-2288-3-25.

ROBIS: Tool to assess risk of bias in systematic reviews

Phase 1: Assessing relevance (Optional)

ROBIS is designed to assess the risk of bias in reviews with questions relating to interventions, aetiology, diagnosis and prognosis. State your overview/guideline question (target question) and the question being addressed in the review being assessed:

Intervention reviews:

Category	Target question (e.g. overview or guideline)	Review being assessed
Patients/Population(s):		
Intervention(s):		
Comparator(s):		
Outcome(s):		

For aetiology reviews:

Category	Target question (e.g. overview or guideline)	Review being assessed
Patients/Population(s):		
Exposure(s) and comparator(s):		
Outcome(s):		

For DTA reviews:

Category	Target question (e.g. overview or guideline)	Review being assessed
Patients):		
Index test(s):		
Reference standard:		
Target condition:		

For prognostic reviews:

Category	Target question (e.g. overview or guideline)	Review being assessed
Patients:		
Outcome to be predicted:		
Intended use of model:		
Intended moment in time:		

Does the question addressed by the review match the target question?	YES/NO/UNCLEAR

DOMAIN 4: SYNTHESIS AND FINDINGS	
Describe synthesis methods:	
4.1 Did the synthesis include all studies that it should?	Y/PY/PN/N/NI
4.2 Were all pre-defined analyses reported or departures explained?	Y/PY/PN/N/NI
4.3 Was the synthesis appropriate given the nature and similarity in the research questions, study designs and outcomes across included studies?	Y/PY/PN/N/NI
4.4 Was between-study variation (heterogeneity) minimal or addressed in the synthesis?	Y/PY/PN/N/NI
4.5 Were the findings robust, e.g. as demonstrated through funnel plot or sensitivity analyses?	Y/PY/PN/N/NI
4.6 Were biases in primary studies minimal or addressed in the synthesis?	Y/PY/PN/N/NI
Concerns regarding the synthesis and findings Rationale for concern:	LOW/HIGH/UNCLEAR

Y=YES, PY=PROBABLY YES, PN=PROBABLY NO, N=NO, NI=NO INFORMATION

Phase 3: Judging risk of bias

Summarize the concerns identified during the Phase 2 assessment:

Domain	Concern	Rationale for concern
1. Concerns regarding specification of study eligibility criteria		
2. Concerns regarding methods used to identify and/or select studies		
3. Concerns regarding methods used to collect data and appraise studies		
4. Concerns regarding the synthesis and findings		

RISK OF BIAS IN THE REVIEW	
Describe whether conclusions were supported by the evidence:	
A. Did the interpretation of findings address all of the concerns identified in Domains 1 to 4?	Y/PY/PN/N/NI
B. Was the relevance of identified studies to the review's research question appropriately considered?	Y/PY/PN/N/NI
C. Did the reviewers avoid emphasizing results on the basis of their statistical significance?	Y/PY/PN/N/NI
Risk of bias in the review Rationale for risk:	RISK: LOW/HIGH/UNCLEAR

Y=YES, PY=PROBABLY YES, PN=PROBABLY NO, N=NO, NI=NO INFORMATION