

## L.4 「急性呼吸器疾患のリスクが高い患者の保護を目的とした医療従事者へのワクチン接種の有効性：システマティックレビュー」の要約

### システマティックレビューの目的

この「急性呼吸器疾患のリスクが高い患者の保護を目的とした医療従事者へのワクチン接種の有効性：システマティックレビュー」(130)のレビューでは、重度のARIまたはARIによる合併症を発症するリスクが高い患者の保護を目的として、医療従事者にインフルエンザワクチンおよび肺炎球菌ワクチンを接種したときの有効性のエビデンスを調査した。

### 方法

著者らは、事前に定めた戦略を使用して、電子医療情報データベース(EMBASE、CINAHL、MEDLINE、PubMed、The Cochrane Library、J-Stage、BDSP、EASTVIEW、Index-F、eLIBRARY、WHO regional indexes、WHO portal of clinical trials)を検索した。また、関連のあるエビデンスに基づくレビュー、ガイドラインおよび灰色文献にもアクセスした。出版物は選択基準に照らして3段階のプロセスでレビューし、試験のタイプ(実験的研究、観察研究またはシステマティックレビュー)、被験者集団(重度のARIまたはARIによる合併症を発症するリスクが高いあらゆる年齢の患者)、介入(接種量、製剤の種類または接種スケジュールを問わず、リスクの高い患者をケアするあらゆる医療従事者へのインフルエンザまたは肺炎球菌ワクチンの接種)、比較(ワクチンの接種なし、プラセボ、または抗ウイルス薬の長期予防内服)、およびアウトカム[ARIの症例またはARIによる受診、ILIの症例、ILIによる受診または検査によるILIのエビデンス(該当する場合)、呼吸器感染症、ILIまたは急性呼吸器疾患あるいは関連合併症による死亡率、呼吸器感染症またはILIあるいは急性呼吸器疾患による医療資源利用の測定]が適切であることを確保した。全文レビュー時に、選択基準を満たしたすべての引用文献に対して、参考文献および引用文献の追跡を実施した。

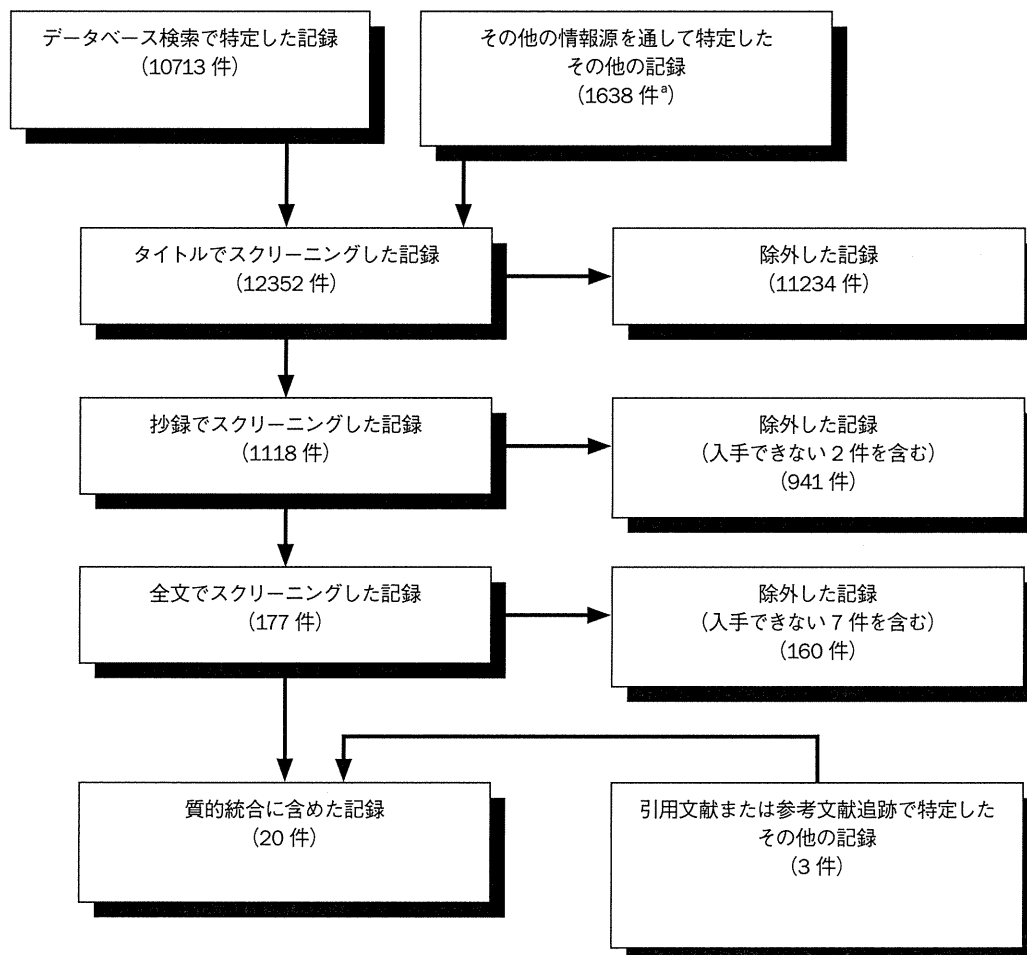
特定した計12352件の引用文献のうち、タイトルのレビュー後に11234件を除外し、抄録のレビュー後に941件を除外し、全文のレビュー後に160件を除外した(図L.4)。計20件の論文(最初の検索で特定した17件と、引用文献または参考文献の追跡で特定した3件の記録)を本レビューの対象とした。このうち14件は一次研究論文であり、6件は2件のシステマティックレビューの報告であった。

### 結果および結論

検討した集団、介入または曝露およびアウトカムに著しい異質性があったため、対象とした論文の比較可能性は限定的であった。14件の一次研究論文のうち、11件は長期居住型介護施設が対象であり、いずれもバイアスのリスクが高いと判断した。4件はRCTであり、これらの試験のデータは前回のシステマティックレビューで併合していた。この併合データから、高齢入居者のILIおよび全原因死亡率の指標に基づき、統計学的に有意な防御効果が明らかになった。本レビューで特定したこの他の観察データから、ILIの複数の指標の間で方向性の一致した効果が示唆され、検査によるインフルエンザ確定例でも同様のパターンが見られた。著者らは、長期居住型介護施設の医療従事者にワクチンを接種した場合、重度のARIまたはARIによる合併症を発症するリスクが高い患者に対し、限定的ではあるが、真の潜在的な防御効果があるようだ結論付けた(表L.3)。

著者らは、この主題分野には研究間に著しいギャップがあることを特定し、既存のエビデンスでは、長期居住型介護施設の入居者以外の集団に関する情報はほとんどないと述べた。他の高リスク患者集団の保護を目的として、医療従事者へのワクチン接種の有効性を検討する研究がさらに必要である。

図 L.4 「急性呼吸器疾患のリスクが高い患者の保護を目的とした医療従事者へのワクチン接種の有効性：システマティックレビュー」のための出版物の選択



a 最初の検索戦略では特定されなかったが、同じ部門が実施した並行レビューから移した 1 件の論文を含む。

表 L.3 「急性呼吸器疾患のリスクが高い患者の保護を目的とする医療従事者へのワクチン接種の有効性：システマティックレビュー」の調査結果の要約

アウトカム	利用可能なエビデンス	ナラティブ統合
急性呼吸器疾患	2つの異なる効果の指標(ウイルス性疾患/下気道感染の発症)を提示した1件のRCT(325)から算出した統計的推定値。	効果に一貫性はないが、効果の方向性は一致していることから、防御効果がある可能性が示唆される。採用した指標の非特異的な性質から、これがインフルエンザの感染に起因するものかどうかを確かめるのは困難である。
臨床的に定義されたILIまたはインフルエンザの症例	異なる定義を使用した3件のRCT(325-327)および2件の前向きコホート研究(328、329)から算出した、臨床的に定義されたILIの統計的推定値。裏付けとなる統計解析が行われていない1件の横断研究の観察データ。1件の横断研究(331)から算出したインフルエンザ症例の追加の統計的推定値(330)。	3件のRCTの併合データ(332)から、クラスターを調整した場合、統計学的に有意な防御効果があることが示唆される。これは、付加的な観察データでも裏付けられている。統計解析を実施した3試験のうち2試験(328、329)では、バイアスのリスクは高いものの、方向性の一致した効果があることが示された。
ILIによるGPの受診	1件のRCT(327)から算出した統計的推定値。	受診率については、ワンシーズンのみで統計学的に有意な小規模の減少が見られたが、調整オッズ比に変換した場合は、全体で統計学的に有意な防御効果が示された(331)。
ILIのアウトブレイク/集団感染	異なる定義を使用した3件の観察研究(329、333、334)から算出した統計的推定値。	3試験とも、推定値が不正確でバイアスのリスクも高いが、統計学的に有意な防御効果が示された。
検査によるインフルエンザ確定例	1件のRCT(335)および2件の観察研究(336、337)から算出した統計的推定値。さらに1件のRCT(325)の観察データ。	2件のRCTの併合データ(331)から、有意性のない防御効果が示唆される。効果の方向性は、統計学的に有意な防御効果を示した他の2件の観察研究(336、337)のデータで裏付けられた。サンプルサイズが非常に小さいため、著しいバイアスリスクと不正確性が存在する。
検査により確認されたインフルエンザのアウトブレイク	1件の観察研究(338)から算出した統計的推定値。	ワクチン接種率はアウトブレイクを経験した家庭の方が高いようであったが、統計学的有意差は認められなかった。しかし、解析結果は未補正であり、サンプル数が少ないため不正確である。
呼吸器疾患による死亡率	それぞれ異なる指標(呼吸器疾患による死亡、肺炎に関連する死亡、ILIによる死亡、死亡時の検査により確定されたインフルエンザ)を使用した4件のRCT(325-327、335)から算出した統計的推定値。	呼吸器疾患による死亡(326)および肺炎に関連する死亡(325)のデータを用いて算出した併合推定値(331)から、有意性のないわずかな防御効果が示唆される。ILIによる死亡(327)および検査により確定されたインフルエンザによる死亡(335)についても、個々の試験で、有意性のないわずかな防御効果が示された。異なる指標を採用したため、一般化可能性は限定的である。
全原因死亡率	4件のRCT(325-327、335)から算出した統計的推定値。	効果に一貫性はないが、効果の方向性は一致している。併合データ(331)では、クラスターを調整した場合、統計学的に有意な防御効果が示唆される。

アウトカム	利用可能なエビデンス	ナラティブ統合
入院	3つの異なる効果の指標(入院、呼吸器に起因する入院、ILIによる入院)を提示した2件のRCT(326、327)から算出した統計的推定値。	明確な効果は認められなかった。

GP = 一般開業医、ILI = インフルエンザ様疾患、RCT = ランダム化比較試験

## 付録 M 利害の対立の管理

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本ガイドライン作成のための GRADE 評価プロセスに参加したガイドライン作成委員会の委員、外部の査読者、および世界感染症予防・コントロールネットワークの代表委員は全員、利害関係申告書と履歴書を提出した。ガイドライン作成委員会および外部の査読委員会の委員とリソースパーソンが申告した利害の対立の可能性を以下にまとめる。

Barry Cookson 教授は、過去 3 年間に討論会のパネリストを 1 回務めた経験があり、また製品の有効性や戦略に関して 1 対 1 の専門的助言を 3 回にわたって提供したと申告した。企業は Wyeth、Rubbermaid、3M および Vernacare/Baxter であった。製品はブドウ球菌ワクチン、マイクロファイバー拭き取り布および消毒薬であった。Cookson 教授が本ガイドラインのレビューに携わった時点では、いずれのコンサルタント業務も終了していた。Cookson 教授が当時受け取った対価は少額であり、業務もすでに終了していたため、これらは本ガイドラインの査読において利害の対立には該当しないと考えられた。

Babacar Ndoeye 教授は、会議、ワークショップまたは学会への参加や企画のため、bioMerieux Clinical Diagnostics、バスツール研究所および地域企業から支援を受けたが、このうち 1,000 米ドルを超えるものはないことを申告した。Wing Hong Seto 教授は、Pfizer が開催した科学会議で発表した際に、交通費の助成を受けたと申告した。これらはいずれも少額であるため、利害の対立には該当しないと考えられた。

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