McMaster University | HEALTH FORUM

RISE

COVID-19 Rapid Evidence Profile #22 (29 October 2020)

Question

What is known about whether vaccine injury-compensation programs and program elements affect vaccine acceptance and uptake and, where evaluations have been planned or conducted, how these programs are complemented by and timed in relation to other strategies to increase vaccine acceptance and uptake?

What we found

We organize the findings in this REP according to the two outcomes of interest, which include:

- vaccine acceptance; and
- vaccine uptake.

We found limited evidence that focused explicitly on the evaluation of vaccine injury-compensation programs. Three primary studies provided highly relevant evidence. We outline findings from the primary studies in narrative form, which is complemented by more detailed findings in Table 1 and hyperlinks to each study.

We did not identify any other types of relevant documents (i.e., guidelines, systematic reviews, rapid reviews, protocols, questions being planned) that evaluated vaccine injury-compensation programs and elements that affect vaccine acceptance and uptake. For those who want to know more about the search results, we provide additional details in Table 2 (the type and number of all documents that were identified).

In addition, we provide a detailed summary of our methods in Appendix 1, the full list of included evidence documents (including one primary study deemed low relevance) in Appendix 2, and abstracts for highly relevant documents in Appendix 3.

We excluded 55 documents on vaccine injury-compensation programs (including two guidelines, five systematic reviews, three rapid reviews, and 45 primary studies) because they did not

Box 1: Our approach

We identified research evidence addressing the question (specifically evaluations of injury-compensation programs) by: 1) searching the COVID-END inventory of best evidence syntheses and the COVID-END guide to key COVID-19 evidence sources on 28 and 29 October 2020; 2) searching PubMed using the following search terms: (vaccine or vaccination) AND injury AND (compensation OR no-fault); and 3) reviewing the references lists from two jurisdictional scans brought to our attention by the Public Health Agency of Canada (Keelan et al., 21 August 2020 and Mungwira et al., 21 May 2020, the latter of which is included in appendix 4).

We searched for guidelines that were developed using a robust process (e.g., GRADE), full systematic reviews (or review-derived products such as overviews of systematic reviews), rapid reviews, protocols for systematic reviews, and titles/questions for systematic reviews or rapid reviews that have been identified as either being conducted or prioritized to be conducted. Single studies were only included if no relevant systematic reviews were identified.

We appraised the methodological quality of full systematic reviews and rapid reviews using AMSTAR. Note that quality appraisal scores for rapid reviews are often lower because of the methodological shortcuts that need to be taken to accommodate compressed timeframes. AMSTAR rates overall quality on a scale of 0 to 11, where 11/11 represents a review of the highest quality. It is important to note that the AMSTAR tool was developed to assess reviews focused on clinical interventions, so not all criteria apply to systematic reviews pertaining to delivery, financial or governance arrangements within health systems or to broader social systems.

This rapid evidence response was prepared in 1.5 days to inform next steps in evidence synthesis, guideline development and/or decision-making related to the question that was posed.

address the research question and/or did not focus on evaluating vaccine acceptance and/or vaccine uptake. Generally, excluded documents described:

- rationales for the development of an injury-compensation program (e.g., ethical, economic and legal considerations);
- overviews or descriptions of vaccine injury-compensation programs;
- approaches to increase vaccine uptake (unrelated to injury-compensation programs);
- types of claims from vaccine injury-compensation programs; and
- challenges related to vaccine acceptance and uptake.

We provide in Appendix 4, hyperlinked titles for the documents excluded at the final stage of reviewing which are categorized using the list above.

Key findings from highly relevant evidence sources

The findings from three highly relevant primary studies are summarized in Table 1. All the studies were based on the evaluation of the U.S. National Vaccine Injury Compensation Program (VICP). Regarding vaccine acceptance, two studies (one published in 2013, and another in 2006) reported that the program's ability to address liability were associated with improved confidence among the public-health workforce and improvement environment for vaccine research and development. There were mixed findings related to the impact of vaccine uptake. The previously mentioned study from 2006 reported an association between increased immunization rates among the general population since the inception of VICP. However, an older study from 1998 reported that there was no evidence related to an increase of vaccination uptake if VICP were to include two vaccines (influenza and pneumococcal vaccines) targeting adults.

Table 1: Key findings from highly relevant primary studies related to vaccine injury-compensation programs on vaccine acceptance and uptake

Question and sub-questions	Key findings from evidence documents
Effect of vaccine injury-compensation programs • Impact on vaccine acceptance • Impact on vaccine uptake	**Findings related to the impact on vaccine acceptance** • Legal protections are attributed as a key aspect in boosting vaccine confidence among the U.S. public health workforce (Source; published 2013) • The National Vaccine Injury Compensation Program (VICP) in the U.S. reported an association with an improvement environment for vaccine research and development, partly due to the program's ability to address liability surrounding immunization (Source; published 2006) **Findings related to the impact on vaccine uptake** • The VICP reported an association between increased immunization rates and the program's ability to address liability surrounding immunization (Source; published 2006) • A 1998 study commissioned by the U.S. National Vaccine Advisory Committee found little to no evidence in the increase of vaccination levels among adults if the influenza and pneumococcal vaccines were included in VICP (Source; published 1998)

Table 2: Overview of type of number of documents that were identified about vaccine injury-compensation programs on vaccine acceptance and uptake

Type of document	Total	Focus on vaccine acceptance	Focus on vaccine uptake
Guidelines developed using a robust process (e.g., GRADE)	0	-	-
Full systematic reviews	0	-	-
Rapid reviews	0	-	
Guidelines developed using some type of evidence synthesis and/or expert opinion	0	-	-
Protocols for reviews that are underway	0	-	-
Titles/questions for reviews that are being planned	0	-	-
Single studies in areas where no reviews were identified	4	2	2

Bhuiya AR, Waddell K, Moat KA, Wilson MG, Gauvin FP, Whitelaw S, Alam S, Sharma K, Drakos A, Lavis JN. COVID-19 rapid evidence profile #22: What is known about whether vaccine injury-compensation programs and program elements affect vaccine acceptance and uptake. Hamilton: McMaster Health Forum, 29 October 2020.

The McMaster Health Forum is one of the three co-leads of RISE, which is supported by a grant from the Ontario Ministry of Health to the McMaster Health Forum. To help Ontario Health Team partners and other health- and social-system leaders as they respond to unprecedented challenges related to the COVID-19 pandemic, the Forum is preparing rapid evidence responses like this one. The opinions, results, and conclusions are those of the McMaster Health Forum and are independent of the ministry. No endorsement by the ministry is intended or should be inferred.

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Appendix 1: Methodological details

We normally use a standard protocol for preparing each rapid evidence profile (REP) to ensure that our approach to identifying research evidence as well as experiences from other countries and from Canadian provinces and territories are as systematic and transparent as possible in the time we were given to prepare the profile. However, in this instance, the requestor already had access to a recently updated jurisdictional scan that described vaccine injury-compensation programs (by Keelan et al., 21 August 2020), so we did not include this step. Also, as noted below, we completed our usual approach with a targeted search of PubMed.

Identifying research evidence

For each REP, we search COVID-END's continually updated inventory of best evidence syntheses and guide to key COVID-19 evidence sources for:

1) guidelines developed using a robust process (e.g., GRADE);
2) full systematic reviews;
3) rapid reviews;
4) guidelines developed using some type of evidence synthesis and/or expert opinion;
5) protocols for reviews or rapid reviews that are underway
6) titles/questions for reviews that are being planned; and
7) single studies (when no guidelines, systematic reviews or rapid reviews are identified)

For this particular REP, we also searched: 1) PubMed using the following search terms: (vaccine or vaccination) AND injury AND (compensation OR no-fault); and 2) reviewed the references lists from two jurisdictional scans brought to our attention by the Public Health Agency of Canada (Keelan et al., 21 August 2020 and Mungwira et al., 21 May 2020, the latter of which is included in appendix 4).

Each source for these documents is assigned to one team member who conducts hand searches (when a source contains a smaller number of documents) or keyword searches to identify potentially relevant documents. A final inclusion assessment is performed both by the person who did the initial screening and the lead author of the rapid evidence profile, with disagreements resolved by consensus or with the input of a third reviewer on the team. The team uses a dedicated virtual channel to discuss and iteratively refine inclusion/exclusion criteria throughout the process, which provides a running list of considerations that all members can consult during the first stages of assessment.

During this process we include published, pre-print and grey literature. We do not exclude documents based on the language of a document. However, we are not able to extract key findings from documents that are written in languages other than Chinese, English, French and Spanish. We provide any documents that do not have content available in these languages in an appendix containing documents excluded at the final stages of reviewing.

Assessing relevance and quality of evidence

We assess the relevance of each included evidence document as being of high, moderate or low relevance to the question and to COVID-19. We then use a colour gradient to reflect high (darkest blue) to low (lightest blue) relevance.

Two reviewers independently appraise the methodological quality of systematic reviews and rapid reviews that are deemed to be highly relevant. Disagreements are resolved by consensus with a third reviewer if needed. AMSTAR rates overall methodological quality on a scale of 0 to 11, where 11/11 represents a review of the highest quality. High-quality reviews are those with scores of eight or higher out of a possible 11, medium-quality reviews are those with scores between four and seven, and low-quality reviews are those with scores less than four. It is important to note that the AMSTAR tool was developed to assess reviews focused on clinical interventions, so not all criteria apply to systematic reviews pertaining to health-system arrangements or to economic and social responses to COVID-19. Where the denominator is not 11, an aspect of the tool was considered not relevant by the raters. In comparing ratings, it is therefore important to keep both parts of the score (i.e., the numerator and denominator) in mind. For example, a review that scores 8/8 is generally of comparable quality to a review scoring 11/11; both ratings are considered 'high scores.' A high score signals that readers of the review can have a high level of confidence in its findings. A low score, on the other hand, does not mean that the review should be discarded, merely that less confidence can be placed in its findings and that the review needs to be examined closely to identify its limitations. (Lewin S, Oxman AD, Lavis JN, Fretheim A. SUPPORT Tools for evidence-informed health Policymaking (STP): 8. Deciding how much confidence to place in a systematic review. *Health Research Policy and Systems* 2009; 7 (Suppl1):S8.

Preparing the profile

Each included document is hyperlinked to its original source to facilitate easy retrieval. For all included guidelines, systematic reviews, rapid reviews and single studies (when included), we prepare declarative headings that provide a brief summary of the key findings and act as the text in the hyperlink. Protocols and titles/questions have their titles hyperlinked given that findings are not yet available. We then draft a brief summary that highlights the total number of different types of highly relevant documents identified (organized by document), as well as their key findings, date of last search (or date last updated or published), and methodological quality.

Appendix 2: Key findings from evidence documents that address the question, organized by document type and sorted by relevance to the question and COVID-19

- vaccine acceptance; and
- vaccine uptake

Type of document	Relevance to question	Key findings	Recency or status
Single studies in areas where no reviews were identified	• Vaccine acceptance	• This study analyzes the use of the Extended Parallel Process Model for understanding the public-health workforce's confidence in vaccines and perceptions of vaccine-injury compensation mechanisms • The analysis reveals the key role of legal protections in boosting confidence in vaccines, since mandatory vaccination for public-health workers is a contentious policy issue Source	Published in June 2013
	• Vaccine acceptance • Vaccine uptake	• The National Vaccine Injury Compensation Program in the U.S. reported an association with increased immunization rates and an improved environment for vaccine research and development, partly due to the program's ability to address liability surrounding immunization Source	Published 1 March 2006
	• Vaccine uptake	• The National Childhood Vaccine Injury Act, passed in 1986, was queried whether it should be expanded the VICP to cover adult influenza and pneumococcal vaccines • In 1996 it was decided that available data provided no compelling reasons to expand the vaccine injury-compensation program to cover adults • It was also concluded that no data existed that suggested a program expansion would improve vaccination levels in adults, that the data did not indicate a liability crisis, the reported injuries could	Published June 1998

Type of document	Relevance to question	Key findings	Recency or status
		not be conclusively attributed to the vaccines, and that there was no strong support for vaccine injury-compensation program expansion • Possible expansion of the vaccine injury-compensation program should be revisited if new developments occur and new data is obtained Source	
	• Vaccine uptake	• Of 1236 American physicians who were actively seeing children as patients, 85% were aware of the Vaccine Injury Compensation Program and 41% of those felt it provided a high level of litigation protection • Physicians' likelihood of encouraging vaccination to argumentative parents was higher among physicians with lower levels of litigation concern • Physicians' likelihood of encouraging vaccination to argumentative parents was not impacted by awareness of the Vaccine Injury Compensation Program Source	Published January 1998

Appendix 3: Abstracts for highly relevant documents

Note that the table below only includes the abstracts for the documents that we identified on page 1 as being highly relevant to the question.

Type of document	Abstract and link to full text
Single studies in areas where no reviews were identified	A threat- and efficacy-based framework to understand confidence in vaccines among the public health workforce The Extended Parallel Process Model (EPPM) is an established threat- and efficacy-based behavioral framework for understanding health behaviors in the face of uncertain risk. A growing body of research has applied this model to understand these behaviors among the public health workforce. In this manuscript, we aim to explore the application of this framework to the public health workforce, with a novel focus on their confidence in vaccines and perceptions of vaccine injury compensation mechanisms. We characterize specific connections between EPPM's threat and efficacy dimensions and relevant vaccine policy frameworks and highlight how these connections can usefully inform training interventions for public health workers to enhance their confidence in these vaccine policy measures.
	Update on vaccine liability in the United States: Presentation at the national vaccine program office workshop on strengthening the supply of routinely recommended vaccines in the United States, 12 February 2002 Two decades ago, a liability crisis brought on by concerns about the safety of diphtheria and tetanus toxoids and pertussis vaccine led to supply shortages and calls for rationing of the vaccine. Vaccine prices skyrocketed, and research on new products was threatened. In response, Congress created the National Vaccine Injury Compensation Program, which is tort reform legislation designed to compensate individuals quickly, easily, and generously. Since 1988, the Vaccine Injury Compensation Program has stabilized the marketplace, as evidenced by high immunization rates, stable pricing, and an increasing number of vaccine candidates in development. Although current vaccine shortages do not appear to be related to issues of liability, a new wave of tort litigation alleging that some vaccines cause autism has led to speculation that history could repeat itself.
	Should the vaccine injury compensation program be expanded to cover adults? In 1996, the National Vaccine Advisory Committee (NVAC) asked for a review of the pros and cons of including adult influenza and pneumococcal vaccines in the Vaccine Injury Compensation Program (VICP). The authors, as staff to the subcommittees charged with undertaking this assessment, looked at the following questions: (a) Would inclusion of VICP of these two vaccines, used primarily by adults, increase adult vaccination levels? (b) is this Federal involvement warranted based on the liability burden for these vaccines? (c) Does the risk of adverse events following vaccinations warrant inclusion of these vaccines? (d) Is there consensus among stakeholders favoring their inclusion? To address these questions, the authors reviewed information on adult vaccines, including data on lawsuits filed and reports of injuries, and sought input from interested groups. They found no evidence that the use of influenza and pneumococcal vaccines would increase if they were included in VICP. They found a low liability burden for these vaccines that serious events were rare, and that no consensus existed among stakeholders. After considering the staff report, NVAC chose, in 1996, not to advise the Department of Health and Human Services to include adult vaccines in VICP.

Appendix 4: Documents excluded at the final stages of reviewing

Type of document	Focus of document	Hyperlinked title
Guidelines developed using a robust process (e.g., GRADE)	• Rationale for the development of vaccine injury compensation programs (e.g., ethical, economic, legal considerations)	• In support of a compensation plan for vaccine-associated injuries. Infectious Diseases and Immunization Committee, Canadian Paediatric Society
	• Approaches to increase vaccine uptake (unrelated to injury compensation program)	• Flu vaccines: Increasing uptake
Full systematic reviews	• Overview of vaccine injury-compensation programs	• Update on the National Vaccine Injury Compensation Program • Global landscape analysis of no-fault compensation programmes for vaccine injuries: A review and survey of implementing countries
	• Approaches to increase vaccine uptake (unrelated to injury-compensation program)	• Interventions to improve vaccination uptake and cost effectiveness of vaccine strategies in newly arrived migrants • Immunization information systems to increase vaccination rates: Cost analysis • The effect of pay-for-performance compensation model implementation on vaccination rate: A systematic review
Rapid reviews	• Overview of vaccine injury-compensation programs	• Australia needs a vaccine injury compensation scheme: Upcoming COVID-19 vaccines make its introduction urgent • Performance of the United States Vaccine Injury Compensation Program (VICP): 1988–2019 • Vaccine injury redress programmes. An evidence review
Guidance developed using some type of evidence synthesis and/or expert opinion		
Protocols for reviews that are underway		
Titles/questions for reviews that are being planned		

Type of document	Focus of document	Hyperlinked title
Single studies in areas where no reviews were identified	• Rationale for the development of vaccine injury-compensation programs (e.g., ethical, economic, legal considerations)	• Rationalizing vaccine injury compensation • The case for a vaccine injury compensation program for Canada • The National Vaccine Injury Compensation Program: Striking a balance between individual rights and community benefit • Vaccine Injury Compensation Programs: Rationale and an overview of the Québec program • A new wave of vaccines for non-communicable diseases: What are the regulatory challenges? • Use of a new global indicator for vaccine safety surveillance and trends in adverse events following immunization reporting 2000–2015
	• Descriptions of vaccine injury-compensation programs	• Economic and immunisation safety surveillance characteristics of countries implementing no-fault compensation programmes for vaccine injuries • The Smallpox Vaccine Injury Compensation Program • Balancing vaccine science and national policy objectives: Lessons from the National Vaccine Injury Compensation Program Omnibus Autism Proceedings • Closing the door to lost earnings under the National Childhood Vaccine Injury Act of 1986 • Smallpox Vaccine Injury Compensation Program: Smallpox (vaccinia) Vaccine Injury Table. Interim final rule • National Vaccine Injury Compensation Program: Revisions to the vaccine injury table. Final rule • Compensation for vaccine-related injuries. Health and Public Policy Committee, American College of Physicians • Compensation under the National Childhood Vaccine Injury Act • Compensation programs for vaccine-related injury abroad: A comparative analysis • National Childhood Vaccine Injury Compensation Act • Compensation programs after withdrawal of the recommendation for HPV vaccine in Japan • A global vaccine injury compensation system • Compensation for vaccination accidents • No-fault vaccine insurance: Lessons from the National Vaccine Injury Compensation Program • Should the vaccine injury compensation program be expanded to cover adults?

Type of document	Focus of document	Hyperlinked title
		• Performance of the United States Vaccine Injury Compensation Program: 1988-2019 • No-fault compensation following adverse events attributed to vaccination: A review of international programmes • Mandatory vaccination and no-fault vaccine injury compensation schemes: An identification of country-level policies • Vaccine injury compensation programs worldwide • No-Fault Compensation In New Zealand: Harmonizing Injury Compensation, Provider Accountability, And Patient Safety • No-fault compensation for adverse events following immunization: a review of Chinese law and practice • Designing a no-fault vaccine-injury compensation programme for Canada: lessons learned from an international analysis of programmes
	• Types of claims from vaccine injury compensation programs	• Seizures, encephalopathy, and vaccines: Experience in the National Vaccine Injury Compensation Program • Reporting vaccine-associated paralytic poliomyelitis: Concordance between the CDC and the National Vaccine Injury Compensation Program • Surveillance and compensation claims for adverse events following immunization from 2011 to 2016 in the Republic of Korea • National Vaccine Injury Compensation Program: Addition of intussusception as injury for rotavirus vaccines to the Vaccine Injury Table. Final rule • Japanese encephalitis immunization in South Korea: Past, present, and future • Reasons for an injury compensation programme for adverse vaccine-related events in Spain (in Spanish) • Disputed claims for pertussis vaccine injuries under the National Vaccine Injury Compensation Program • Reporting vaccine-associated paralytic poliomyelitis: Concordance between the CDC and the National Vaccine Injury Compensation Program • Influenza vaccination is not associated with increased number of visits for shoulder pain • Compensating pharmaceutical injuries in the absence of fault • Shoulder Injury Related to Vaccine Administration (SIRVA): Petitioner claims to the National Vaccine Injury Compensation Program, 2010-2016 • Surveillance and compensation claims for adverse events following immunization from 2011 to 2016 in the Republic of Korea

Type of document	Focus of document	Hyperlinked title
	• Challenges related to vaccine uptake and vaccine hesitancy	• Vaccine hesitancy and (fake) news: Quasi-experimental evidence from Italy • Vanishing vaccinations: Why are so many Americans opting out of vaccinating their children? • Impact of Australian mandatory 'No Jab, No Pay' and 'No Jab, No Play' immunisation policies on immunisation services, parental attitudes to vaccination and vaccine uptake, in a tertiary paediatric hospital, the Royal Children's Hospital, Melbourne • The web and public confidence in MMR vaccination in Italy