Dear reviewers,

Thank you for your review and constructive feedback on our manuscript: "An Interoperable Vaccine Record: A Roadmap to Realization" (Ref: Submission ID 4133489 to Vaccines). We have incorporated your suggestions into the revised version of the manuscript. Here, we have included (1) a version with tracked changes, (2) a clean version, and (3) a response letter with point-by-point responses (responses are in yellow, and the revisions are in green) to all the review comments.

Please let us know if anything else is needed. We believe that we have addressed all your concerns. We hope the revisions are satisfactory. We look forward to hearing from you soon.

Best regards,

Xia Jing, on behalf of all co-authors

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Reviewer 1:

Dear Authors,

My recommendation: Major Revision

The manuscript addresses an important and timely topic—interoperable vaccination records—and presents a broad, cross-national perspective enriched by examples from the Nordic countries, the UK, and the US. The paper is well-organized and readable, and the roadmap it proposes is conceptually sound.

However, the manuscript in its current form has several limitations:

The novelty of the work is insufficiently articulated; much of the content synthesizes existing knowledge without clearly stating what new insights the manuscript contributes.

Response: Thank you for pointing this out. We have added a new Section 1.4 to better articulate the paper's contribution to the existing literature.

1.4. Contribution of This Paper to the Existing Literature

We propose the concept of the "interoperable vaccine record" for the first time as a natural extension of healthcare interoperability. The paper contextualizes the existing infrastructure within the interoperable vaccine record framework and articulates the necessity of an interoperable vaccine record across countries, drawing on examples from the Nordic countries, the UK, and the USA, on progress toward interoperability, and on the

challenges that remain. The paper can inform healthcare professionals, technical personnel, and the general public about what an interoperable vaccine record is, how it differs from an electronic vaccine record, and the necessity of such a record. It can also guide future efforts to achieve interoperable vaccine records. However, this manuscript provides a conceptual-level roadmap rather than a day-by-day implementation plan with actionable steps.

The evidence base lacks methodological description, making the manuscript read more like an opinion piece than a rigorous scientific analysis.

Response: Thank you, reviewer, for the feedback. This manuscript is intended to be a perspective paper rather than an original research study. The paper is based on our group's knowledge, experiences, expertise, and long-term research interest, i.e., interoperability in healthcare. Vaccine record is a use case. However, we have added a brief description of the approach we used in the abstract and also in a new section 1.5.

1.5. Methods Used

We used the Nordic countries, the UK, and the USA as examples to compare the vaccination practices and vaccine record-keeping. A convenient sample among coauthors, aiming to demonstrate the realities in vaccination and the necessity of interoperable vaccine records. All authors' decades of experience and expertise in interoperability, medicine, and HealthIT, as well as the existing literature, have informed the paper's content, structure, and organization. In this manuscript, healthcare providers refer to healthcare professionals who can administer vaccines and maintain their records; individuals are used interchangeably with patients or citizens, i.e., recipients of vaccines, who may need interoperable vaccine records for travel, relocation, or school enrollment; authority refers to government at different levels (school, county, state, national, or international) or the trusted brokers, such as those enabled by blockchain technology; authority typically establishes the rules related to vaccine requirements and enforce their implementation.

Several claims regarding feasibility and benefits of interoperability are not supported by empirical data.

Response: Thank you for your feedback. We have added references 14 to 22 for the feasibility and benefits of interoperability in clinical care to provide evidence per the reviewer's suggestions.

A recent national survey showed that only 18% of the family physicians have ideal immunization-related interoperability, and the overall ideal interoperability is between 8% to 19%[14]. Interoperability can play a critical role in providing complete patient records for medical referrals, second-opinion consultations, hospital admissions and discharges, emergencies, relocations, and travel, all of which directly contribute to safer, timely, more effective, non-redundant clinical care, better outcomes, and reduced cost [15-22].

The roadmap, while thoughtful, is too high-level and needs operational detail to be actionable.

Response: Thank you for the suggestion. “Interoperable vaccine records” is not a common concept among healthcare personnel or the general public. This paper serves as a medium to raise awareness of this concept while outlining the opportunities and challenges to achieving interoperable vaccine records. We have revised the Moving Forward Section to add additional, more actionable recommendations.

Regarding the social and cultural aspect, it is critical to balance medical benefit, risks, social responsibility, individual cultural choices, and spiritual practices. To achieve optimal outcomes, a practical solution is to improve health literacy among the general public, ensuring that every vaccination-related decision is well-informed and unbiased. Large-scale health education may require novel content and diverse delivery methods to reach a broader audience. Local vaccination rates can inform the design of a more precise health education campaign. High vaccination coverage is necessary to achieve the required herd immunity for most infectious and preventable diseases; therefore, education and awareness campaigns about vaccination should focus on both the individual and community levels to amplify their effects.

Regarding the political aspect, the key points include at least the following: leave medicine, public health, and science out of the political battlefield; let healthcare professionals fulfill their roles without labeling them politically; ensure mainstream media is full of authentic scientific information relevant to vaccination, i.e., minimize the generation of misinformation of vaccination and its distribution among the general public, especially in a systematic manner. This requires large social media companies to fulfill their social responsibility at the algorithmic level by combating misinformation, but not to rely entirely on voluntarism. The necessary legislation and any consequences of violations should be explicitly established to ensure optimal outcomes.

On the technical side, agreeing on the data standards and controlled vocabularies used to capture vaccine records is essential, though it may seem straightforward and can

be very time-consuming. Given the variety of data standards and controlled vocabularies, and their ever-expanding scope, a more granular consensus is necessary, such as a minimal information model[62] for vaccine records, which could serve as a starting point. In addition, the stakeholders also need to agree on what constitutes a comprehensive vaccine record (including the fields, the values that can be used in the fields, and the metadata of the comprehensive records), where to save the external vaccine records, what to do if there are discrepancies between external records and internal records, or between two external records. Well-documented, accurate, and complete vaccination records are critical, but not a simple task; operationalizing data reuse to achieve once-entry, multiple-reuse whenever needed.

On the policy side, the work needs to take place at different levels: national, international, vendors, and institutional. The policies at different levels must not only be in place but also be aligned with one another. In the USA, the state-level legislation also plays a critical role in achieving interoperability. At a minimum, agreeing on who can do what and when across regional, national, and international borders is a prerequisite for interoperable vaccination records; moreover, balancing individual confidentiality, user convenience, and broad accessibility for citizens, healthcare providers, and authorities is necessary. From a more practical perspective, consensus among vendors and institutional-level policies can be a key facilitator or accelerator to achieve interoperable vaccine records. For example, agreeing on a minimal information model for vaccine records and on the standards (at the level of data elements) for the model's metadata can be a concrete first step. Last but not least, citizens must agree to share their vaccination records; without their consent, Figure 3 will lose a third of the stakeholders. Meanwhile, the consent per se requires careful procedural and language preparation, such as when to provide the consent, how to provide it, whether the vaccination information sharing is part of a broader health information sharing, or requires a separate consent.

Figure 4 summarizes key points for each aspect, and the challenge section provides further elaboration. Where there is a challenge, there are opportunities to overcome the challenge. Regarding an interoperable vaccination record, it is simpler than a complete interoperable electronic health record, but more complicated than reusable CDSS rules. More importantly, we are unlikely to achieve this through purely technical advances; rather, all aspects shown in Figure 4 must progress in a coherent, interconnected manner to enable interoperable vaccination records for all.

With revisions that clarify novelty, formalize the methodological approach, strengthen evidence, and operationalize the roadmap, the manuscript has the potential to make a meaningful contribution to the field.

Response: Thank you for your constructive feedback. We have revised the manuscript to clarify its novelty, formalize the methodology, strengthen the supporting evidence, and operationalize the roadmap. We believe these changes enhance the manuscript's clarity and potential to make a meaningful contribution to the field.

Summary for the Authors

Dear Authors,

Thank you for submitting your manuscript on interoperable vaccination records. Your work addresses an increasingly important global challenge in health informatics. Below is a summary of the key points that, if addressed, will significantly strengthen the manuscript.

1. Clarify the Novel Contributions

Your manuscript synthesizes existing practices in vaccination records across the Nordic countries, the UK, and the US, and proposes a conceptual roadmap. However, the paper does not clearly articulate what is new compared with existing literature on interoperability, immunization information systems, or computable vaccination artifacts.

Consider highlighting:

- What unique insights your cross-national comparison reveals

Response: We have added two revisions to address this point. One revision in the abstract summarizes the cross-national comparison and how the interoperable vaccine record plays a role in the picture. The other is a new Section 1.4 which clearly articulates the paper's contribution to the existing literature.

In summary, the Nordic countries' national vaccine registries are better organized than those in the USA; however, the portability of vaccine records across countries remains a challenge. The UK NHS has made significant progress in enabling patients to view their vaccination records via their GP; however, it is unclear whether vaccinations received outside the GP offices are also recorded in the GP's records. Meanwhile, in the USA, vaccine records are maintained by multiple healthcare providers, and some are still in paper format, which adds an additional layer of complexity to achieving interoperability. Figure 1 illustrates the realities of vaccination records and the barriers to a consolidated, longitudinal vaccination record for everyone in the USA, the UK, the Nordic countries, and many other countries.

1.4. Contribution of This Paper to the Existing Literature

We propose the concept of the "interoperable vaccine record" for the first time as a natural extension of healthcare interoperability. The paper contextualizes the existing infrastructure within the interoperable vaccine record framework and articulates the necessity of an interoperable vaccine record across countries, drawing on examples from the Nordic countries, the UK, and the USA, on progress toward interoperability, and on the challenges that remain. The paper can inform healthcare professionals, technical personnel, and the general public about what an interoperable vaccine record is, how it differs from an electronic vaccine record, and the necessity of such a record. It can also guide future efforts to achieve interoperable vaccine records. However, this manuscript provides a conceptual-level roadmap rather than a day-by-day implementation plan with actionable steps.

- How your roadmap advances or diverges from existing frameworks

Response: Thank you for this comment. A quick PubMed search did not turn up any interoperable vaccine records. One reference about Canada's experience is relevant, but the paper did not clarify whether such interoperability among vaccine records is realized. From the recommendations of the paper, we infer that it is not yet a reality. Therefore, there is no existing or successful framework on the topic yet. Although our roadmap is conceptual, not a day-by-day implementation and actionable plan, the insights can still shed a lot of light on the realization journey of interoperable vaccine records.

- Any original technical, policy, or operational recommendations

Response: Thank you for this comment. We have revised the Moving Forward Section as answered above.

Regarding the social and cultural aspect, it is critical to balance medical benefit, risks, social responsibility, individual cultural choices, and spiritual practices. To achieve optimal outcomes, a practical solution is to improve health literacy among the general public, ensuring that every vaccination-related decision is well-informed and unbiased. Large-scale health education may require novel content and diverse delivery methods to reach a broader audience. Local vaccination rates can inform the design of a more precise health education campaign. High vaccination coverage is necessary to achieve the required herd immunity for most infectious and preventable diseases; therefore, education and awareness campaigns about vaccination should focus on both the individual and community levels to amplify their effects.

Regarding the political aspect, the key points include at least the following: leave medicine, public health, and science out of the political battlefield; let healthcare

professionals fulfill their roles without labeling them politically; ensure mainstream media is full of authentic scientific information relevant to vaccination, i.e., minimize the generation of misinformation of vaccination and its distribution among the general public, especially in a systematic manner. This requires large social media companies to fulfill their social responsibility at the algorithmic level by combating misinformation, but not to rely entirely on voluntarism. The necessary legislation and any consequences of violations should be explicitly established to ensure optimal outcomes.

On the technical side, agreeing on the data standards and controlled vocabularies used to capture vaccine records is essential, though it may seem straightforward and can be very time-consuming. Given the variety of data standards and controlled vocabularies, and their ever-expanding scope, a more granular consensus is necessary, such as a minimal information model[62] for vaccine records, which could serve as a starting point. In addition, the stakeholders also need to agree on what constitutes a comprehensive vaccine record (including the fields, the values that can be used in the fields, and the metadata of the comprehensive records), where to save the external vaccine records, what to do if there are discrepancies between external records and internal records, or between two external records. Well-documented, accurate, and complete vaccination records are critical, but not a simple task; operationalizing data reuse to achieve once-entry, multiple-reuse whenever needed.

On the policy side, the work needs to take place at different levels: national, international, vendors, and institutional. The policies at different levels must not only be in place but also be aligned with one another. In the USA, the state-level legislation also plays a critical role in achieving interoperability. At a minimum, agreeing on who can do what and when across regional, national, and international borders is a prerequisite for interoperable vaccination records; moreover, balancing individual confidentiality, user convenience, and broad accessibility for citizens, healthcare providers, and authorities is necessary. From a more practical perspective, consensus among vendors and institutional-level policies can be a key facilitator or accelerator to achieve interoperable vaccine records. For example, agreeing on a minimal information model for vaccine records and on the standards (at the level of data elements) for the model's metadata can be a concrete first step. Last but not least, citizens must agree to share their vaccination records; without their consent, Figure 3 will lose a third of the stakeholders. Meanwhile, the consent per se requires careful procedural and language preparation, such as when to provide the consent, how to provide it, whether the vaccination information sharing is part of a broader health information sharing, or requires a separate consent.

Figure 4 summarizes key points for each aspect, and the challenge section provides further elaboration. Where there is a challenge, there are opportunities to overcome the challenge. Regarding an interoperable vaccination record, it is simpler than a complete interoperable electronic health record, but more complicated than reusable CDSS rules. More importantly, we are unlikely to achieve this through purely technical advances; rather, all aspects shown in Figure 4 must progress in a coherent, interconnected manner to enable interoperable vaccination records for all.

2. Enhance Methodological Transparency

As a perspective paper, your narrative approach is understandable, but the manuscript would benefit from a brief description of:

- How you selected countries, examples, and references
- What criteria guided the synthesis of challenges and solutions
- How stakeholder roles were defined (e.g., individuals, providers, authorities)

Response: Thank you for your suggestions. We have added section 1.5 to articulate the methods we used. We have to admit that the Nordic Countries, the UK, and the US are a convenient sample based on the coauthors' experience. We did several other countries, including Canada, as examples by adding references 54, 55, 56. The stakeholder roles are explained in section 1.5.

Other vaccine records-related examples include Canada and Asia[54-56]; however, they were all at the preparation or feasibility stages, and none have realized interoperable vaccine records.

1.5. Methods Used

We used the Nordic countries, the UK, and the USA as examples to compare the vaccination practices and vaccine record-keeping. A convenient sample among coauthors, aiming to demonstrate the realities in vaccination and the necessity of interoperable vaccine records. All authors' decades of experience and expertise in interoperability, medicine, and HealthIT, as well as the existing literature, have informed the paper's content, structure, and organization. In this manuscript, healthcare providers refer to healthcare professionals who can administer vaccines and maintain their records; individuals are used interchangeably with patients or citizens, i.e., recipients of vaccines, who may need interoperable vaccine records for travel, relocation, or school enrollment;

authority refers to government at different levels (school, county, state, national, or international) or the trusted brokers, such as those enabled by blockchain technology; authority typically establishes the rules related to vaccine requirements and enforce their implementation.

This addition will improve the perceived scientific integrity of the work.

3. Strengthen Empirical Support for Claims

Certain statements—such as the improvements in safety, reduction in redundant vaccination, and enhanced data quality from interoperable records—are well reasoned but not empirically demonstrated.

Where possible:

- Include data from countries with existing national registries
- Cite evidence on the impact of interoperability on patient outcomes or system efficiency
- Add examples showing measurable improvements from existing digital immunization systems

Response: Thank you for your comments. We have added references 14 to 22 to provide the impact of interoperability in clinical care, cost effectiveness and references 54 to 56 add other countries as examples. The goal is not to enumerate all countries with immunization registries; rather, we used these countries as examples to highlight the need for interoperable vaccine records, even with national immunization registries.

A recent national survey showed that only 18% of the family physicians have ideal immunization-related interoperability, and the overall ideal interoperability is between 8% to 19%[14]. Interoperability can play a critical role in providing complete patient records for medical referrals, second-opinion consultations, hospital admissions and discharges, emergencies, relocations, and travel, all of which directly contribute to safer, timely, more effective, non-redundant clinical care, better outcomes, and reduced cost [15-22].

Other vaccine records-related examples include Canada and Asia[54-56]; however, they were all at the preparation or feasibility stages, and none have realized interoperable vaccine records.

4. Provide Evidence for Sociopolitical Assertions

Your discussion of cultural, political, and social barriers is important, but some assertions (e.g., media misinformation, politicization of vaccines) are not accompanied by specific sources.

To improve overall rigor:

- Support statements with public health studies or surveys
- Distinguish between observations grounded in evidence and author interpretations
- Consider adding regional differences where relevant

Response: Thank you for your suggestions. All the evidence from references is cited accordingly. The rest of the statements are by authors. The goal of the paper is to elaborate on the necessity and significance of interoperable vaccine records, the challenges they pose, and what we can do moving forward. These issues are beyond individual regions; in addition, the paper is not at the day-by-day implementation plan, but rather at a conceptual level.

5. Operationalize the Proposed Roadmap

Figure 4 captures the high-level dimensions (social/cultural, political, technical, policy) needed for interoperability. Yet, the roadmap remains conceptual.

Strengthen it by adding:

- Specific implementation steps
- Stakeholder roles and accountabilities
- Milestones or maturity levels
- Examples of successful approaches
- Guidance on harmonizing national versus regional policies

Response: Thank you for your comments. Based on your feedback, we have added more content to the Moving Forward Section. However, our intention is not to provide a day-by-day implementation or actionable plan in this paper. There are more prerequisites are required before we can have a detailed action plan. In our view, now is a bit premature to develop such a plan, considering where we are regarding interoperability. The closest example we can find is in Canada; unfortunately, from the paper, it sounds like even they have not realized the interoperable vaccine records, considering the paper included recommendations to achieve interoperable vaccine records.

This would greatly improve the manuscript's utility for policymakers and implementers.

Closing Remarks:

Your manuscript offers a valuable multidisciplinary perspective on an important global health challenge. With revisions addressing novelty, evidence, methodological clarity, and practical applicability, it can become a strong contribution to the literature on vaccination informatics and interoperability.

I look forward to seeing a revised version.

Response: Thank you very much for your constructive and very valuable feedback, which improved the clarity of our manuscript significantly.

Reviewer 2

Comments and Suggestions for Authors

The study briefly described vaccination records and their practices in the Nordic countries, the UK, and the USA. The comments are as follows:

1. The authors selected Nordic countries, US and USA as study sites. The reasons of selection need to be elaborated, e.g., similitary and difference of vaccination records and practices policies among the sites. It is better to use tables to compare them.

Response: Thank you for your feedback. The goal of this paper is not to compare the different practices in vaccination in different countries. We used these countries as examples to establish the background about the necessity of interoperable vaccine records, even among those with national registries. We have revised the wording to make it more explicit that the countries are used as a convenient sample as examples, not a thorough comparison.

2. For Figure 1, has it drawn by the authors or from literature? If latter, the authors need to provide the origin of the figure, as well as figures 3 and 4.

Response: Figures 1, 3, and 4 were made from scratch by us.

3. Line 81-83, can the figure explain the situation in UK and Nordic countries, besides the USA?

Response: Yes. We have modified the wording to reflect that.

Figure 1 illustrates the realities of vaccination records and the barriers to a consolidated, longitudinal vaccination record for everyone in the USA, the UK, the Nordic countries, and many other countries.

4. Figure 2 can be presented as a supplementary file.

Response: We could include Figure 2 as a supplementary file if the reviewer insists. We feel it is necessary to provide tangible examples of why interoperable vaccine records are needed.

5. It is better to present more comparison between the three regions (Nordic countries, UK and USA) in the manuscript, as more details in the USA system have been presented in this study.

Response: Thank you for your comment. We have added a summary section about the comparison of the Nordic countries, the UK, and the USA. They are used as examples to elaborate on the necessity of interoperable vaccine records. The goal is to conduct a thorough comparison side-by-side among the three.

In summary, the Nordic countries' national vaccine registries are better organized than those in the USA; however, the portability of vaccine records across countries remains a challenge. The UK NHS has made significant progress in enabling patients to view their vaccination records via their GP; however, it is unclear whether vaccinations received outside the GP offices are also recorded in the GP's records. Meanwhile, in the USA, vaccine records are maintained by multiple healthcare providers, and some are still in paper format, which adds an additional layer of complexity to achieving interoperability. Figure 1 illustrates the realities of vaccination records and the barriers to a consolidated, longitudinal vaccination record for everyone in the USA, the UK, the Nordic countries, and many other countries.

6. The reference style needs to follow the requirement of the journal.

Response: Thank you for pointing this out. We have revised the reference format accordingly.