BACKGROUND DOCUMENT

AIB Technical Meeting 2026

Vaccine records and recall systems in Europe to strengthen adult vaccination

Antwerp, Belgium
07 – 08 May 2026

Prepared by:
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Purpose of the background document

This pre-meeting background document contains a list of, AIB secretariat selected, abstracts/references from a PubMed Medline and grey literature search on the adult immunization related topic(s) of the technical meeting.

Literature Search Strategy; The literature search was conducted primarily in PubMed (2015 onwards) using combinations of keywords related to vaccination records, registries, digital vaccination systems, and reminder/recall interventions, with a focus on adult and life-course vaccination in Europe. Additional searches targeted implementation, evaluation, barriers, and cross-border data use to capture policy-relevant and harmonization aspects. From 2021 onwards, search queries were expanded to include terms related to the European Health Data Space (EHDS) and General Data Protection Regulation (GDPR). Complementary searches were performed using Google (first and, where relevant, second page results) with similar keyword combinations to identify grey literature and practical examples from across European countries.

The search was supplemented by backward citation chaining from key publications, as well as literature identified by invited speakers and participants. This approach was necessary to ensure comprehensive coverage of grey literature and specialized topics not readily captured through standard database searches, though it might introduce a potential selection bias toward expert-identified sources.

Reference List; References are ordered by publication year (most recent first) and, within each year, alphabetically by first author's last name. Publications from EU/EEA countries are the primary focus; key contributions from non-EU research institutes are included where relevant and are indicated as '*Good Practice*'.

This document should guide you in the preparation of the meeting, it should not be considered as a complete literature review, but hopefully it will give an overview of what has been published on the topic(s) of the technical meeting.
Inclusion of references in this document does not indicate that the AIB secretariat agrees with the content or correctness of the content.

Access the meeting objectives, intended impact, target audience and the full agenda with all presentations here;

Short Meeting Agenda

Sessions	Topics	Speaker(s)
Session 1: Opening, introduction and objectives	Introduction of Adult Immunization Board	Paolo Bonanni
	Meeting objectives (background and rationale)	Pierre Van Damme
Session 2: Setting the scene; Current landscape of adult vaccination records and data infrastructure across Europe	Designing and implementing an immunization information system (IIS)	Roberta Pastore
	Building the backbone: IIS and digital technologies for vaccination in Europe	Anna Odone
	Leveraging the upcoming Council recommendations on immunisation against respiratory infections and herpes zoster to advance digital infrastructure and data collection	Colin Russell
	Optimizing adult pneumococcal vaccination: leveraging IIS architecture for smarter pathway design	Tudor Pitulac
Session 3: Lessons learned from national and regional vaccination record systems	European coordination of vaccination record systems; focus on MesVaccins from France	Jean-Louis Koeck
	Denmark; from registers to impact: using IIS for research, reminders, and surveillance	Peter Henrik Andersen
	Belgium: Vaccinnet	Rosanne Wouters
	Validation of the Swedish vaccination register - Accuracy and completeness of register data	Anna Nilsson
Session 4: Role of data quality, interoperability, and access in shaping vaccination policy	Interoperability of IIS in the EU	Tamara Buble
	Policy brief: Improving national vaccination decision-making through data	Sandra Evans
	Insights from the Vaccine Monitoring Platform: reflections to shape a European Vaccination Card	Alessandra Buoninfante

Session 5: Improving European vaccination data: research potential and cross-border cooperation	Estimating statistical models when individual patient data are not accessible	Marie Analiz April (Liz) Limpoco
	Digital integration between hospitals and local health authorities for enhanced vaccination coverage among frail patients: the CareVax study protocol	Patrizia Laurenti
	Estimating vaccine effectiveness against hospitalisation and death using electronic health records (EHRs)	Toon Braeye
	Pilot from Latvia; implementation of Clinical Decision Support (CDS) system	Dace Zavadska
Session 6: Safeguarding health records with privacy, consent, and EHDS compliance	European Health Data Space Regulation	Petr Cermak
	Harmonization after the GDPR? Divergences in the rules for health data sharing	Fruzsina Molnár-Gábor
	Panel Discussion: From data to implementation: building vaccination record systems that work for citizens, science, and society	Francois Kaag Bo Lars Thorvald Terning Hansen Marta Giovanetti Francesca Tassinari Mariano Votta
Session 7: Value and feasibility of a European Vaccination Card (EVC)	Lessons learnt from the implementation of the portable European Vaccination Card in seven countries	Francois Kaag
	Ethical, legal, and social implications of vaccination passports or card	Francesca Tassinari
	EUVAC: supporting the development and national deployment of a cross-border digital vaccination card	Sofia Terzi
Session 8: Strategies for improving adult vaccine uptake: reminders, recalls, and best practices	Effectiveness of email-based reminders to increase vaccine uptake	Anna Odone
	Effectiveness of Text Messaging Nudging to Increase Coverage of Influenza Vaccination Among Older Adults in Norway (InfluSMS Study)	Bo Terning Hansen
	Key lecture: Tailored reminder strategies for	Allegra Ferrari

	underserved populations: evidence from a randomized trial in breast cancer screening	
Session 9: Breakout Groups and meeting closing		

Article References by session

Session 1. Introduction of Adult Immunization Board (AIB)

Potential questions/outcomes: What is the mission and objectives of the AIB? What is the operating procedure of the AIB? What is an AIB technical and country meeting? Who are the AIB advisors? How is the AIB funded?

1.1 Boccalini S, Del Riccio M, ….Pattyn J. Overcoming barriers to adult immunization in Europe: A decalogue for policy action by the Adult Immunization Board. Health Policy Technol. 2026;15(4):101179. doi:10.1016/j.hlpt.2026.101179 .

Adult immunization is a critical yet underdeveloped area within European public health, as fragmented systems and implementation barriers persist. With a growing burden of vaccine-preventable diseases among adults due to demographic aging and emerging pathogens, this policy comment aims to address key barriers impeding a high vaccination uptake, including data availability, feasibility issues, political and financial constraints, vaccine confidence and literacy among the population and healthcare providers, and access issues and organization. Drawing on insights from Adult Immunization Board (AIB) meetings and discussions, a decalogue of actionable policy recommendations is proposed to overcome these barriers. This comprehensive strategy underscores the need for coordinated, multidisciplinary efforts and sustained political commitment to optimize adult immunization programs, leveraging lessons from the recent COVID-19 pandemic response.

1.2 AIB Technical meeting (April 2024) - Boccalini S, Bechini A, Del Riccio M, Weinberger B, Wysocki J, Martinelli D, Wichmann O, Likki T, Hendrickx G, Van Damme P, Wyndham-Thomas C, Bonanni P, Pattyn J. Strategies for introducing and implementing vaccines for adults into national immunization programs in Europe: Good practices and key insights of the adult immunization board meeting. Hum Vaccin Immunother. 2025 Dec;21(1):2451487.

In April 2024, the Adult Immunization Board convened a technical meeting to explore the latest strategies and identify exemplary approaches regarding the implementation of vaccines for adults into Europe's National Immunization Programmes (NIPs). The meeting was built around 3 pillars: decision making for introducing a new vaccine, implementation, monitoring and evaluation. The increasing number of new and improved vaccines available in a context of competing health priorities warrants transparent and evidence-based decision-making processes for vaccine introduction. In Europe, burden of disease, vaccine efficacy or effectiveness, and safety are universally used decision-making criteria. While economic evaluations and the quality of evidence are being increasingly considered, public acceptance, equity, and operational criteria remain

underutilised. Vaccine implementation requires careful planning and coordination. Implementation activities discussed during the meeting were vaccine targets, target population identification, communication, training of healthcare professionals, and the involvement of pharmacists. Once operational, NIPs are to be monitored in terms of safety, effectiveness, and impact. Implementation science and behavioural and cultural insights can be used to identify tangible interventions to improve vaccine uptake. As vaccine programmes in Europe shift towards a life-long approach, success stories and problem-solving strategies should continue to be identified and leveraged.

1.3 Pattyn J, Launay O, Steffen R, Weinberger B, Gabutti G, Ihan A, Weinke T, Jancoriene L, Bonanni P, Van Damme P: Overview of vaccines for adults authorized, recommended, and implemented in the European Union. NPJ Vaccines. 2025 Aug 28;10(1):205

An increasing number of vaccines for adults are being implemented in vaccination programs, reflecting the growing recognition of immunization as a lifelong public health strategy. However, no comprehensive overview of all vaccines for adults authorized, recommended, and implemented in the EU currently exists. To address this, the Adult Immunization Board developed a "vaccines for adults tracker and landscape" to map the range of vaccines for adults approved across the EU.

1.4 AIB Country meeting Italy (December 2023) – Bechini, A., Boccalini, S., Del Riccio, M., Pattyn, J., Hendrickx, G., Wyndham-Thomas, C., … Bonanni, P. (2024). Overview of adult immunization in Italy: Successes, lessons learned and the way forward. Human Vaccines & Immunotherapeutics

The exchange of knowledge and best practices in adult immunization are essential to improve vaccination strategies across the European region. Italy has made groundbreaking progress in the field, being one of the first countries to propose a life-course vaccination schedule, broadening the traditional focus on childhood immunization to include adults. All vaccines included in Italy's vaccination schedule are free of charge. Moreover, the country's National Immunization Plan sets clear coverage targets, immunization priorities, and actions to reduce disparities. However, the fragmentation of its National Health System following the constitutional reform of 2001 has led to an increased complexity and regional inequalities regarding immunization. Other challenges the country faces include growing vaccine hesitancy, data gaps and underserved populations. This review describes Italy's adult immunization system, from policy to implementation. The successes, challenges and lessons learned were shared during the first Adult Immunization Board country meeting in Italy, where local experts, healthcare providers, public health representatives, and policymakers engaged in collaborative discussions and shared insights through case studies and presentations (December 2023). These insights are reviewed and discussed in this manuscript.

1.5 Pattyn J, Del Riccio M, Bechini A, Hendrickx G, Boccalini S, Van Damme P, Bonanni P. The Adult Immunization Board (AIB): A new platform to provide multidisciplinary guidelines for the implementation and optimization of adult immunization in Europe. Vaccine. 2024 Jan 1;42(1):1-3. doi: 10.1016/j.vaccine.2023.11.060. Epub 2023 Dec 3. PMID: 38044243.

No abstract available

1.6 Pattyn J, Bonanni P, on behalf of the Adult Immunization Board working group. Assessing the health burden of vaccine-preventable infections in European adults: challenges and opportunities translated into action. Euro Surveill. 2023;28(48)

Abstract: Background - Accurate information on the health burden of vaccine-preventable infections (VPIs) is needed to support evidence-based vaccine policy recommendations and programs. The first technical meeting of the Adult Immunization Board (AIB) was dedicated to the assessment of health burden evidence of VPIs in European adults. Methods - The AIB technical meeting, held in Antwerp, Belgium, in April 2023, convened international experts on health burden of VPIs. Presentations by subject-matter experts and group discussions were held based on pre-defined meeting objectives, covering multiple topics on the availability and use of health burden evidence of adult VPIs in Europe. Results - Both opportunities and challenges were identified. Key points discussed included (1) the need for further harmonization of Burden of Disease (BoD) methodologies for cross-study and cross-country comparison, (2) the recognition that health burden studies require significant resources and high-quality data, and therefore improved infectious disease surveillance and collaborative efforts in Europe, (3) the important geographical differences and inequalities found at all levels of adult immunization in Europe that are to be considered when interpreting BoD results, and (4) the importance of tailored communication of VPI health burden data to each stakeholder for an effective translation into vaccine policy decisions. Conclusion - Several European initiatives promote health BoD harmonized methodologies and/or capacity building collaborations that are to be further built upon. Although VPI health burden data is available and is a key component in the evidence-based decision-making processes behind immunization strategies, data gaps remain, particularly for certain diseases and at-risk populations.

1.7 Adult Immunization Board website (link): www.adultimmunizationboard.org

All meeting materials (background document + slides + conclusions) are published on the AIB website. Summary meeting reports are published in peer-reviewed journals.

1.8 Adult Immunization Board video (link): https://www.youtube.com/watch?v=4lbpByoI6Ow

Session 2: Setting the scene; Current landscape of adult vaccination records and data infrastructure across Europe

Potential questions/outcomes: Present the state of adult immunization registries, data systems, and digital health solutions across Europe. Highlight differences in implementation, coverage, and technological maturity. Encourage discussion on how these infrastructures support immunization policy and practice.

2.1 Vigezzi, G. P., Maggioni, E., Clavario, L., Clerico Mosina, L., Raso, E., Marjin, C., … Odone, A. (2025). **Immunization information systems' implementation and characteristics across the world: a systematic review of the literature. Expert Review of Vaccines**, 24(1), 668–702. https://doi.org/10.1080/14760584.2025.2510338

Introduction

Immunization Information Systems (IISs) are essential public health tools, supporting the management and analysis of vaccination data to aid clinical and strategic decision-making.
Methods
Following PRISMA guidelines, this systematic review investigated global state and operational characteristics of IISs. A comprehensive search across multiple databases up to 6th of June 2023, identified 2,612 articles, with 238 included.
Results
A significant increase in IIS research was observed in recent years, with a strong preference (84.5%) for electronic immunization registers (EIRs). Notably, 36% of IISs operate at the national level, and 47.7% meet the U.S. CDC definition, 17.0% are interoperable with personal health records, and 11.7% provide direct access to vaccination data for vaccinees or their guardians. Other key features include automated reminder systems for recipients and providers (12.1%), near real-time or real-time data entry (11.0%), the inclusion of demographic and socioeconomic data (16.7%), and the capacity to document vaccine refusal or hesitancy (10.2%).
Conclusions
IISs contribute to improving population-level surveillance of vaccine-preventable diseases. Persistent limitations related to data standardization, interoperability, and cost-effectiveness evaluation must be addressed. Strengthening these aspects is crucial to fully harness the potential of IISs in various healthcare settings, where enhanced vaccination tracking and targeting are most urgently needed.

2.2 **GOOD PRACTICE -** Eiden, A. L., Hartley, L., Garbinsky, D., Saande, C., Russo, J., Hufstader Gabriel, M., Price, M., & Bhatti, A. (2024**). Adult vaccination coverage in the United States: A database analysis and literature review of improvement strategies**. Human Vaccines & Immunotherapeutics, 20(1), 2381283. https://doi.org/10.1080/21645515.2024.2381283

Despite vaccines being instrumental in reducing vaccine-preventable disease, adult vaccination rates in the United States (US) are below optimal levels. To better understand factors affecting vaccination rates, we analyzed trends in adult vaccination coverage using data from the Behavioral Risk Factor Surveillance System (BRFSS) and conducted a targeted literature review (TLR) on interventions to improve adult vaccination rates in the US. Both the BRFSS analysis and the TLR focused on influenza; pneumococcal disease; tetanus and diphtheria or tetanus, diphtheria, and acellular pertussis; herpes zoster; and human papillomavirus vaccination for US adults aged 18–64 years. The TLR additionally included hepatitis A and hepatitis B vaccination. Vaccination coverage rates (VCRs) and changes in VCRs were calculated using the 2011–2019 BRFSS survey data. For the TLR, the MEDLINE and MEDLINE In-Process databases were searched for articles on vaccination interventions published between January 2015 and June 2021. The BRFSS analysis showed that changes in VCRs were generally modest and positive for most states over the study period. The TLR included 32 articles that met the eligibility criteria; intervention strategies that improved adult vaccination outcomes incorporated an educational component, vaccination reminders or reinforcement at the point of care, or authorized non-clinician members of the healthcare team to vaccinate. Furthermore, interventions combining more than one approach appeared to enhance effectiveness. The strategies identified in this TLR will be valuable for policymakers and stakeholders to inform the development and implementation of evidence-based policies and practices to improve adult vaccination coverage.

2.3 Pavia, G., Branda, F., Ciccozzi, A., Romano, C., Locci, C., Azzena, I., Pascale, N., Marascio, N., Quirino, A., Matera, G., Giovanetti, M., Casu, M., Sanna, D.,

Ceccarelli, G., Ciccozzi, M., & Scarpa, F. (2024**). Integrating Digital Health Solutions with Immunization Strategies: Improving Immunization Coverage and Monitoring in the Post-COVID-19 Era**. Vaccines, 12(8), 847. https://doi.org/10.3390/vaccines12080847

The COVID-19 pandemic underscored the critical importance of vaccination to global health security and highlighted the potential of digital health solutions to improve immunization strategies. This article explores integrating digital health technologies with immunization programs to improve coverage, monitoring, and public health outcomes. It examines the current landscape of digital tools used in immunization initiatives, such as mobile health apps, electronic health records, and data analytics platforms. Case studies from different regions demonstrate the effectiveness of these technologies in addressing challenges such as vaccine hesitancy, logistics, and real-time monitoring of vaccine distribution and adverse events. The paper also examines ethical considerations, data privacy issues, and the need for a robust digital infrastructure to support these innovations. By analyzing the successes and limitations of digital health interventions in immunization campaigns during and after the COVID-19 pandemic, we provide recommendations for future integration strategies to ensure resilient and responsive immunization systems. This research aims to guide policymakers, health professionals, and technologists in leveraging digital health to strengthen immunization efforts and prepare for future public health emergencies.

2.4 Eiden, A. L., Barratt, J., & Nyaku, M. K. (2023). **A review of factors influencing vaccination policies and programs for older adults globall**y. Human Vaccines & Immunotherapeutics, 19(1), 2157164. https://doi.org/10.1080/21645515.2022.2157164

Policies and programs to increase vaccine coverage rates among adults 50 years of age or older are limited and vaccine uptake is often suboptimal. Our review evaluated evidence on the effectiveness and success of adult-targeted vaccination interventions and identified literature gaps. Literature was retrieved (2021) from PubMed, Embase, and Google Scholar databases. Outcomes assessed included data on an intervention's effectiveness and impact on vaccine uptake. Interventions were characterized thematically: affordability (n = 9), awareness (n = 25), and vaccination access (n = 6); and included influenza, pneumococcal, tetanus-containing, and herpes zoster vaccines. Interactive interventions directed toward patients, including provider-led educational initiatives and provider recommendations showed more positive associations than less interactive interventions, such as posters and reminder-recall letters. Provider interventions, including awareness campaigns, incentives, affordability efforts, or vaccination site expansion generally showed positive associations. Combining interventions was found to be successful across several studies. Barriers and interventions varied for population subgroups, therefore, tailoring programs is critical.

2.5 **GOOD PRACTICE -** Kpozehouen, E. B., Heywood, A. E., Menzies, R., Seale, H., Brotherton, J., & Raina Macintyre, C. (2023). **Informing the design of a whole of life immunisation register for Australia**. Vaccine, 41(19), 3011–3018. https://doi.org/10.1016/j.vaccine.2023.03.037

Introduction: In 2016, Australia launched a whole life immunisation register, the Australian Immunisation Register (AIR), building on a universal childhood register established in 1997. Immunisation Information Systems are well established in Europe, the US and elsewhere. However, a national system covering immunisation across the lifespan, with complete capture of the population and satisfactory data quality, is rare. Methods: A national workshop was convened in 2016 with key stakeholders from the government, new and existing vaccine users, and vaccine

providers to review the ideal features of the AIR to ensure optimal effectiveness. This workshop focused on the functionality needed to identify population groups newly included in the register and support the achievement of high immunisation coverage in these groups eligible for National Immunisation Program vaccines. Results: Key recommendations included the need for bidirectional data flow between the AIR and providers; systematic approaches to the capture and recording of accurate and complete data to ascertain important denominators for subpopulations, including Aboriginal and Torres Strait Islander status, medical risk factors, occupation, ethnicity, country of birth, and vaccines given during pregnancy; linkage with other government datasets including notifiable diseases; the capture of adverse events following immunisation; ease of access by patients, providers; and by researchers. Conclusions: Some recommendations from the workshop have informed the development and future utility of the AIR. Some recommendations from the workshop have been integrated into the current iteration of the AIR, which is more important than ever given the roll-out of COVID-19 vaccines. The accuracy and validity of data have subsequently improved through data entry controls, data integrity checks and reporting requirements. Access to AIR data for research remains protracted and costly, limiting research potential.

2.6 Odone, A., Gianfredi, V., Sorbello, S., Capraro, M., Frascella, B., Vigezzi, G. P., & Signorelli, C. (2021). **The Use of Digital Technologies to Support Vaccination Programmes in Europe: State of the Art and Best Practices from Experts' Interviews.** Vaccines, 9(10), 1126. https://doi.org/10.3390/vaccines9101126

Digitalisation offers great potential to improve vaccine uptake, supporting the need for effective life-course immunisation services. We conducted semi-structured in-depth interviews with public health experts from 10 Western European countries (Germany, Greece, Italy, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, and the United Kingdom) to assess the current level of digitalisation in immunisation programmes and retrieve data on interventions and best practices. Interviews were performed using an ad hoc questionnaire, piloted on a sample of national experts. We report a mixed level of digital technologies deployment within vaccination services across Europe: Some countries are currently developing eHealth strategies, while others have already put in place robust programmes. Institutional websites, educational videos, and electronic immunisation records are the most frequently adopted digital tools. Webinars and dashboards represent valuable resources to train and support healthcare professionals in immunisation services organisation. Text messages, email-based communication, and smartphone apps use is scattered across Europe. The main reported barrier to the implementation of digital-based programmes is the lack of resources and shared standards. Our study offers a comprehensive picture of the European context and shows the need for robust collaboration between states and international institutions to share best practices and inform the planning of digital intervention models with the aim of countering vaccine hesitancy and increasing vaccine uptake.

2.7 **GOOD PRACTICE -** Cataldi, J. R., Kerns, M. E., & O'Leary, S. T. (2020). **Evidence-based strategies to increase vaccination uptake: A review.** Current Opinion in Pediatrics, 32(1), 151–159. https://doi.org/10.1097/MOP.0000000000000843

Purpose of review
To summarize evidence-based strategies for improving pediatric immunization rates including physician behaviors, clinic and public health processes, community-based and parent-focused interventions, and legal and policy approaches
Recent findings

Studies continue to show the effectiveness of audit and feedback, provider reminders, standing orders, and reminder/recall to increase immunization rates. Provider communication strategies may improve immunization rates including use of a presumptive approach and motivational interviewing. Centralized reminder/recall (using a state Immunization Information System) is more effective and cost-effective compared to a practice-based approach. Recent work shows the success of text messages for reminder/recall for vaccination. Web-based interventions, including informational vaccine websites with interactive social media components, have shown effectiveness at increasing uptake of pediatric and maternal immunizations. Vaccination requirements for school attendance continue to be effective policy interventions for increasing pediatric and adolescent vaccination rates. Allowance for and ease of obtaining exemptions to vaccine requirements are associated with increased exemption rates.

Summary

Strategies to increase vaccination rates include interventions that directly impact physician behavior, clinic and public health processes, patient behaviors, and policy. Combining multiple strategies to work across different settings and addressing different barriers may offer the best approach to optimize immunization coverage.

2.8 Crowcroft, N. S., & Levy-Bruhl, D. (2017). **Registries: An essential tool for maximising the health benefits of immunisation in the 21st century**. Euro Surveillance: Bulletin Europeen Sur Les Maladies Transmissibles = European Communicable Disease Bulletin, 22(17), 30523. https://doi.org/10.2807/1560-7917.ES.2017.22.17.3052343

No abstract available

2.9 Derrough, T., Olsson, K., Gianfredi, V., Simondon, F., Heijbel, H., Danielsson, N., Kramarz, P., & Pastore-Celentano, L. (2017). **Immunisation Information Systems—Useful tools for monitoring vaccination programmes in EU/EEA countries, 2016**. Euro Surveillance: Bulletin Europeen Sur Les Maladies Transmissibles = European Communicable Disease Bulletin, 22(17), 30519. https://doi.org/10.2807/1560-7917.ES.2017.22.17.30519

Immunisation Information Systems (IIS) are computerised confidential population based-systems containing individual-level information on vaccines received in a given area. They benefit individuals directly by ensuring vaccination according to the schedule and they provide information to vaccine providers and public health authorities responsible for the delivery and monitoring of an immunisation programme. In 2016, the European Centre for Disease Prevention and Control (ECDC) conducted a survey on the level of implementation and functionalities of IIS in 30 European Union/European Economic Area (EU/EEA) countries. It explored the governance and financial support for the systems, IIS software, system characteristics in terms of population, identification of immunisation recipients, vaccinations received, and integration with other health record systems, the use of the systems for surveillance and programme management as well as the challenges involved with implementation. The survey was answered by 27 of the 30 EU/EEA countries having either a system in production at national or subnational levels (n = 16), or being piloted (n = 5) or with plans for setting up a system in the future (n = 6). The results demonstrate the added-value of IIS in a number of areas of vaccination programme monitoring such as monitoring vaccine coverage at local geographical levels, linking individual immunisation history with health outcome data for safety investigations, monitoring vaccine effectiveness and failures and as an educational tool for both vaccine providers and vaccine recipients. IIS represent a significant way forward for life-long vaccination programme monitoring.

Grey literature

2.10 Immunisation Information Systems: Making interoperable data systems for vaccination a reality in Europe 2022 RECOMMENDATIONS BASED ON CALLS TO ACTION ON HEALTH DATA ECOSYSTEMS https://globalhealthconnector.com/wp-content/uploads/2024/06/RT5-Report.pdf

This report presents the findings of two multi-stakeholder Round Table meetings that explored, and have proposed recommendations for how Europe and its Member States can advance effectively and rapidly towards having the most functionally suitable and interoperable information systems used to run, document, and evaluate immunisation programmes. This report is a consensus of 28 invited expert stakeholders in vaccine research and development, immunisation programmes, public health, clinicians, vaccination registries, immunisation information systems, health informatics and policy-setting. The Round Tables were held on 23rd June and 7th July 2022.

2.11 INOVIGATE – Maes I., Van Nuwenborg J., Rey S., Debruyn V., Adult vaccination action framework with policy proposals for Belgium https://pharma.be/sites/default/files/2025-04/2025_adult-vaccination-action-framework-with-policy-proposals-for-belgium_eng.pdf

Vaccination is a cornerstone of public health, yet adult vaccination rates in Belgium remain low, posing significant challenges to achieving WHO immunization goals. The COVID-19 pandemic highlighted critical gaps in adult immunization coverage and the need for a more cohesive vaccination framework. The 2020 report "Belgian vaccines landscape analysis"1 listed barriers to adult vaccination and systemic inefficiencies, forming the basis for this detailed adult vaccination plan with recommendations. This report outlines detailed policy proposals on planning, governance, budget and implementation aspects, with tailored solutions for the federal and regional Belgian context, as well as defined responsibilities for public health authorities, healthcare providers, and others. This action framework aims to improve adult vaccination rates, enhance public health resilience, and meet WHO targets.

2.12 LIFE COURSE IMMUNISATION IN EUROPE - NATIONAL EMPOWERMENT UNDER EU-SET GOALS - CLCI https://www.cl-ci.org/wp-content/uploads/2025/10/CLCI_LCI-policy-brief-1.pdf

Vaccination across the life course is a cornerstone of resilient health systems and healthy ageing. Yet, adult vaccination remains one of the most underutilized tools in public health across Europe. While all EU Member States operate National Immunisation Programmes (NIPs),the absence of consistent adult vaccination targets, strategies, and funding mechanisms has left significant gaps in coverage, access, and impact. This policy brief outlines a realistic and politically feasible approach to enhancing adult vaccination through nationally led solutions, supported by EU-set goals and coordination. By agreeing on measurable targets for coverage, ensuring robust documentation of disease reduction, strengthening surveillance and data systems, improving delivery models and logistics, and countering misinformation, Europe can advance public health protection while respecting subsidiarity and national diversity.

2.13 European Centre for Disease Prevention and Control. Designing and implementing an immunisation information system. Stockholm: ECDC; 2018. https://www.ecdc.europa.eu/sites/default/files/documents/designing-implementing-immunisation-information-system_0.pdf

This technical guidance is intended for all those involved in the design, implementation, management or continuous improvement of immunisation information systems (IIS): primarily immunisation programme managers and operational IIS staff; more broadly public health experts and policymakers, health researchers, health information specialists, IT developers, and healthcare professionals and providers. This technical guidance collates guiding principles and good practices from all aspects of IIS development and implementation. It proposes strategies that build on the experiences of IIS experts; provides case studies from actual programmes to highlight particular aspects of IIS practice, including functionalities, benefits, challenges, and implementation. It aims to share experiences and explore ideas that IIS experts consider valuable for upgrading an existing IIS, or developing a new IIS. Each IIS will be tailored to a specific set of objectives and thus be unique, both with regard to the type of data it collects and the functionalities it offers. In particular, this technical guidance aims to: • define immunisation information systems, • provide information on immunisation information systems and their added-value to immunisation programmes, • share best practices to advocate for immunisation information systems towards main stakeholders, • describe the functionalities and attributes that immunisation information systems can offer, and • give step-by-step guidance on the major steps to be considered for the design, implementation, or further development of an immunisation information system. The process of setting up an IIS is broken down into a series of steps that cover the entire project cycle. For each step this document will: • highlight key considerations, • give examples of lessons learned in a variety of contexts, and • provide references to a suite of more detailed resources on IIS.

2.14 EUVABECO PROJECT; https://euvabeco.eu/

The COVID-19 crisis reshaped global vaccination strategies, leading to the swift development of innovative practices. The EUVABECO project, funded by the European Commission's EU4Health program, aims to equip European Union Member States with validated implementation plans for these practices, accommodating diverse contexts to enable cross-border deployment. https://euvabeco.eu/

2.15 WHO EFFECTIVE COMMUNICATION OF IMMUNIZATION DATA https://iris.who.int/server/api/core/bitstreams/f5ca3219-6325-454f-96ec-740635f8093b/content

The aim of this document is to encourage and support effective communication of data related to vaccine-preventable diseases, vaccines and immunization (collectively referred to here as 'immunization data'). It is written for staff of immunization programmes or related entities to help build their capacities and interest in optimizing data communication to further achievement of immunization targets and goals.

2.16 DATA TO SUPPORT THE IMMUNISATION AGENDA 2030: A GLOBAL STRATEGY TO LEAVE NO ONE BEHIND https://www.immunizationagenda2030.org/images/documents/IA2030_Data_Action_Framework_-_FINAL_format_210630.pdf

Immunisation is the foundation of the primary health care system and an indisputable human right. It is also one of the best health investments money can buy. Yet despite tremendous progress, far too many people around the world—including nearly 20 million infants each year—have insufficient access to vaccines. In some countries, progress has stalled or even reversed, and there is a real risk that complacency will undermine past achievements. To address these challenges over the next decade, a new global vision and strategy, co-created by countries

and development partners, has been endorsed by the World Health Assembly. The Immunisation Agenda 2030 (IA2030) is structured according to the framework of vision and related impact goals in this report.

2.17 Driving life-course immunisation in National Immunisation Programs (NIPs) – a policy paper – CLCI https://www.cl-ci.org/wp-content/uploads/2023/10/Data-driven-decisions_FINAL-2.pdf

CLCI works towards a vision where everyone, regardless of age or life stage, can be vaccinated and shielded from vaccine-preventable diseases (VPDs). Comprehensive life course immunisation (LCI) is critical for protecting the health of individuals and communities across Europe. The complexity of today's health landscape and persistent vaccine access and uptake inequities call for a more systematic, data-driven approach to policymaking. Furthermore, harnessing the potential of data in vaccination decision-making requires a coordinated effort across various sectors.

Session 3: Lessons learned from national and regional vaccination record systems

Potential questions/outcomes: Explore real-world implementation experiences, challenges, and innovations in national and regional vaccination registries. Compare approaches across countries, identify common barriers, and discuss strategies for improving coverage, data quality, and usability. Encourage sharing of practical insights to inform future harmonization.

3.1 **GOOD PRACTICE -** Kim, T. H., Lee, K., Cho, J., Oh, J., Lee, S., Smith, L., Branda, F., Jung, J., Lee, J., Lee, H., & Yon, D. K. (2026). **Live Zoster Vaccination and the Reduced Risk of Chronic Respiratory Diseases: An Emulated Target Trial**. Allergy, 81(1), 209–219. https://doi.org/10.1111/all.70056

Background
Recent previous study suggests that live zoster vaccination may reduce the risk of diseases like dementia and cardiovascular diseases, through prevention of herpes zoster. Thus, this study aims to evaluate whether live zoster vaccination can reduce the risk of chronic respiratory disease including chronic obstructive pulmonary disease (COPD), asthma, and interstitial lung disease (ILD).
Methods
This target trial emulation study utilized a nationwide, population-based cohort of 2,519,582 individuals aged ≥ 50 years in South Korea. The cohort was constructed by integrating health insurance data from the Korea Health Insurance Review and Assessment Service, national health examination data from the Korean National Health Insurance Service, and vaccination records from the Korea Disease Control and Prevention Agency. The exposure was receipt of at least one dose of live zoster vaccination between January 1, 2012, and December 31, 2021. Outcomes included the incidence of newly diagnosed COPD, asthma, and ILD, as well as hospitalizations associated with these conditions. Following stabilized inverse probability of treatment weighting, we employed the Cox proportional hazards model to estimate adjusted hazard ratios (aHRs) and 95% confidence intervals (CIs) and calculated restricted mean survival time (RMST) for the risk of outcomes associated with live zoster vaccination. The observation period extends from the index date to January 31, 2024.
Measurements and Main Results

After stabilized inverse probability of treatment weighting, 745,644 individuals were assigned to the vaccinated group and 1,069,230 to the unvaccinated group, with a mean age of 62.12 years (SD, 3.45) and 49.18% were male. Live zoster vaccination significantly reduced the risk of COPD (aHR, 0.70 [95% CI, 0.69–0.71]; RMST difference, 23.22 days [95% CI, 21.72–24.71]), asthma (0.68 [0.67–0.69]; 25.96 days [24.52–27.40]) and ILD (0.78 [0.73–0.82]; 2.39 days [2.05–2.74]). Additionally, the vaccination significantly reduced the risk of hospital admissions due to these conditions: COPD (0.59 [0.53–0.65]), asthma (0.54 [0.49–0.59]), and ILD (0.68 [0.58–0.79]). The observed protective benefit was more pronounced in non-smokers compared to current smokers. The time-attenuated effect was strongest during 1 to 2 years following live zoster vaccination and remained evident for up to 6 years.

Conclusions

Live zoster vaccination significantly reduced the incidence of chronic respiratory disease and related hospitalizations. These findings suggest that live zoster vaccination may provide public health benefits beyond preventing herpes zoster in adults aged ≥ 50 years.

3.2 Mateo-Urdiales, A., Fabiani, M., Mayer, F., Sacco, C., Belleudi, V., Da Cas, R., Fotakis, E. A., De Angelis, L., Cutillo, M., Petrone, D., Morciano, C., Cannone, A., Del Manso, M., Riccardo, F., Bella, A., Menniti-Ippolito, F., Pezzotti, P., Spila Alegiani, S., & Massari, M. (2024). **Risk of breakthrough infection and hospitalisation after COVID-19 primary vaccination by HIV status in four Italian regions** during 2021. BMC Public Health, 24(1), 1569. https://doi.org/10.1186/s12889-024-19071-y

Background

As of 2024, vaccination remains the main mitigation measure against COVID-19, but there are contradictory results on whether people living with HIV (PLWH) are less protected by vaccines than people living without HIV (PLWoH). In this study we compared the risk of SARS-CoV-2 infection and COVID-19 hospitalisation following full vaccination in PLWH and PLWoH.

Methods

We linked data from the vaccination registry, the COVID-19 surveillance system and from healthcare/pharmacological registries in four Italian regions. We identified PLWH fully vaccinated (14 days post completion of the primary cycle) and matched them at a ratio of 1:4 with PLWoH by week of vaccine administration, age, sex, region of residence and comorbidities. Follow-up started on January 24, 2021, and lasted for a maximum of 234 days. We used the Kaplan-Meier estimator to calculate the cumulative incidence of infection and COVID-19 hospitalisation in both groups, and we compared risks using risk differences and ratios taking PLWoH as the reference group.

Results

We matched 42,771 PLWH with 171,084 PLWoH. The overall risk of breakthrough infection was similar in both groups with a rate ratio (RR) of 1.10 (95% confidence interval (CI):0.80–1.53). The absolute difference between groups at the end of the study period was 8.28 events per 10,000 person-days in the PLWH group (95%CI:-18.43-40.29). There was a non-significant increase the risk of COVID-19 hospitalisation among PLWH (RR:1.90; 95%CI:0.93–3.32) which corresponds to 6.73 hospitalisations per 10,000 individuals (95%CI: -0.57 to 14.87 per 10,000).

Conclusions

Our findings suggest PLWH were not at increased risk of breakthrough SARS-CoV-2 infection or COVID-19 hospitalisation following a primary cycle of mRNA vaccination.

3.3 Chrapkowska, C., Galanis, I., Kark, M., Lepp, T., Lindstrand, A., Roth, A., & Nilsson, A. (2020). **Validation of the new Swedish vaccination register - Accuracy and completeness of register data**. Vaccine, 38(25), 4104–4110. https://doi.org/10.1016/j.vaccine.2020.04.020

Objective
The aims of this study are to validate infant vaccination data in the Swedish Vaccination Register (SVR) to the Swedish administrative coverage reports, and to assess differences in register-based vaccination coverage estimates between providers using different data reporting methods.
Methods
The study population included all infants born in Sweden with a Swedish Personal Identity Number during 2014 and 2015 (n = 230,220). Data on all National Immunisation Programme vaccinations administered before 24 months of age were collected from the SVR and from administrative coverage reports. Information regarding data registration methods in the SVR were collected from national and regional authorities. Coverage from health care providers using single registration methods, where vaccination data were transferred automatically from the electronic health care record to the SVR, was compared to that from providers using double registration methods where data had to be added into the SVR in a separate process.
Results
For 98,4% of the study population at least one vaccination was recorded in the SVR. The coverage of 3-dose DTP-containing (87,1%) and 1 dose MMR (91,1%) in the register did not reach administrative data coverage (97,4% for 3-dose DTP-containing and 97,0% for MMR). Single registration procedures yielded significantly higher coverage than double registration procedures (92,24% vs 87,10%, $p < 0,0001$). A regional switch from double to single registration increased coverage from 80,0 to 95,2%.
Conclusions
The SVR is a valuable data source for vaccination coverage monitoring. For research purposes, the SVR provides valuable data, since every health care provider is obliged to register all vaccine doses given within the national immunisation program. The SVR shows a high completeness validated by comparison to a very well-functioning administrative data system. Single-registration procedures give more complete data and should be supported by health systems while creating health care registers.

3.4 Baum, U., Sundman, J., Jääskeläinen, S., Nohynek, H., Puumalainen, T., & Jokinen, J. (2017). **Establishing and maintaining the National Vaccination Register in Finland. Euro surveillance** : bulletin Europeen sur les maladies transmissibles = European communicable disease bulletin, 22(17), 30520. https://doi.org/10.2807/1560-7917.ES.2017.22.17.30520

Computerised, population-based vaccination registers are valuable tools for assessing the vaccine uptake and impact in populations. However, reliable impact assessment is only possible if the data quality can be reviewed and monitored continuously. This report describes the establishment and maintenance of the National Vaccination Register (NVR) in Finland. Currently, the NVR covers nationwide records of vaccinations given within the frame of the National Vaccination Programme since 2009. All vaccinations registered in the NVR contain a record of the personal identity code, the administered vaccine, and the date of vaccination. The vaccine lot number is the key component for recording and identifying vaccinations, because of its broad availability across patient information systems and its importance in vaccine safety monitoring. Vaccination records are accumulated and updated daily into the NVR, and their completeness is monitored monthly to assess deficiencies in data entry and data collection. Additionally, an

alert system reports unexpected changes in data accumulation prompting the validation of observed changes in vaccination coverage. The presented process documentation may serve as basis to improve the design and quality of other vaccination or healthcare registers and aims to inspire the set-up of vaccination registers in those countries which still do not have one.

3.5 Grove Krause, T., Jakobsen, S., Haarh, M., & Mølbak, K. (2012). **The Danish vaccination register.** Euro surveillance : bulletin Europeen sur les maladies transmissibles = European communicable disease bulletin, 17(17), 20155. https://doi.org/10.2807/ese.17.17.20155-en

Immunisation information systems (IIS) are valuable tools for monitoring vaccination coverage and for estimating vaccine effectiveness and safety. Since 2009, an advanced IIS has been developed in Denmark and will be implemented during 2012-14. This IIS is based on a database existing since 2000. The reporting of all administered vaccinations including vaccinations outside the national programme will become mandatory. Citizens will get access to data about their own vaccinations and healthcare personnel will get access to information on the vaccinations of their patients. A national concept of identification, a national solution combining a personal code and a card with codes, ensures easy and secure access to the register. From the outset, the IIS will include data on childhood vaccinations administered from 1996 and onwards. All Danish citizens have a unique identifier, a so called civil registration number, which allows the linking of information on vaccinations coming from different electronic data sources. The main challenge will be to integrate the IIS with the different electronic patient record systems currently existing at general practitioner, vaccination clinic and hospital level thereby avoiding double-entry. A need has been identified for an updated international classification of vaccine products on the market. Such a classification would also be useful for the future exchange of data on immunisations from IIS between countries.

Grey literature

3.6 Vaccines Today - How the Danish Vaccination Registry became a cornerstone of Denmark's immunisation service (2023) https://www.vaccinestoday.eu/stories/how-the-danish-vaccination-registry-became-a-cornerstone-of-denmarks-immunisation-service/

No summary available

Session 4: Role of data quality, interoperability, and access in shaping vaccination policy

Potential questions/outcomes: Examine how differences in data completeness, accessibility, and interoperability influence policy decisions and research. Highlight lessons from EU, WHO and EMA frameworks, and discuss strategies to strengthen evidence-informed vaccination policies.

4.1 Evans, S., Schmitt, J., Kalra, D., Sokol, T., & Holt, D. (2024). **Policy brief: Improving national vaccination decision-making through data**. Frontiers in public health, 12, 1407841. https://doi.org/10.3389/fpubh.2024.1407841

Life course immunisation looks at the broad value of vaccination across multiple generations, calling for more data power, collaboration, and multi-disciplinary work.

Rapid strides in artificial intelligence, such as machine learning and natural language processing, can enhance data analysis, conceptual modelling, and real-time surveillance. The GRADE process is a valuable tool in informing public health decisions. It must be enhanced by real-world data which can span and capture immediate needs in diverse populations and vaccination administration scenarios. Analysis of data from multiple study designs is required to understand the nuances of health behaviors and interventions, address gaps, and mitigate the risk of bias or confounding presented by any single data collection methodology. Secure and responsible health data sharing across European countries can contribute to a deeper understanding of vaccines.

4.2 Steffen, C. A., Henaff, L., Durupt, A., Omeiri, N. E., Ndiaye, S., Batmunkh, N., Liyanage, J. B. L., Hasan, Q., Mosina, L., Jones, I., O'Brien, K., & Hombach, J. **Evidence-informed vaccination decision-making in countries: Progress, challenges and opportunities** Vaccine. 2021 Apr 8;39(15):2146-2152 https://doi.org/10.1016/j.vaccine.2021.02.055

Countries face an increasingly complex vaccination landscape. As well as ever-changing infectious disease epidemiology, the number and diversity of vaccine-preventable diseases, vaccine products, and vaccine technologies continue to increase. To ensure that vaccination decision-making is transparent, country-owned and informed by sound scientific evidence, many countries have established national immunization technical advisory groups (NITAGs) to provide independent expert advice. The past decade has seen substantial growth in NITAG numbers and functionality, and there is now a need to consolidate this progress, by further capacity building, to ensure that NITAGs are responsive to the changing face of immunization over the next decade.

Grey literature

4.3 WHO's Global Digital Health Certification Network
https://www.who.int/initiatives/global-digital-health-certification-network

One of the key tools used by many Member States in reopening economies during the COVID-19 pandemic has been digital COVID-19 test and vaccine certificates. As the directing and coordinating authority on international health work, at the onset of the pandemic, WHO engaged with all WHO Regions to define overall guidance for such certificates and published the Digital Documentation of COVID-19 Certificates: Vaccination status and Test results in 2021 and 2022, respectively.
Learning from the COVID-19 pandemic response, there is a recognition of an existing gap and continued need for a global mechanism that can support bilateral verification of the provenance of health documents for pandemic preparedness and continuity of care. The GDHCN can be used as an infrastructural building block to support additional use cases, which may include, for example, the digitisation of the International Certificate of Vaccination or Prophylaxis, verification of prescriptions across borders, the International Patient Summary, verification of vaccination certificates within and across borders, and certification of public health professionals (through WHO Academy). Expanding such digital solutions will be essential to deliver better health for people across the globe.
To meet this need, in line with the Global strategy on digital health priority actions, WHO has established the Global Digital Health Certification Network (GDHCN). The GDHCN is builds upon the experience of regional networks for COVID-19 Certificates and takes up the infrastructure and experiences with the digital European Union Digital COVID Certificate (EU DCC) system, which has seen adoption across all Member States of the EU as well as 51 non-EU countries and territories. The GDHCN

has been designed to be interoperable with other existing regional networks (e.g., ICAO VSD-NC, DIVOC, LACPass, SMART Health Cards) specifications.

4.4 European Commission GDHCN - https://health.ec.europa.eu/ehealth-digital-health-and-care/international-cooperation_en

What is the Global Digital Health Certification Network?
A technology that allows countries to share and verify digital health certificates (e.g. vaccination certificates). With over 80 countries connected, this network makes travelling, working, and obtaining medical care abroad easier.
Protecting privacy
The Global Digital Health Certification Network protects privacy. It uses advanced technology that follows EU standards to keep personal information safe and secure:

- personal information remains on your device and is not shared across the network
- only those keys certifying that a trusted partner has issued the document are shared
- data is protected from unauthorised access.

4.5 European Commission - A European strategy for data; https://digital-strategy.ec.europa.eu/en/policies/strategy-data

A European strategy for data
The strategy for data focuses on putting people first in developing technology, and defending and promoting European values and rights in the digital world.
Data is an essential resource for economic growth, competitiveness, innovation, job creation and societal progress in general. In the future, the development of data-driven applications will bring various benefits to both citizens and businesses:

- improve healthcare
- create safer and cleaner transport systems
- generate new products and services
- reduce the costs of public services
- improve sustainability and energy efficiency

The European strategy for data aims at creating a single market for data that will ensure Europe's global competitiveness and data sovereignty. This will lead to the creation of Common European Data Spaces. They will ensure that more data becomes available for use in the economy and society, while keeping the companies and individuals who generate the data in control.

4.6 Publications Office of the European Union, Data.europa.eu data quality guidelines, Publications Office, 2021, https://data.europa.eu/doi/10.2830/79367

The publication 'Data.europa.eu data quality guidelines' contains a set of recommendations for delivering high-quality. They are addressed to data providers to support them in preparing their data, developing their data strategy and ensuring data quality. It is composed of the following four parts: 1. Recommendations for providing high-quality data. The recommendations cover general aspects of quality issues regarding the findability, accessibility, interoperability and reusability of data (including specific recommendations for common file formats like CSV, JSON, RDF and XML); 2. Recommendations for data standardization (with EU controlled vocabularies) and data enrichment; 3. Recommendations for documenting data; 4. Recommendations for improving the 'openness level'. At the end of the publication the reader will find a glossary, a table with the overview of quality indicators and metrics, a checklist with the most important steps for improving the quality of data and metadata and a list of literature.

4.7 New European Interoperability Framework Promoting seamless services and data flows for European public administrations
https://ec.europa.eu/isa2/sites/default/files/eif_brochure_final.pdf

Summary by the AIB Secretariat: The European Union's internal market is built on four fundamental freedoms: the free movement of goods, capital, services, and people across all Member States. These freedoms rely on shared policies and interoperable systems that allow citizens and businesses to work, relocate, trade, and communicate seamlessly throughout the EU. As public administrations increasingly digitise their services to reduce bureaucracy and improve efficiency, there is a growing risk that isolated national digital systems could create new electronic barriers. Such fragmentation may hinder cross-border access to digital public services and undermine the functioning of the EU's digital single market.
To prevent this, digital transformation efforts must be coordinated at both national and European levels. The EU faces challenges that require common policy responses, supported by legislation mandating cross-border cooperation and interoperable digital systems. These systems ensure smooth communication between devices, networks, and data repositories, enabling more efficient interactions among public authorities, communities, and countries.
The European Interoperability Framework (EIF) provides guidance to public administrations to enhance interoperability governance, create effective cross-organisational relationships, streamline end-to-end digital processes, and ensure that legislation supports, rather than obstructs, interoperability. Through these measures, the EU aims to sustain a cohesive digital environment that strengthens the digital single market.

4.8 STRENGTHENING THE EUROPEAN VACCINE ECOSYSTEM: MANAGING THE DIGITAL TRANSITION https://ehma.org/app/uploads/2023/01/Strengthening-the-EU-Vaccine-Ecosystem.pdf

Summary by the AIB Secretariat: Vaccination remains one of the most effective and affordable public health interventions, yet vaccination coverage across Europe has stagnated and continues to vary widely between countries. This plateau, already present before the COVID-19 pandemic, is driven by multiple factors, including administrative and financial barriers, insufficient public awareness, and the growing influence of vaccine misinformation. These challenges have weakened public confidence and pose significant concerns for health authorities.
In this context, the paper examines how the ongoing digital transformation of healthcare will influence Europe's vaccine ecosystem. It proposes several policy recommendations aimed at ensuring that digital advances strengthen, rather than exacerbate, existing inequalities. These recommendations target EU-level and national policymakers, as well as health managers, who play a crucial role in implementing digital technologies while maintaining the social, economic, and workforce sustainability of vaccination systems.
The recommendations were developed through a rigorous, multi-stage process that included literature review, expert workshops, stakeholder interviews, and a survey of health managers to assess feasibility across different European contexts. As Europe advances initiatives such as the European Health Data Space, understanding the perspectives of all stakeholders—especially health managers on the front lines of digital transformation—is essential. Supporting them in overcoming digital transition challenges will be key to strengthening the future European vaccine ecosystem.

4.9 Buble T, European Joint Action on Vaccination — EU-JAV; WP5 - Report on interoperability of IIS in the EU area (2022)

No abstract available

Session 5: Improving European vaccination data: research potential and cross-border cooperation

Potential questions/outcomes: Showcase examples of cross-country data initiatives and federated designs. Explore research opportunities, methodological challenges, and strategies to harmonize data for comparability. Encourage discussion on collaboration to strengthen European vaccination surveillance, data sharing, and health outcomes research.

5.1 Hansen, B. T., Dahl, J., Greve-Isdahl, M., Winje, B. A., Rydland, K. M., Campbell, S., Pay, A. S. D., Michelsen, T. M., & Meijerink, H. (2025). **Low and inequitable influenza and COVID-19 vaccination coverage among pregnant women in Norway: Nationwide population-based cohort study**. Vaccine, 61, 127386. https://doi.org/10.1016/j.vaccine.2025.127386

Background
Many countries recommend vaccination against influenza and COVID-19 during pregnancy, but surveillance of coverage is often lacking. We aim to quantify nationwide coverage of influenza and COVID-19 vaccination during pregnancy in Norway and identify its sociodemographic correlates.
Methods
We combined nationwide individual-level registry data on childbirth, vaccinations and sociodemographic factors for all pregnancies in Norway between 1 September 2021 and 31 December 2022. We estimated maternal influenza and COVID-19 vaccination coverage and its correlates among women whose only indication for vaccination was pregnancy, i.e., during the second and third trimester.
Results
Among 52,833 women eligible for influenza vaccination during pregnancy in the 2021/2022 influenza season, 27.7 % (*n* = 14,646) received the influenza vaccine. Similarly, among 50,108 women eligible for COVID-19 vaccination during pregnancy in the study period, 31.8 % (*n* = 15,951) received the COVID-19 vaccine. Coverage estimates were lower among mothers with immigrant background, low education, low income, low maternal age, multiple children, those living rurally and those outside the workforce. The lowest coverage was observed among immigrant women (14.5 % for influenza, 16.0 % for COVID-19 vaccination), with corresponding relative risks (RR) compared to native Norwegian women of 0.44 (95 % CI: 0.42, 0.46) and 0.41 (95 % CI: 0.39, 0.43). The highest coverage was observed among women with the highest education (38.2 % for influenza, 43.6 % for COVID-19), with corresponding RRs compared to women with the lowest education of 2.47 (95 % CI: 2.33, 2.62) and 2.36 (95 % CI: 2.24, 2.49).
Conclusion
The coverage of maternal vaccination against influenza and COVID-19 is insufficient. Additionally, there is high and consistent inequity in uptake. Timely and comprehensive surveillance of maternal vaccination programs should be prioritized to ensure that program performance can be adequately assessed and improved.

5.2 Humphreys, J., Nicolay, N., Braeye, T., Van Evercooren, I., Hansen, C. H., Moustsen-Helms, I. R., Sacco, C., Mateo-Urdiales, A., Castilla, J., Martínez-Baz, I., Machado, A., Soares, P., de Gier, B., Meijerink, H., Monge, S., Bacci, S., Nunes, B., & VEBIS-EHR working group. (2025). **Unmeasured confounding and misclassification in studies estimating vaccine effectiveness against hospitalisation and death using electronic health records (EHRs): An evaluation of a multi-country European retrospective cohort study**. BMC

Medical Research Methodology, 26(1), 9. https://doi.org/10.1186/s12874-025-02742-8

Background
Electronic health record (EHR)-based observational studies can rapidly provide real-world data on vaccine effectiveness (VE), though EHR data may be prone to misclassification and unmeasured confounding.
Methods
In VEBIS-EHR, a retrospective multi-country COVID-19 VE cohort study, we examined unmeasured confounding using a negative control outcome (death not related to COVID-19) and misclassification due to timing of data extraction. The evaluation spanned two periods (November–December 2023, January–February 2024), encompassing up to 18.7 million individuals across six EU/EEA countries. Vaccine confounding-adjusted hazard ratios (aHRs) were pooled using random-effects meta-analysis.
Results
aHRs against non-COVID-19 mortality ranged from 0.35 (95% CI: 0.28–0.44) to 0.70 (0.66–0.73) when comparing vaccinated versus unvaccinated. Delaying EHR data extraction modestly increased the capture of outcome and exposure events, with some variation by vaccination status. Site-level fluctuations in aHRs did not meaningfully alter the overall pooled VE, suggesting stable estimates despite misclassification related to extraction timing.
Conclusions
We observed some evidence of unmeasured confounding when using non-COVID-19 deaths as a negative outcome, though the specificity of our negative control must be considered. This result may suggest overestimation of VE, but also the need for further analysis with more specific negative control outcomes and confounding-adjustment techniques. Addressing such confounding using richer data sources and more refined approaches remains critical to ensure accurate, timely VE estimates based on retrospective cohorts constructed using registry data. Extending the delay between the end of observation and data extraction modestly improves the completeness of exposure and outcome data, with limited effect on pooled VE estimates.

5.3 Kettlitz, R., Harries, M., Contreras, S., Reinecke, J., Wieder, M. S., von Lengerke, T., Castell, S., Lange, B., Klett-Tammen, C. J., PCR-4-ALL study group, & MuSPAD study group (2025). **Self-reported poliomyelitis vaccination and documentation in adults indicates high uptake: a digital German epidemic panel, December 2024.** BMC public health, 25(1), 3514. https://doi.org/10.1186/s12889-025-24865-9

Background
On 12 December 2024, the Standing Committee on Vaccination (STIKO) recommended universal polio catch-up vaccination for children and adolescents up to 16, urging parents to check their children's immunization status following detections of vaccine-derived poliovirus in wastewater. The Robert Koch Institute (RKI) also advised healthcare professionals to ensure vaccination coverage in priority groups. Regional health authorities, called on all citizens to review their vaccination records to address any immunization gaps. We investigated vaccine uptake (documented / recalled) to improve estimates of immunity against poliovirus among the German population and gain insights into the proportion of undocumented vaccines.
Methods
We conducted a survey in December 2024 using the eResearch System PIA (Prospective Monitoring and Management—App) to collect data on self-reported vaccine uptake among a German cohort. We calculated the frequency of vaccinations that were documented and undocumented, as well as the types of

vaccines and the number of doses received. Vaccination status was classified as received ≤ 2 doses versus ≥ 3 doses of any polio-containing vaccine. We applied survey weights to calculate frequencies according the general German population (by age, sex, region) and logistic regression to examine the relationships between the vaccinations that were not documented but recalled, and the factors associated with these undocumented vaccinations.
Results
Among 1,124 participants who completed the survey on vaccination uptake, 1,097 (96.9%) participants stated to have a vaccination record. A total of 823/1,124 (74.3%) reported having a vaccination record, where at least one poliomyelitis vaccine was documented, whereas 233 (19.0%) participants recalled at least one poliomyelitis vaccination without documentation or vaccination record. Of 1,124, 68 participants (6.7%) did not report any polio vaccination neither documented nor recalled without documentation. Among the 823 participants with documented vaccination and at least one vaccination, 592 (75.1%) received at least three doses of a poliomyelitis vaccine, with a decline in older age groups, less than three doses were reported by 164 (17.6%), and the remaining 7.3% ($n = 67$) did not have information on the number of doses administered. Of 2,768 documented vaccine doses, 898 (29.9%) were oral poliovirus vaccines (OPV) and 704 (26.2%) were inactivated poliovirus vaccines (IPV). In 1,166 vaccines (43.9%), the type could not be derived by the participants from the vaccination record. The odds of having a recalled vaccination (not documented) was higher in male and the older age groups compared to females and younger participants.
Discussion
We found similar poliomyelitis vaccination uptake compared to other data sources e.g., of the Robert Koch Institute (RKI). Vaccine-derived immunity to poliomyelitis may be underestimated based on vaccination records only. There is a need to address potential gaps in health literacy and vaccination documentation. Efforts should be made to conduct continuous seroprevalence surveys in the population in response to emerging public health threats and deduce parameters to inform modelling infection dynamics in specific outbreak scenarios.

5.4 Lontano, A., Regazzi, L., Tona, D. M., Di Pumpo, M., Porcelli, M., Cacciuttolo, M. G., Parente, P., Gasbarrini, A., Grandaliano, G., Panocchia, N., Lopetuso, L., Pasciuto, T., Cadeddu, C., Bruno, S., Laurenti, P., Pascucci, D., & Pastorino, R. (2025**). Digital integration between hospitals and local health authorities for enhanced vaccination coverage among frail patients: the CareVax study protocol**. Frontiers in public health, 13, 1490244. https://doi.org/10.3389/fpubh.2025.1490244

Background:
The 2022–2025 Italian Plan for vaccine prevention (PNPV), recognizes vaccine-preventable diseases (VPDs) as significant contributors to mortality, morbidity, and healthcare expenditure. The digitalization of the national vaccine registry is underway. Initiatives aimed at enhancing digital integration between hospitals and territories are limited, and there is still a gap in the development of automated systems for identifying patients who could benefit from vaccinations directly offered from hospitals.
Methods:
Adult frail patients who access the hospital will be recruited over 4 years, following the acquisition of informed consent. With the assistance of a privacy-preserving automated algorithm, electronic hospital and vaccination records will be utilized to assess eligibility for vaccinations against *SARS-CoV-2*, *Herpes Zoster*, *Influenza*, *Streptococcus pneumoniae,* and *Hepatitis B*. Eligible patients will be invited to schedule a vaccination appointment and will be asked to fill in a questionnaire evaluating patient-reported experience measures (PREMs).

Outcomes of interest are the feasibility of the pathway, patients' satisfaction and concerns with it, and its impact on vaccination coverage.
Ethics and dissemination:
The study has been approved by the ethics committee of the "Fondazione Policlinico Universitario Agostino Gemelli" -FPG- (comitato.etico@policlinicogemelli.it), with approval number 5819. Furthermore, it has been published on ClinicalTrial.gov with the approval number NCT06127563. The results of the study will be disseminated via conference presentations and peer-reviewed publications.

5.5 Rodríguez-Blanco, N., Sánchez-Más, J., Herrero, E. G., Moreno, P. C., Gonzalez-Román, M. M., & Duro-Torrijos, J. L. (2025). **The impact of SARS-CoV-2 infection on vaccinated versus unvaccinated pregnant women: A retrospective cohort study**. BMC Pregnancy and Childbirth, 25(1), 519. https://doi.org/10.1186/s12884-025-07630-z

Background/Objectives
Pregnant women were included in the COVID-19 vaccination strategy adopted in Spain in May 2021. We evaluated the obstetric and neonatal symptoms and complications presented by these first pregnant women infected with SARS-CoV-2, vaccinated and unvaccinated.
Methods
A retrospective observational cohort study of 156 pregnant women with a positive diagnosis of SARS-CoV-2 (infection rate of 4.2%, 156/3719 births), treated at two public hospitals in the Valencian Community (Spain) over two years (2020–2022). Of those pregnant women infected, 28.8% (45) had received at least one dose of the COVID-19 vaccine before infection. The data were obtained from the digital medical record, the Nominal Vaccination Registry (RNV), and symptom data from the Epidemiological Surveillance Application (AVE) of the CV, supervised by the epidemiology units. We analyzed the symptoms of the disease and the main obstetric and neonatal variables depending on whether or not they were vaccinated with mRNA vaccines.
Results
Most pregnant women were diagnosed in the third trimester of pregnancy ($p = 0.003$) and reported symptoms associated with the infection (73%), but vaccinated women reported all the symptoms described to a lesser extent, with headache (R1.38, 95%IC 1.15 to 1.66) and vomiting (R 1.38, 95%IC 1.15 to 1.66) statistically significant. All cases of pneumonia occurred in unvaccinated pregnant women who required ventilatory assistance and referral to the Intensive Care Unit. Pregnant women vaccinated against SARS-CoV-2 infection had lower rates of gestational pathology, milder symptoms, and fewer postpartum complications than unvaccinated women, although the small sample size did not allow for a significant difference to be seen. Neonatal outcomes were similar in both groups.
Conclusions
COVID-19 vaccination in pregnant women with at least one dose is associated with reduced symptoms, less headache and vomiting, and fewer maternal complications, including pneumonia, which did not occur in the vaccinated cohort. Furthermore, the Apgar score at one and five minutes is higher than 7 in children of immunized mothers. Public health strategies should promote access to vaccines during pregnancy as an urgent priority, to minimize the risk of complications from COVID-19.

5.6 Vande Catsyne, C.-A., Slot, M., Buble, T., Eriksen, K., Svajda, M., Bradasevic, E., Vukovic, J., Jensen, S. K., Ivanković, H., Doupi, P., Christiansen, C. F., & Schutte, N. (2025). **Feasibility of mapping cross-country population coronavirus disease 2019 metrics in a federated design: Learnings from a HealthData@EU Pilot use case.** European Journal of Public Health, 35(Supplement_3), iii11–iii17. https://doi.org/10.1093/eurpub/ckaf017

The European Health Data Space aims to transform health data management across the EU, supporting both primary and secondary uses of health data while ensuring trust through General Data Protection Regulation compliance. As part of the HealthData@EU Pilot, this study investigates coronavirus disease 2019 (COVID-19) testing, vaccination, and hospitalization metrics across six European countries, with a focus on socioeconomic disparities and challenges in cross-border data access and standardization. This observational, retrospective cohort study used a federated analysis framework across Belgium, Croatia, Denmark, Finland, and France. Data were linked from administrative, social, health, and care records within each country's trusted research environment. A Common Data Model (CDM)-guided data harmonization, enabling nodes to perform independent analyses and share aggregated results. Key data processes (discovery, access, preparation, and analysis) were decentralized, with significant variability in data access procedures, security protocols, and available resources among nodes. The study revealed substantial differences in COVID-19 testing, vaccination, and hospitalization rates across countries. Denmark exhibited notably higher testing and infection rates. However, the study encountered key challenges: complex data access procedures, fragmented and incomplete socioeconomic data, and the need for extensive harmonization. Learnings from this pilot underscore the importance of streamlined, cross-country data access and standardization processes, which the European Health Data Space (EHDS) framework aims to address. The pilot demonstrates the feasibility of federated health data analysis across multiple countries while highlighting limitations in data access and interoperability. The EHDS framework offers a promising path to overcome these barriers, supporting efficient and standardized cross-border health research in the EU.

5.7 Andersson, N. W., Thiesson, E. M., Pihlström, N., Perälä, J., Faksová, K., Gram, M. A., Poukka, E., Leino, T., Ljung, R., & Hviid, A. (2024). **Comparative effectiveness of monovalent XBB.1.5 containing covid-19 mRNA vaccines in Denmark, Finland, and Sweden: target trial emulation based on registry data**. BMJ medicine, 3(1), e001074. https://doi.org/10.1136/bmjmed-2024-001074

Objective; To estimate the effectiveness of vaccination with a monovalent covid-19 mRNA vaccine containing the omicron XBB.1.5 subvariant against severe covid-19 disease in Denmark, Finland, and Sweden.
Design; Target trial emulation based on registry data.
Setting; Denmark, Finland, and Sweden, 1 October 2023 to 21 April 2024.
Participants; Source population of 3 898 264 individuals eligible for vaccination with the XBB.1.5 containing covid-19 mRNA vaccine at the start of the study on 1 October 2023. Study cohort comprised 1 876 282 recipients of an XBB.1.5 containing vaccine during the study period matched with 1 876 282 non-recipients. Individuals were aged ≥65 years (mean age 75.4 years, standard deviation 7.4 years) and had received at least four doses of a previous covid-19 vaccine.
Main outcome measures; Cumulative incidences of hospital admissions and deaths related to covid-19 in a follow-up period of 24 weeks after immunisation (defined as one week after vaccination) in recipients of an XBB.1.5 containing covid-19 mRNA vaccine and matched non-recipients. Cumulative incidences were used to calculate comparative vaccine effectiveness (1−risk ratio) and risk differences.
Results; The associated comparative vaccine effectiveness was 57.9% (95% confidence interval (CI) 49.9% to 65.8%) against hospital admission for covid-19 (1085 *v* 2635 events) and 75.2% (70.6% to 79.9%) against deaths related to covid-19 disease (348 *v* 1458 events) after 24 weeks of follow-up. This result corresponded to 154.7 (95% CI 78.3 to 231.0) hospital admissions for covid-19 and 120.3 (110.5 to 130.2) deaths prevented per 100 000 individuals who were vaccinated with an XBB.1.5 containing vaccine. The associated comparative vaccine

effectiveness was similar irrespective of sex, age group (65-74 *v* ≥75 years), number of doses of previous covid-19 vaccines, subgroup of co-administered seasonal influenza vaccines, and period of when either the omicron XBB or BA.2.86 sublineage was predominant. Although the observed reduction in risk was highest during the first weeks after vaccination, comparative vaccine effectiveness was well maintained after 24 weeks of follow-up.
Conclusions; In this study, in adults aged ≥65 years, vaccination with a monovalent XBB.1.5 containing covid-19 mRNA vaccine was associated with reduced rates of hospital admissions for covid-19 and deaths related to covid-19, during the autumn and winter of 2023-24 in Denmark, Finland, and Sweden.

5.8 Steens, A., Bergsaker, M. A. R., Aaberge, I. S., Rønning, K., & Vestrheim, D. F. (2013). **Prompt effect of replacing the 7-valent pneumococcal conjugate vaccine with the 13-valent vaccine on the epidemiology of invasive pneumococcal disease in Norway**. Vaccine, 31(52), 6232–6238. https://doi.org/10.1016/j.vaccine.2013.10.032

The introduction of the 7-valent pneumococcal conjugate vaccine (PCV7) in the childhood immunisation programme in Norway in 2006 substantially decreased the incidence of vaccine-type (VT) invasive pneumococcal disease (IPD) in all age groups. Additionally, a slight increase in the non-vaccine (NVT) serotype IPD incidence (serotype replacement) was observed. After replacing PCV7 with PCV13 in 2011, a further decrease in IPD incidence is expected. However, the protection by the six additional serotypes opens new nasopharyngeal niches for colonisation, which favours conditions for serotype replacement. Close monitoring of IPD therefore remains important in order to quickly detect changes.
In this observational retrospective population-based cohort study we used data notified nationally between 1 January 2004 and 31 December 2012 to determine the VT- and NVT-IPD incidences. The diversity in serotype distribution per year was analysed using the Simpson's index of diversity. Immunisation history of young children was obtained from the Norwegian Vaccination Registry to determine vaccine failure.
The incidence of VT-IPD decreased in the targeted (<5 years) and non-targeted (≥5) age groups since PCV7 introduction and further decreased after the replacement with PCV13. Only two cases of vaccine failure were identified. This indicates very high effectiveness of the 2 + 1 schedules with PCV7 or PCV13 and suggests that non-vaccinated individuals profit through indirect protection. The decrease in incidence of PCV7-IPD in non-targeted age groups became larger in later years, indicating a lag phase for the indirect effects, and suggests that the indirect protection of PCV13 will increase in coming years. The incidence of some NVT, specifically serotypes 23B and 15A, increased after PCV13 introduction. This coincided with an increased Simpson's index of diversity in the targeted age group. As this suggests that serotype replacement is again occurring, continues monitoring of IPD is important so that adaptations to vaccine recommendations can be promptly issued.

Session 6: Safeguarding health records with privacy, consent, and EHDS compliance

Potential questions/outcomes: Discuss legal, ethical, and technical aspects of health data management, including GDPR and European Health Data Space compliance. Explore mechanisms for consent, secure data exchange, and privacy-preserving research, while highlighting national examples and innovative approaches. Engage participants in considering risks and mitigation strategies.

6.1 Kruus, M. (2025). **Opting Out of Scientific Research with Health Data: The Limits of the EHDS and the GDPR**. European Journal of Health Law, 32(2), 165–189. https://doi.org/10.1163/15718093-bja10141

In the future, the European Health Data Space (EHDS) Regulation will enhance the secondary use of electronic health data in the EU, including for scientific research purposes. From the data subjects' perspective, the EHDS introduces a significant change, a new opt-out mechanism for the secondary use of data, in which data subjects shall have the right to opt out at any time without stating reasons. However, not all scientific research with health data will be covered by the opt-out rules of the EHDS. This article aims to clarify the effects of the EHDS' opt-out mechanism and its scope of application. It also suggests a balanced approach for Member States to implement the EHDS opt-out mechanism and reassess the implementation of the GDPR's right to object that remains relevant in the future in addition to the opt-out introduced by the EHDS.

6.2 Limpoco, M. A. A., C.Faes, and N.Hens. (2025). **Federated Mixed Effects Logistic Regression Based on One-Time Shared Summary Statistics**. Biometrical Journal67, no. 5: e70080. https://doi.org/10.1002/bimj.70080

Upholding data privacy, especially in medical research, has become tantamount to facing difficulties in accessing individual-level patient data. Estimating mixed effects binary logistic regression models involving data from multiple data providers, like hospitals, thus becomes more challenging. Federated learning has emerged as an option to preserve the privacy of individual observations while still estimating a global model that can be interpreted on the individual level, but it usually involves iterative communication between the data providers and the data analyst. In this paper, we present a strategy to estimate a mixed effects binary logistic regression model that requires data providers to share summary statistics only once. It involves generating pseudo-data whose summary statistics match those of the actual data and using these in the model estimation process instead of the actual unavailable data. Our strategy is able to include multiple predictors, which can be a combination of continuous and categorical variables. Through simulation, we show that our approach estimates the true model at least as good as the one that requires the pooled individual observations. An illustrative example using real data is provided. Unlike typical federated learning algorithms, our approach eliminates infrastructure requirements and security issues while being communication efficient and while accounting for heterogeneity.

6.3 Limpoco, M.A.A., Faes, C. and Hens, N. (2025), **Linear Mixed Modeling of Federated Data When Only the Mean, Covariance, and Sample Size Are Available**. Statistics in Medicine, 44: e10300. https://doi.org/10.1002/sim.10300

In medical research, individual-level patient data provide invaluable information, but the patients' right to confidentiality remains of utmost priority. This poses a huge challenge when estimating statistical models such as a linear mixed model, which is an extension of linear regression models that can account for potential heterogeneity whenever data come from different data providers. Federated learning tackles this hurdle by estimating parameters without retrieving individual-level data. Instead, iterative communication of parameter estimate updates between the data providers and analysts is required. In this article, we propose an alternative framework to federated learning for fitting linear mixed models. Specifically, our approach only requires the mean, covariance, and sample size of multiple covariates from different data providers once. Using the principle of statistical sufficiency within the likelihood framework as theoretical support, this proposed strategy achieves estimates identical to those derived from actual individual-level data. We demonstrate this approach through real data on 15 068

patient records from 70 clinics at the Children's Hospital of Pennsylvania. Assuming that each clinic only shares summary statistics once, we model the COVID-19 polymerase chain reaction test cycle threshold as a function of patient information. Simplicity, communication efficiency, generalisability, and wider scope of implementation in any statistical software distinguish our approach from existing strategies in the literature.

6.4 Murgia, Y., Gazzarata, R., Ciampi, M., Sicuranza, M., Cirillo, F., Esposito, C., Maggi, N., Balestra, G., Sacchi, L., & Giacomini, M. (2025). **The challenges of national health data ecosystems in feeding the European health data space: The Italian example**. Frontiers in Medicine, 12, 1644719. https://doi.org/10.3389/fmed.2025.1644719

The European Health Data Space (EHDS) is an European Union (EU) initiative, aimed at helping facilitate the secure and standardized sharing of health data to improve continuity of care, research and innovation. However, the successful implementation of such an ecosystem requires the active participation and cooperation of EU Member States (MS), each of which needs to adapt its local health data infrastructure to meet the requirements at the European level. The specific characteristics of the various European countries, such as size, number of citizens, and internal organization greatly influence the ease with which a country can integrate its health data structure into this supra-national system. States with higher levels of local autonomy are experiencing significant challenges in this process. For instance, the Italian National Healthcare System (NHS) is highly decentralized, with significant variability among regions and localities. This fragmentation raises problems for health data sharing and the integration of the Italian health ecosystem into the broader EHDS framework. This paper explores Italy's organizational and regulatory challenges, the technical barriers to interoperability, and the implications of data sharing in a decentralized environment. Moreover, by examining key Italian projects, such as Digital Health Solutions in Community Medicine (DHEAL-COM), and the tools developed by Standards Developing Organizations (SDOs) and affiliated bodies, such as Health Level 7 (HL7) Europe and Italy, the paper identifies successful initiatives and proposes strategies to overcome existing obstacles, also including security and privacy aspects of healthcare data.

6.5 Brück, O., Sanmark, E., Ponkilainen, V., Bützow, A., Reito, A., Kauppila, J. H., & Kuitunen, I. (2024**). European health regulations reduce registry-based research.** Health Research Policy and Systems, 22(1), 135. https://doi.org/10.1186/s12961-024-01228-1

Background
The European Health Data Space (EHDS) regulation has been proposed to harmonize health data processing. Given its parallels with the Act on Secondary Use of Health and Social Data (Secondary Use Act) implemented in Finland in 2020, this study examines the consequences of heightened privacy constraints on registry-based medical research.
Methods
We collected study permit counts approved by university hospitals in Finland in 2014–2023 and the data authority Findata in 2020–2023. The changes in the study permit counts were analysed before and after the implementation of the General Data Protection Regulation (GDPR) and the Secondary Use Act. By fitting a linear regression model, we estimated the deficit in study counts following the Secondary Use Act.
Results
Between 2020 and 2023, a median of 5.5% fewer data permits were approved annually by Finnish university hospitals. On the basis of linear regression modelling,

we estimated a reduction of 46.9% in new data permits nationally in 2023 compared with the expected count. Similar changes were neither observed after the implementation of the GDPR nor in permit counts of other medical research types, confirming that the deficit was caused by the Secondary Use Act.
Conclusions
This study highlights concerns related to data privacy laws for registry-based medical research and future patient care.

6.6 Minssen, T., Solaiman, B., Köttering, L., Wested, J., & Malik, A. (2024). **Governing AI in the European Union: Emerging infrastructures and regulatory ecosystems in health**. In B. Solaiman & I. G. Cohen (Eds.), Research Handbook on Health, AI and the Law. Edward Elgar Publishing Ltd. http://www.ncbi.nlm.nih.gov/books/NBK613197/

The European Union (EU) has been at the forefront of developing sophisticated artificial intelligence (AI) and data governance frameworks, driven by a commitment to data protection, digital rights, fundamental values and ethical standards. This chapter examines the evolving EU AI-related regulations and their potential implications for healthcare, highlighting key instruments including the Artificial Intelligence Act (AI Act), the AI Liability Directive (AILD) and the revised Product Liability Directive (revised PLD), and their intersection with AI medical devices under the Medical Device Regulation (MDR) and generative AI (GenAI). Additionally, it delves into the complex interplay between the General Data Protection Regulation (GDPR) and the AI Act, alongside an examination of the sector-specific European Health Data Space (EHDS) regulation, underscoring the need for additional instruments to govern non-personal data sharing. While the EU's multifaceted regulatory framework aims to strike a balance between seizing the opportunities of recent AI developments and safeguarding against potential harms, challenges arise from overlapping regulations and the lack of specific healthcare focus. As these regulations come into force, systematic analyses will be imperative to fully assess their impact. Ultimately, calibrating the risks of over- and under-regulation will be a delicate task where potential trade-offs will have to be carefully considered with a keen eye on international competition and the protection of fundamental values.

6.7 Rodríguez-Mejías, S., Degli-Esposti, S., González-García, S., & Parra-Calderón, C. L. (2024). **Toward the European Health Data Space: The IMPaCT-Data secure infrastructure for EHR-based precision medicine research.** Journal of Biomedical Informatics, 156, 104670. https://doi.org/10.1016/j.jbi.2024.104670

Background:
Art. 50 of the proposal for a Regulation on the European Health Data Space (EHDS) states that "health data access bodies shall provide access to electronic health data only through a secure processing environment, with technical and organizational measures and security and interoperability requirements".
Objective:
To identify specific security measures that nodes participating in health data spaces shall implement based on the results of the IMPaCT-Data project, whose goal is to facilitate the exchange of electronic health records (EHR) between public entities based in Spain and the secondary use of this information for precision medicine research in compliance with the General Data Protection Regulation (GDPR).
Data and methods:
This article presents an analysis of 24 out of a list of 72 security measures identified in the Spanish National Security Scheme (ENS) and adopted by members of the federated data infrastructure developed during the IMPaCT-Data project.
Results:

The IMPaCT-Data case helps clarify roles and responsibilities of entities willing to participate in the EHDS by reconciling technical system notions with the legal terminology. Most relevant security measures for Data Space Gatekeepers, Enablers and Prosumers are identified and explained.
Conclusion:
The EHDS can only be viable as long as the fiduciary duty of care of public health authorities is preserved; this implies that the secondary use of personal data shall contribute to the public interest and/or to protect the vital interests of the data subjects. This condition can only be met if all nodes participating in a health data space adopt the appropriate organizational and technical security measures necessary to fulfill their role.

6.8 Staunton, C., Shabani, M., Mascalzoni, D., Mežinska, S., & Slokenberga, S. (2024). **Ethical and social reflections on the proposed European Health Data Space.** European Journal of Human Genetics: EJHG, 32(5), 498–505. https://doi.org/10.1038/s41431-024-01543-9

The COVID-19 pandemic demonstrated the benefits of international data sharing. Data sharing enabled the health care policy makers to make decisions based on real-time data, it enabled the tracking of the virus, and importantly it enabled the development of vaccines that were crucial to mitigating the impact of the virus. This data sharing is not the norm as data sharing needs to navigate complex ethical and legal rules, and in particular, the fragmented application of the General Data Protection Regulation (GDPR). The introduction of the draft regulation for a European Health Data Space (EHDS) in May 2022 seeks to address some of these legal issues. If passed, it will create an obligation to share electronic health data for certain secondary purposes. While there is a clear need to address the legal complexities involved with data sharing, it is critical that any proposed reforms are in line with ethical principles and the expectations of the data subjects. In this paper we offer a critique of the EHDS and offer some recommendations for this evolving regulatory space.

6.9 Molnár-Gábor, F., Beauvais, M. J. S., Bernier, A., Jimenez, M. P. N., Recuero, M., & Knoppers, B. M. (2022). **Bridging the European Data Sharing Divide in Genomic** Science. Journal of Medical Internet Research, 24(10), e37236. https://doi.org/10.2196/37236

In this viewpoint, we argue for the importance of creating data spaces for genomic research that are detached from contexts in which fundamental rights concerns related to surveillance measures override a purpose-specific balancing of fundamental rights. Genomic research relies on molecular and phenotypic data, on comparing findings within large data sets, on searchable metadata, and on translating research results into a clinical setting. These methods require sensitive genetic and health data to be shared across borders. International data sharing between the European Union (EU) or the European Economic Area and third countries has accordingly become a cornerstone of genomics. The EU General Data Protection Regulation contains rules that accord privileged status to data processing for research purposes to ensure that strict data protection requirements do not impede biomedical research. However, the General Data Protection Regulation rules applicable to international transfers of data accord no such preferential treatment to international data transfers made in the research context. The rules that govern the international transfer of data create considerable barriers to international data sharing because of the cost-intensive procedural and substantive compliance burdens that they impose. For certain jurisdictions and select use cases, there exist practically no lawful mechanisms to enable the international transfer of data because of concerns about the protection of fundamental rights. The proposed solutions further fail to address the need to share large data sets of local and

regional cohorts across national borders to enable joint analyses. The European Health Data Space is an emerging federated, EU-wide data infrastructure that is intended to function as an infrastructure bringing together EU health data to improve patient care and enable the secondary use of health-related data for research purposes. Such infrastructure is implementing new institutions to support its functioning and is being implemented in reliance on a new enabling law, the regulation on the European Health Data Space. This innovation provides the opportunity to facilitate EU contribution to international genomic research efforts. The draft regulation for this data space provides for a concept of data infrastructure intended to enable cross-border data exchange and access, including access to genetic and health data for scientific analysis purposes. The draft regulation also provides for obligations of national actors aimed at making data widely available. This effort is laudable. However, in the absence of further, more fundamental changes to the manner in which the EU regulates the secondary use of health data, it is reasonable to believe that EU participation in international genomic research efforts will remain impeded.

6.10 Molnár-Gábor, F., Sellner, J., Pagil, S., Slokenberga, S., Tzortzatou-Nanopoulou, O., & Nyström, K. (2022). **Harmonization after the GDPR? Divergences in the rules for genetic and health data sharing in four member states and ways to overcome them by EU measures: Insights from Germany, Greece, Latvia and Sweden.** Seminars in Cancer Biology, 84, 271–283. https://doi.org/10.1016/j.semcancer.2021.12.001

The EU member states' healthcare and health-related research sectors are both characterized by an emerging infrastructural coalescence on a national and European level. The culmination of this coalescence is the planned creation of a European Health Data Space, an EU-wide infrastructure for the processing of personal data for healthcare and for secondary uses such as scientific research. In contrast to growing technical interoperability, the legal framework for such integration is not yet defined in detail, particularly with regard to data protection law. Its development is accompanied by discussions about divergent member state implementations of the EU General Data Protection Regulation (GDPR) that affect data sharing between healthcare and scientific research actors and across various sectors driven by divergent processing purposes.
The article presents four member states' main rules on data sharing based on the respective provision of the GDPR in six health-related contexts regarding data sharing across the healthcare and research sector and between the main actors of those sectors. The striking differences are then evaluated from the perspective of their factual effect on European data sharing depending on the legal characteristics of the GDPR provisions they rely on. Against this backdrop, the planned regulatory measures for the setup of the European Health Data Space are introduced and evaluated with regard to further harmonization between member states' laws and possibilities to overcome divergences in data protection rules relevant for European data sharing.
The results of the analysis point to the conclusion that the destructive effect of divergent member state rules depends on the legal qualification of the EU provisions they rely on and that this qualification also determines which further EU regulatory measure would be the most effective to set the framework for the European Health Data Space.

6.11 Alaqra, A. S., Fischer-Hübner, S., & Framner, E. (2018). **Enhancing Privacy Controls for Patients via a Selective Authentic Electronic Health Record Exchange Service: Qualitative Study of Perspectives by Medical Professionals and Patients**. Journal of medical Internet research, 20(12), e10954. https://doi.org/10.2196/10954

Background: Patients' privacy is regarded as essential for the patient-doctor relationship. One example of a privacy-enhancing technology for user-controlled data minimization on content level is a redactable signature. It enables users to redact personal information from signed documents while preserving the validity of the signature, and thus the authenticity of the document. In this study, we present end users' evaluations of a Cloud-based selective authentic electronic health record (EHR) exchange service (SAE-service) in an electronic health use case. In the use case scenario, patients were given control to redact specified information fields in their EHR, which were signed by their doctors with a redactable signature and transferred to them into a Cloud platform. They can then selectively disclose the remaining information in the EHR, which still bears the valid digital signature, to third parties of their choice.
Objective: This study aimed to explore the perceptions, attitudes, and mental models concerning the SAE-service of 2 user roles: signers (medical professionals) and redactors (patients with different technical knowledge) in Germany and Sweden. Another objective was to elicit usability requirements for this service based on the analysis of our investigation.
Methods: We chose empirical qualitative methods to address our research objective. Designs of mock-ups for the service were used as part of our user-centered design approach in our studies with test participants from Germany and Sweden. A total of 13 individual walk-throughs or interviews were conducted with medical staff to investigate the EHR signers' perspectives. Moreover, 5 group walk-throughs in focus groups sessions with (N=32) prospective patients with different technical knowledge to investigate redactor's perspective of EHR data redaction control were used.
Results: We found that our study participants had correct mental models with regard to the redaction process. Users with some technical models lacked trust in the validity of the doctor's signature on the redacted documents. Main results to be considered are the requirements concerning the accountability of the patients' redactions and the design of redaction templates for guidance and control.
Conclusions: For the SAE-service to be means for enhancing patient control and privacy, the diverse usability and trust factors of different user groups should be considered.

6.12 Papoutsi, C., Reed, J.E., Marston, C. et al**. Patient and public views about the security and privacy of Electronic Health Records (EHRs) in the UK: results from a mixed methods study**. BMC Med Inform Decis Mak 15, 86 (2015). https://doi.org/10.1186/s12911-015-0202-2

Background
Although policy discourses frame integrated Electronic Health Records (EHRs) as essential for contemporary healthcare systems, increased information sharing often raises concerns among patients and the public. This paper examines patient and public views about the security and privacy of EHRs used for health provision, research and policy in the UK.
Methods
Sequential mixed methods study with a cross-sectional survey (in 2011) followed by focus group discussions (in 2012-2013). Survey participants ($N = 5331$) were recruited from primary and secondary care settings in West London (UK). Complete data for 2761 (51.8 %) participants were included in the final analysis for this paper. The survey results were discussed in 13 focus groups with people living with a range of different health conditions, and in 4 mixed focus groups with patients, health professionals and researchers (total $N = 120$). Qualitative data were analysed thematically.
Results
In the survey, 79 % of participants reported that they would worry about the security of their record if this was part of a national EHR system and 71 % thought

the National Health Service (NHS) was unable to guarantee EHR safety at the time this work was carried out. Almost half (47 %) responded that EHRs would be less secure compared with the way their health record was held at the time of the survey. Of those who reported being worried about EHR security, many would nevertheless support their development (55 %), while 12 % would not support national EHRs and a sizeable proportion (33 %) were undecided. There were also variations by age, ethnicity and education. In focus group discussions participants weighed up perceived benefits against potential security and privacy threats from wider sharing of information, as well as discussing other perceived risks: commercial exploitation, lack of accountability, data inaccuracies, prejudice and inequalities in health provision.
Conclusions
Patient and public worries about the security risks associated with integrated EHRs highlight the need for intensive public awareness and engagement initiatives, together with the establishment of trustworthy security and privacy mechanisms for health information sharing.

Grey literature

6.13 European Commission - European Health Data Space Regulation (EHDS) https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en

The European Health Data Space (EHDS) is a cornerstone of the European Health Union and the first common EU data space dedicated to a specific sector as part of the European strategy for data.
The EHDS Regulation aims to establish a common framework for the use and exchange of electronic health data across the EU. It enhances individuals' access to and control over their personal electronic health data, while also enabling certain data to be reused for public interest, policy support, and scientific research purposes. It fosters a health-specific data environment that supports a single market for digital health services and products. Additionally, the regulation establishes a harmonised legal and technical framework for electronic health record (EHR) systems, fostering interoperability, innovation, and the smooth functioning of the internal market.
The EHDS will:

1. empower individuals to access, control and share their electronic health data across borders for the healthcare delivery (primary use of data);
2. enable the secure and trustworthy reuse health data for research, innovation, policy-making, and regulatory activities (secondary use of data);
3. foster a single market for electronic health record (EHR) systems, supporting both primary and secondary use.

By doing so, the EHDS will enable the EU to benefit from the full potential offered by a safe and secure exchange, use and reuse of health data to benefit patients, health professionals, researchers, regulators, and innovators.

6.14 INOVIGATE - Patient perspective on the use and reuse of real-world data in Belgium (in the context of the ATHENA project)

No abstract available

Session 7: Value and feasibility of a European Vaccination Card (EVC)

Potential questions/outcomes: Present the concept, technical feasibility, and expected benefits of a citizen-held European Vaccination Card. Discuss lessons

learned from EUVAC and COVID certificate initiatives. Explore potential challenges and opportunities for cross-border implementation.

7.1 Klausen, T.; Hartig, V.; Fuchs, D.; Krueger, N.; Jeltsch, V.M.; Bild, R.; Scheible, R. **A Digital Vaccination Pass Using Fast Healthcare Interoperability Resources: A Proof of Concept**. Digital 2024, 4, 389-409. https://doi.org/10.3390/digital4020019

The traditional manual recording of vaccination records in Germany faced challenges during the COVID-19 pandemic, prompting the introduction of a COVID smartphone app with QR codes. However, this solution brought new challenges, emphasizing the need for a centrally managed European digital vaccination record for efficiency and validity. This study assesses the feasibility of using the HL7 FHIR standard in the healthcare industry for implementing a digital vaccination pass management and monitoring system. The system aims to offer convenience and improved efficiency for both patients and healthcare providers while promoting interoperability with other healthcare systems. To this end, we developed a prototype using modern technologies, such as React, Quarkus, and Keycloak. Results indicate potential benefits for patients and healthcare providers, offering access to immunization records, personalized recommendations, and streamlined management. However, integrating nuanced vaccination processes into the standardized FHIR system requires custom extensions, which might hinder interoperability. Manual data entry and the integration of an identity provider present further obstacles in industry scenarios. Despite these challenges, this study suggests that implementing HL7 FHIR can enhance efficiency, data accessibility, and accuracy in the vaccination process, supporting broader digitization efforts in the German healthcare system and beyond.

7.2 de Miguel Beriain, Í., & Rueda, J. (2022). **Digital Covid Certificates as Immunity Passports: An Analysis of Their Main Ethical, Legal, and Social Issues.** Journal of Bioethical Inquiry, 19(4), 635–642. https://doi.org/10.1007/s11673-022-10209-4

Digital COVID certificates are a novel public health policy to tackle the COVID-19 pandemic. These immunity certificates aim to incentivize vaccination and to deny international travel or access to essential spaces to those who are unable to prove that they are not infectious. In this article, we start by describing immunity certificates and highlighting their differences from vaccination certificates. Then, we focus on the ethical, legal, and social issues involved in their use, namely autonomy and consent, data protection, equity, and international mobility from a global fairness perspective. The main conclusion of our analysis is that digital COVID certificates are only acceptable if they meet certain conditions: that they should not process personal data beyond what is strictly necessary for the aimed goals, that equal access to them should be guaranteed, and that they should not restrict people's autonomy to access places where contagion is unlikely. We conclude that, if such conditions are guaranteed, digital COVID certificates could contribute to mitigating some of the most severe socioeconomic consequences of the pandemic.

7.3 Nehme, M., Baysson, H., Pullen, N., Wisniak, A., Pennacchio, F., Zaballa, M.-E., Fargnoli, V., Kaiser, L., Hurst, S., Burton-Jeangros, C., Stringhini, S., Guessous, I., & Specchio-COVID19 study group. (2021**). Perceptions of vaccination certificates among the general population in Geneva, Switzerland.** Swiss Medical Weekly, 151, w30079. https://doi.org/10.4414/smw.2021.w30079

OBJECTIVE: This study aimed to assess the public perception of COVID-19 vaccination certificates as well as potential differences between individuals.
METHODS: Between 17 March and 1 April 2021, a self-administered online questionnaire was proposed to all persons aged 18 years and older participating in the longitudinal follow-up of SARS-CoV-2 seroprevalence studies in Geneva, Switzerland. The questionnaire covered aspects of individual and collective benefits, and allowed participants to select contexts in which vaccination certificates should be presented. Results were presented as the proportion of persons agreeing or disagreeing with the implementation of vaccination certificates, selecting specific contexts where certificates should be presented, and agreeing or disagreeing with the potential risks related to certificates. Logistic regression was used to calculate odds ratios for factors associated with certificate non-acceptance.
RESULTS: Overall, 4067 individuals completed the questionnaire (response rate 77.4%; mean age 53.3 ± standard deviation 14.4 years; 56.1% were women). About 61.0% of participants agreed or strongly agreed that a vaccination certificate was necessary in certain contexts and 21.6% believed there was no context where vaccination certificates should be presented. Contexts where a majority of participants perceived a vaccination certificate should be presented included jobs where others would be at risk of COVID-related complications (60.7%), jobs where employees would be at risk of getting infected (58.7%), or to be exempt from quarantine when travelling abroad (56.0%). Contexts where fewer individuals perceived the need for vaccination certificates to be presented were participation in large gatherings (36.9%), access to social venues (35.5%), or sharing the same workspace (21.5%). Younger age, no intent for vaccination, and not believing vaccination to be an important step in surmounting the pandemic were factors associated with certificate non-acceptance.
CONCLUSION: This large population-based study showed that the general adult population in Geneva, Switzerland, agreed with the implementation of vaccination certificates in work-related and travel-related contexts. However, this solution was perceived as unnecessary for access to large gatherings or social venues, or to share the same workspace. Differences were seen with age, sex, education, socioeconomic status, and vaccination willingness and perception, highlighting the importance of taking personal and sociodemographic variation into consideration when predicting acceptance of such certificates.

7.4 Nehme, M., Stringhini, S., Guessous, I., & SEROCoV-Pop Study Team, null. (2020). **Perceptions of immunity and vaccination certificates among the general population: A nested study within a serosurvey of anti-SARS-CoV-2 antibodies (SEROCoV-POP).** Swiss Medical Weekly, 150, w20398. https://doi.org/10.4414/smw.2020.20398

At a time when COVID-19 immunity certificates are debated and vaccination certificates might potentially be made available if an effective vaccine is established, we conducted a study to elucidate public opinion on this issue. Our objective was to determine social and individual perceptions of COVID-19 immunity certificates through a population-based study.
A nested survey within the SEROCoV-POP study, a population-based serosurvey of anti-SARS-CoV-2 IgG antibodies in Geneva, Switzerland, was conducted with a self-administered questionnaire. The questionnaire was proposed to 1520 SEROCoV-POP participants. Measures included percentage of participants agreeing or disagreeing with statements on immunity and vaccination certificates. Stratification by age, gender, education and work status was used to examine socio-demographic variations.
Of the 1520 SEROCoV-POP participants, 1425 completed the questionnaire (response rate 93%; mean age ± standard deviation 52 ± 15.1 years; 51.9% women). About 80% of participants agreed that knowing one's serology status

would lead to a change in one's behaviour. In the event that the presence of antibodies correlated with immunity, 60% of participants reported that certificates should be offered to the general population. The results showed variations in perceptions of certificates depending on the context (73% agreed on certificates' utility for travel, 72% for entering a country, and 32% for the right to work). Provided an effective vaccine was available, 55% of participants agreed that vaccination should be mandatory and 49% agreed that a vaccination certificate should be mandatory. About 68% reported a potential risk of discrimination and 28% a risk of deliberate infection. Differences were seen with age, gender and education level.
This study shows that the general adult population in Geneva, Switzerland can envisage scenarios where COVID-19 immunity, and eventually vaccination, certificates would be useful. Seroprevalence estimates of anti-SARS-CoV-2 antibodies remain low to date, and the interpretability of serological testing and immunity remains undefined. However, the information from this study is important, especially the differences based on context and the socio-demographic variations, and should be taken into account if COVID-19-related certificates are to be implemented.

Grey literature

7.5 European Vaccination Card (EVC): A citizen-held card to foster informed decision-making on vaccination, and improve continuity of care across the EU. (EUVABECO) https://euvabeco.eu/news/european-vaccination-card-evc-a-citizen-held-card-to-foster-informed-decision-making-on-vaccination-and-improve-continuity-of-care-across-the-eu/

In response to the critical need to restore trust in vaccination programs, the European Council proposed a series of actions in 2018 aimed at strengthening cooperation against vaccine-preventable diseases. This led to a 2019 study funded by the European Health and Digital Executive Agency (HaDEA), which explored the feasibility of a European Vaccination Card (EVC). The study involved analysing existing vaccination documents, creating and evaluating EVC prototypes, assessing public acceptance, and developing strategies for potential EU-wide deployment. Building on these efforts, EUVABECO is now launching EVC pilot projects in Latvia, Greece, Belgium, Germany, and Portugal. The EVC is designed to empower individuals by giving them control over their vaccination data, thus facilitating the management, review, and sharing of their vaccination records as needed. By providing citizens with accurate and current vaccination information, this tool aims to foster informed decision-making, enhance healthcare continuity, and reinforce confidence in both national and European vaccination strategies.

7.6 WHAT IS EUVAC? https://euvac.eu/about/

EUVAC is a collaborative European project supporting the development and national deployment of a cross-border digital vaccination card. It builds on the MyHealth@EU infrastructure to facilitate the secure and standardized exchange of vaccination information. EUVAC supports public health systems in improving disease monitoring, outbreak response, and preventive care.

7.7 Vaccines Today - European Vaccination Card will be piloted in five countries – (2024) https://www.vaccinestoday.eu/stories/european-vaccination-card-will-be-piloted-in-five-countries/

No summary available

7.8 Vaccines Today - EU COVID pass paves the way for digital vaccination card – (2021) https://www.vaccinestoday.eu/stories/eu-covid-pass-paves-the-way-for-digital-vaccination-card/

No summary available

Session 8: Strategies for improving adult vaccine uptake: reminders, recalls, and best practices

Potential questions/outcomes: Share evidence-based strategies for reminders and recalls. Identify communication strategies that increase vaccination coverage, particularly among vulnerable populations. Encourage discussion on scalability and effectiveness of interventions.

8.1 Reminder/ recall strategies for vaccinations

8.1.1 Hansen, B. T., Klungsøyr, O., Labberton, A. S., Sääksvuori, L., Rydland, K. M., Ødeskaug, L. E., Wisløff, T., & Meijerink, H. (2025). **Effectiveness of Text Messaging Nudging to Increase Coverage of Influenza Vaccination Among Older Adults in Norway (InfluSMS Study): Protocol for a Randomized Controlled Trial**. JMIR Research Protocols, 14, e63938. https://doi.org/10.2196/63938

Background: The coverage of influenza vaccination among older adults in Norway is insufficient, especially in some immigrant groups. To improve public health, there is a need for an intervention that can increase influenza vaccination coverage. Further, interventions tailored to reduce potential barriers among immigrants can reduce health inequities.
Objective: InfluSMS aims to determine if SMS nudging increases vaccination coverage among those aged 65 years or older (1) in Norway's general population; (2) among immigrants born in Poland; and (3) among immigrants born in Ukraine; and evaluate the impact of SMS nudging in Norwegian versus in the official language of the native country of immigrants born in Poland or Ukraine.
Methods: InfluSMS is a pragmatic randomized controlled trial conducted among people aged 65 years or older residing in Norway. Influenza vaccination coverage is the main outcome, measured in control and intervention arms for each of the 3 populations listed earlier. In all 3 populations, the control arm is standard care, that is, no individual reminder for influenza vaccination. All populations have an intervention arm that will receive an SMS nudge in the Norwegian language. In addition, the Polish and Ukrainian immigrant populations include a second intervention arm that will receive an SMS nudge in Polish or Ukrainian, respectively. In the general population, at least 23,485 individuals will be randomized to the SMS intervention arm while the rest of the population constitutes the control arm. In each of the 2 immigrant populations, we will randomize all eligible individuals 1:1:1 into the 3 arms. The intervention will take place at the start of the 2025-2026 influenza season. All eligible individuals will be passively followed up through the National Immunisation Registry, SYSVAK, from which individual influenza vaccination status 3 months after the SMS nudge will be collected. Coverage rates between arms within each population and effect sizes between the populations will be compared. The cost-effectiveness of SMS nudging will also be assessed.
Results: The inclusion of participants will start in the third quarter of 2025, and the registry data will be available in the first quarter of 2026. Coverage rates of each strategy and coverage differences between strategies will be presented.

Conclusions: SMS nudging is a scalable, inexpensive, and nonintrusive intervention that could be integrated into the national influenza vaccination program if the trial shows it effectively increases influenza vaccination coverage among older adults. Further, the trial will establish whether language is a barrier to influenza vaccination uptake among recent immigrant groups that have low influenza vaccination coverage, and to what extent this potential barrier can be diminished by SMS nudging in the official language of their native country.

8.1.2 Iannizzi, C., Andreas, M., Bohndorf, E., Hirsch, C., Zorger, A. M., Brinkmann-Paulukat, J., Bormann, B., Kaufman, J., Lischetzki, T., Monsef, I., Neufeind, J., Schmid-Küpke, N., Thole, S., Worbes, K., & Skoetz, N. (2025). **Communication-based interventions to increase COVID-19 vaccine willingness and uptake: a systematic review with meta-analysis**. *BMJ open*, *15*(5), e072942. https://doi.org/10.1136/bmjopen-2023-072942

Objective: This systematic review investigates the effectiveness of different communication strategies to increase COVID-19 vaccine uptake and willingness.
Design: Systematic review and meta-analysis of randomised controlled trials (RCTs), following recommendations from the *Cochrane Handbook* and reporting according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guideline.
Data sources: We searched the following databases until 27 July 2022: Cochrane COVID-19 Study Register, PsycINFO, CINAHL, Web of Science Core Collection and WHO COVID-19 Global literature.
Eligibility criteria for study selection: We included RCTs investigating, any population, communication-based interventions to increase COVID-19 vaccine uptake and comparing these with no intervention (with or without placebo), another communication strategy or another type of intervention.
Methods: Screening, data extraction and bias assessment, using the Cochrane ROB 1.0 tool, were conducted by two authors independently. We performed meta-analyses if studies were homogeneous using the Review Manager (RevMan 5) software, synthesised the remaining results narratively and assessed the certainty in the evidence using the Grading of Recommendations Assessment, Development, and Evaluation approach.
Results: We identified 49 studies reporting on the predefined four categories of communication interventions. Evidence from our meta-analyses shows that COVID-19 vaccine uptake may increase when education and information strategies are applied (risk ratio (RR) 1.23, 95% CI 1.17 to 1.28; high-certainty evidence) or social norms are communicated (RR 1.28, 95% CI 1.23 to 1.33; high-certainty evidence) compared with no intervention. The different communication strategies mostly have little to no impact on vaccine intention; however, there may be a slight increase in vaccine confidence when gain framing is applied compared with no intervention.
Conclusion: Overall, we found that education and information-based interventions or social norm-framing strategies are most effective compared with no intervention given. Our findings show that some of the investigated communication strategies might influence policy decision-making, and our results could be useful for future pandemics as well.

8.1.3 Meeldijk, A., Vandeberg, L., Akkermans, R., & Hautvast, J. (2025). **How text message reminders increase COVID-19 booster vaccine uptake: Two randomized controlled trials.** Vaccine, 43(Pt 2), 126533. https://doi.org/10.1016/j.vaccine.2024.126533

Background
Vaccines are effective and affordable health prevention measures to prevent vaccine-preventable diseases, but achieving sufficient vaccine uptake population-

wide is challenging. In this work, we assess the impact of various text messages reminders on COVID-19 booster uptake and the extent to which the effect of messages holds over time. Additionally, we analyse whether people's self-reported vaccination intentions (measured in response to message prompts) corresponds to actual vaccine uptake and whether this relationship differs between message variants.
Methods
We performed two large sequential randomized controlled trials (RCTs) in the Netherlands (*N* = 140.973), with the design of RCT2 building on the findings of RCT1. We 1) analyzed the effect of various text messages on COVID-19 booster uptake; 2) assessed the extent to which these effects hold over time; and 3) tested whether a positive response to message prompts moderates the effect of message variant on vaccine uptake.
Results
First, the results of RCT1 demonstrate that text messages with an *ownership frame* ("your [vaccine] is ready for you") result in highest vaccine uptake (e.g., compared to no text message: OR = 1.28 [99 % CI 1.03–1.59]). RCT2 showed that text messages with an *ownership frame* and a *specific date*, *time and location* result in highest vaccine uptake (e.g., compared to no text message: OR = 2.10 [99 % CI 1.85–2.38]). Second, most message effects hold over a longer period of time (e.g., 'date, time, location' message versus no message: OR = 2.10 [99 % CI 1.85–2.38] on day 6 and OR = 1.36 [99 % CI 1.25–1.48] on day 50). Third, we find that participants who received our most effective text and replied that they will take the vaccine, are more inclined to actually take the vaccine compared to the message with broad opening hours OR = 2.86 [99 % CI 2.14–3.82].
Conclusion
Text message reminders are able to increase vaccine uptake. From the tested variations, messages with an *ownership* frame providing a *specific date, time and location* are most effective. Because text messages demonstrate no notable disadvantages, we advise Public Health authorities to include this effective intervention in their vaccination campaign strategies.

8.1.4 Takla, A., Wulkotte, E., Bichel, Y., Lachmann, J., Trübswetter, A., Wilhelm, J., Zettel, A., & Schmid-Küpke, N. (2025). [**Vaccination reminders in Germany: Inventory and ideas for tomorrow using the example of HPV vaccination : Report on the results of the InveSt HPV project**]. Bundesgesundheitsblatt, Gesundheitsforschung, Gesundheitsschutz, 68(4), 398–407. https://doi.org/10.1007/s00103-025-04030-8

In Germany, vaccinations take place almost exclusively in physicians' private practices. This means that every contact with a practice or physician is an important opportunity to receive a recommended vaccination. The effectiveness of invitation and reminder systems for the implementation of recommended vaccinations has already been proven by studies, but in contrast to many other countries, such systems are not used across the board in Germany. The "Intervention Study to Increase HPV Vaccination Coverage in Germany" (InveSt HPV) therefore addresses, among other things, the question of what barriers exist to the use and dissemination of invitation and vaccination reminder systems. To this end, two nationwide quantitative surveys of (i) 345 pediatricians in private practices and (ii) 1805 parents with children aged 9 to 14 as well as a survey of 46 statutory health insurances with around 51 million insured persons were conducted. The survey results and other evidence compiled by the project team formed the basis for a workshop with vaccination-relevant stakeholders from the healthcare sector. The aim of the workshop was to work together on concepts for a future invitation and vaccination reminder system in Germany using the specific example of the HPV (Human Papillomavirus) vaccination. This report presents the

core results of the surveys conducted and selected additional evidence compiled by the project team for the workshop. Finally, the workshop and the key elements developed by the participants for an HPV-related invitation and vaccination reminder system 2.0 are described.

8.1.5 Fallucca, A., Priano, W., Carubia, A., Ferro, P., Pisciotta, V., Casuccio, A., & Restivo, V. (2024). **Effectiveness of Catch-Up Vaccination Interventions Versus Standard or Usual Care Procedures in Increasing Adherence to Recommended Vaccinations Among Different Age Groups: Systematic Review and Meta-Analysis of Randomized Controlled Trials and Before-After Studies.** JMIR Public Health and Surveillance, 10, e52926. https://doi.org/10.2196/52926

Background:To address the global challenge of vaccine hesitancy, the Strategic Advisory Group of Experts on Immunization strongly promotes vaccination reminder and recall interventions. Coupled with the new opportunities presented by scientific advancements, these measures are crucial for successfully immunizing target population groups.
Objective: This systematic review and meta-analysis aims to assess the effectiveness of various interventions in increasing vaccination coverage compared with standard or usual care. The review will cover all vaccinations recommended for different age groups.
Methods: In February 2022, 2 databases were consulted, retrieving 1850 studies. Following the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines, 79 manuscripts were included after the assessment phase. These comprised 46 trials/randomized controlled trials (RCTs) and 33 before-after studies. A meta-analysis using a random-effects model was performed with STATA software (version 14.1.2). The selected outcome was the risk ratio (RR) of vaccination coverage improvement effectiveness. Additionally, meta-regression analyses were conducted for the included manuscripts.
Results: The analyses showed an overall efficacy of RR 1.22 (95% CI 1.19-1.26) for RCTs and RR 1.70 (95% CI 1.54-1.87) for before-after studies when considering all interventions cumulatively. Subgroup analyses identified multicomponent interventions (RR 1.58, 95% CI 1.36-1.85) and recall clinical interventions (RR 1.24, 95% CI 1.17-1.32) as the most effective in increasing vaccination coverage for RCTs. By contrast, educational interventions (RR 2.13, 95% CI 1.60-2.83) and multicomponent interventions (RR 1.61, 95% CI 1.43-1.82) achieved the highest increases for before-after studies. Meta-regression analyses indicated that the middle-aged adult population was associated with a higher increase in vaccination coverage (RCT: coefficient 0.54, 95% CI 0.12-0.95; before-after: coefficient 1.27, 95% CI 0.70-1.84).
Conclusions: Community, family, and health care–based multidimensional interventions, as well as education-based catch-up strategies, effectively improve vaccination coverage. Therefore, their systematic implementation is highly relevant for targeting undervaccinated population groups. This approach aligns with national vaccination schedules and aims to eliminate or eradicate vaccine-preventable diseases.

8.1.6 Norman, G., Kletter, M., & Dumville, J. (2024). **Interventions to increase vaccination in vulnerable groups: Rapid overview of reviews**. BMC Public Health, 24(1), 1479. https://doi.org/10.1186/s12889-024-18713-5

Objective
Groups which are marginalised, disadvantaged or otherwise vulnerable have lower uptake of vaccinations. This differential has been amplified in COVID-19 vaccination compared to (e.g.) influenza vaccination. This overview assessed the effectiveness

of interventions to increase vaccination in underserved, minority or vulnerable groups.
Methods
In November 2022 we searched four databases for systematic reviews that included RCTs evaluating any intervention to increase vaccination in underserved, minority or vulnerable groups; our primary outcome was vaccination. We used rapid review methods to screen, extract data and assess risk of bias in identified reviews. We undertook narrative synthesis using an approach modified from SWiM guidance. We categorised interventions as being high, medium or low intensity, and as targeting vaccine demand, access, or providers.
Results
We included 23 systematic reviews, including studies in high and low or middle income countries, focused on children, adolescents and adults. Groups were vulnerable based on socioeconomic status, minority ethnicity, migrant/refugee status, age, location or LGBTQ identity. Pregnancy/maternity sometimes intersected with vulnerabilities. Evidence supported interventions including: home visits to communicate/educate and to vaccinate, and facilitator visits to practices (high intensity); telephone calls to communicate/educate, remind/book appointments (medium intensity); letters, postcards or text messages to communicate/educate, remind/book appointments and reminder/recall interventions for practices (low intensity). Many studies used multiple interventions or components.
Conclusion
There was considerable evidence supporting the effectiveness of communication in person, by phone or in writing to increase vaccination. Both high and low intensity interventions targeting providers showed effectiveness. Limited evidence assessed additional clinics or targeted services for increasing access; only home visits had higher confidence evidence showing effectiveness. There was no evidence for interventions for some communities, such as religious minorities which may intersect with gaps in evidence for additional services. None of the evidence related to COVID-19 vaccination where inequalities of outcome are exacerbated.

8.1.7 **GOOD PRACTICE -** Louw, G. E., Hohlfeld, A. S.-J., Kalan, R., & Engel, M. E. (2024). **Mobile Phone Text Message Reminders to Improve Vaccination Uptake: A Systematic Review and Meta-Analysis**. Vaccines, 12(10), 1151. https://doi.org/10.3390/vaccines12101151

Introduction: Mobile phone text message reminders (MPTMRs) have been implemented globally to promote vaccination uptake and recall rates. This systematic review evaluated the effectiveness of MPTMRs on vaccination recall rates. Methods: We included randomized controlled trials of caregivers of children, adolescents, or adults who received MPTMRs for improving vaccine uptake and recall visits. We searched the Cochrane Central Register of Controlled Trials (CENTRAL), PubMed, and Scopus to identify relevant studies published up to 24 January 2024. We used Cochrane's Risk of Bias tool to assess the included studies and reported the results as risk ratios with 95% confidence intervals, using a random effects model. Results: We identified 25 studies for inclusion. All studies were assessed as having a low risk of bias. The evidence supports MPTMRs for improving vaccination uptake compared to usual care (RR = 1.09 [95%CI: 1.06, 1.13], I^2 = 76%). Intervention characteristics, country setting, country economic status, and vaccination type had no bearing on the effectiveness of the intervention. Conclusions: MPTMRs have a positive effect, albeit relatively small, on vaccination uptake. These findings may assist public health practitioners, policymakers, and vaccine researchers in evidence-based decision making that focuses on MPTMRs and their impact on vaccination coverage.

8.1.8 **GOOD PRACTICE -** Milkman, K. L., Ellis, S. F., Gromet, D. M., Jung, Y., Luscher, A. S., Mobarak, R. S., Paxson, M. K., Silvera Zumaran, R. A., Kuan, R., Berman, R., Lewis, N. A., List, J. A., Patel, M. S., Van den Bulte, C., Volpp, K. G., Beauvais, M. V., Bellows, J. K., Marandola, C. A., & Duckworth, A. L. (2024). **Megastudy shows that reminders boost vaccination but adding free rides does not**. Nature, 631(8019), 179–188. https://doi.org/10.1038/s41586-024-07591-x

Encouraging routine COVID-19 vaccinations is likely to be a crucial policy challenge for decades to come. To avert hundreds of thousands of unnecessary hospitalizations and deaths, adoption will need to be higher than it was in the autumn of 2022 or 2023, when less than one-fifth of Americans received booster vaccines. One approach to encouraging vaccination is to eliminate the friction of transportation hurdles. Previous research has shown that friction can hinder follow-through and that individuals who live farther from COVID-19 vaccination sites are less likely to get vaccinated. However, the value of providing free round-trip transportation to vaccination sites is unknown. Here we show that offering people free round-trip Lyft rides to pharmacies has no benefit over and above sending them behaviourally informed text messages reminding them to get vaccinated. We determined this by running a megastudy with millions of CVS Pharmacy patients in the United States testing the effects of (1) free round-trip Lyft rides to CVS Pharmacies for vaccination appointments and (2) seven different sets of behaviourally informed vaccine reminder messages. Our results suggest that offering previously vaccinated individuals free rides to vaccination sites is not a good investment in the United States, contrary to the high expectations of both expert and lay forecasters. Instead, people in the United States should be sent behaviourally informed COVID-19 vaccination reminders, which increased the 30-day COVID-19 booster uptake by 21% (1.05 percentage points) and spilled over to increase 30-day influenza vaccinations by 8% (0.34 percentage points) in our megastudy. More rigorous testing of interventions to promote vaccination is needed to ensure that evidence-based solutions are deployed widely and that ineffective but intuitively appealing tools are discontinued.

8.1.9 **GOOD PRACTICE -** Debroy, P., Balu, R., Burnett, R., Johnson, R. A., Kappes, H. B., Wallace, J. M., & Marconi, V. C. (2023). **A cluster randomized controlled trial of a modified vaccination clinical reminder for primary care providers.** Health Psychology: Official Journal of the Division of Health Psychology, American Psychological Association, 42(3), 195–204. https://doi.org/10.1037/hea0001218

Adult vaccination rates in the United States fall short of national goals, and rates are particularly low for Black Americans. We tested a provider-focused vaccination uptake intervention: a modified electronic health record clinical reminder that bundled together three adult vaccination reminders, presented patient vaccination history, and included talking points for providers to address vaccine hesitancy. Method: Primary care teams at the Atlanta Veterans Affairs Medical Center, who saw 28,941 patients during this period, were randomly assigned to receive either the modified clinical reminder (N = 44 teams) or the status quo (N = 40 teams). Results: Uptake of influenza and other adult vaccinations was 1.6 percentage points higher in the intervention group, which was not statistically significant (confidence interval, CI [−1.3, 4.4], p = .28). The intervention had similar effects on Black and White patients and did not reduce the disparity in vaccination rates between these groups. Conclusion: Provider-focused interventions are a promising way to address vaccine hesitancy, but they may need to be more intensive than a modified clinical reminder to have appreciable effects on vaccination uptake.

8.1.10 Domnich, A.; Grassi, R.; Fallani, E.; Costantini, G.; Panatto, D.; Ogliastro, M.; Salvatore, M.; Cambiaggi, M.; Vasco, A.; Orsi, A.; et al. **Increasing Influenza Vaccination Uptake by Sending Reminders: A Representative Cross-Sectional Study on the Preferences of Italian Adults.** Vaccines 2023, 11, 1601. https://doi.org/10.3390/vaccines11101601

Evidence from countries that achieved a high seasonal influenza vaccination (SIV) coverage suggests that reminders to get vaccinated may increase SIV uptake. The goal of this study was to explore the experience and attitudes of Italian adults toward an active invitation to receive SIV, triggered by different sources and delivered via different communication channels, and to assess the projected benefits of this strategy. A cross-sectional survey on a representative sample of Italian adults was conducted by using computer-assisted web interviewing. Responses from 2513 subjects were analyzed. A total of 52.2% of individuals previously received invitations to undergo SIV and compared with people who did not receive any reminder were three times more likely (68.2% vs. 22.2%) to be vaccinated in the last season. Compared with other sources, reminders sent by general practitioners (GPs) were perceived as the most attractive. As for communication channels, most participants preferred text/instant messaging (24.6%) or email (27.2%), suggesting an acceleration in the Italian digital transformation triggered by the COVID-19 pandemic. Conversely, traditional postal letters or phone calls were preferred by only 17.0% and 8.6% of respondents, respectively. Reminders sent by GPs via text/instant messages or email are a valuable option for increasing SIV uptake among Italian adults.

8.1.11 Johansen, N. D., Vaduganathan, M., Bhatt, A. S., Lee, S. G., Modin, D., Claggett, B. L., Dueger, E. L., Samson, S. I., Loiacono, M. M., Køber, L., Solomon, S. D., Sivapalan, P., Jensen, J. U. S., Martel, C. J., Valentiner-Branth, P., Krause, T. G., & Biering-Sørensen, T. (2023). **Electronic nudges to increase influenza vaccination uptake in Denmark: a nationwide, pragmatic, registry-based, randomised implementation trial**. Lancet (London, England), 401(10382), 1103–1114. https://doi.org/10.1016/S0140-6736(23)00349-5

Background
Influenza vaccination rates remain suboptimal despite effectiveness in preventing influenza infection and related complications. We investigated whether behavioural nudges, delivered via a governmental electronic letter system, would increase influenza vaccination uptake among older adults in Denmark.
Methods
We did a nationwide, pragmatic, registry-based, cluster-randomised implementation trial during the 2022–23 influenza season in Denmark. All Danish citizens aged 65 years or older or turning 65 years by Jan 15, 2023 were included. We excluded individuals living in nursing homes and individuals who had an exemption from the Danish mandatory governmental electronic letter system. Households were randomly assigned (9:1:1:1:1:1:1:1:1:1) to usual care or nine different electronic letters designed on the basis of different behavioural nudging concepts. Data were sourced from nationwide Danish administrative health registries. The primary endpoint was receipt of influenza vaccination on or before Jan 1, 2023. The primary analysis assessed an analytical set of one randomly selected individual per household, and a sensitivity analysis included all randomly assigned individuals and accounted for within-household correlation. The trial is registered with ClinicalTrials.gov, NCT05542004.
Findings
We identified 1 232 938 individuals aged 65 years or older in Denmark and excluded 56 436 (4·6%) individuals living in nursing homes and 211 632 (17·2%) with an exemption from the electronic letter system. We randomly assigned

964 870 (78·3%) participants across 691 820 households. Compared with usual care, influenza vaccination rates were higher in the group receiving an electronic letter highlighting potential cardiovascular benefits of vaccination (81·00% *vs* 80·12%; difference 0·89 percentage points [99·55% CI 0·29–1·48]; p<0·0001) and the group receiving repeated letters at randomisation and at day 14 (80·85% *vs* 80·12%; difference 0·73 percentage points [0·13–1·34]; p=0·0006). These strategies improved vaccination rates across major subgroups including those with and without established cardiovascular disease. The cardiovascular gain-framed letter was particularly effective among participants who had not been vaccinated for influenza in the previous season ($p_{interaction}$=0·0002). A sensitivity analysis of all randomly assigned individuals accounting for within-household clustering yielded similar findings.
Interpretation
Electronically delivered letters highlighting potential cardiovascular benefits of influenza vaccination or sent again as a reminder significantly increased vaccination uptake across Denmark. Although the magnitude of effectiveness was modest, the low-touch, inexpensive, and highly scalable nature of these electronic letters might be informative for future public health campaigns.

8.1.12 Frascella, B., Oradini-Alacreu, A., Balzarini, F., Signorelli, C., Lopalco, P. L., & Odone, A. (2020). **Effectiveness of email-based reminders to increase vaccine uptake: a systematic review**. Vaccine, 38(3), 433–443. https://doi.org/10.1016/j.vaccine.2019.10.089

Background
In times of vaccine hesitancy and decreasing immunization coverage, it is crucial to exploit the potential of digital solutions to support immunization programmes and ultimately increase vaccine uptake. Scant evidence exists on the impact of email-based immunization reminders. In particular, while email communication is exponentially increasing at the global level, its use for health communication is still sporadic and limited data exists on its application to immunization programmes. The objective of this study is to systematically retrieve and critically appraise the available literature on the effectiveness of email-based reminders to increase vaccine uptake, with the ultimate aim to inform and encourage its integration in the implementation of immunization programmes.
Methods
We conducted a systematic review of literature following the PRISMA. We included studies providing quantitative comparative data on any measure of vaccine uptake. We extracted data on study design, study population, vaccine type and details of email-based interventions; data were pooled by type of comparison (no reminders, traditional reminders, other digital reminders).
Results
Eleven studies were included, 90% with experimental study designs. While email communication succeeds in increasing vaccine uptake when compared with no intervention, weak and heterogeneous data exist supporting the superiority of email reminders, as compared to traditional methods or other digital reminders. Encouraging evidence report the effectiveness of reminder methods combining different strategies and tailored to target populations' preferences.
Conclusions
Theoretically, email communication offers many advantages: it is cheaper and faster, it can be automated and linked to electronic immunization registries, and reach people on the move. As we urge the need for further research to prove email communication impact on vaccine uptake in different settings, we underline the importance of identifying how to best integrate email communication in vaccine delivery equipping immunization programmes with technical infrastructures and normative frameworks suitable to embrace innovation.

8.1.13 **GOOD PRACTICE -** Jacobson Vann, J. C., Jacobson, R. M., Coyne-Beasley, T., Asafu-Adjei, J. K., & Szilagyi, P. G. (2018). **Patient reminder and recall interventions to improve immunization rates. The Cochrane database of systematic reviews,** 1(1), CD003941. https://doi.org/10.1002/14651858.CD003941.pub3

Aim of this review
The aim of this review is to determine whether strategies to remind people to receive vaccinations increase the number of people who receive vaccinations. This is an update of a previously published Cochrane Review.
Key messages
Reminding people to receive their vaccinations increases vaccination rates across different populations.
What was studied
Vaccinations are used to prevent a number of diseases but there is wide variation in vaccination coverage across different regions and countries. This can lead to diseases that are otherwise preventable by vaccines, having a large effect on individuals and communities. Informing people of an upcoming vaccination or telling them that they have missed a vaccination might help to increase coverage and reduce the effect and impact of disease preventable by vaccine. We reviewed 75 studies to evaluate whether reminding people to get vaccinated worked. The studies we looked at were from different settings, such as rural areas, schools, private practices, and state health departments. Most studies were done in the USA. The studies included a range of different groups: infants and children, adolescents and adults requiring routine vaccination, as well as adults who required the influenza vaccine. In most of the studies reminders took the form of person to person telephone calls, automated calls, letters or postcards. In few recent studies text messaging was used.
Main results of the review
Our review found that reminding people to have vaccinations likely increases the number of people who receive vaccinations by an average of 8 percentage points, although there was variation in the results of the studies. Reminding people by telephone and autodialer calls, sending a letter or postcard, or sending a text message increased vaccinations. Combinations of reminders were also effective. Reminding people over the telephone was more effective than the other types of reminders. The increases in vaccinations were observed among children, adolescents, and adults.

8.1.14 **GOOD PRACTICE** - Kempe, A., Saville, A. W., Beaty, B., Dickinson, L. M., Gurfinkel, D., Eisert, S., Roth, H., Herrero, D., Trefren, L., & Herlihy, R. (2017). **Centralized Reminder/Recall to Increase Immunization Rates in Young Children: How Much Bang for the Buck?** Academic Pediatrics, 17(3), 330–338. https://doi.org/10.1016/j.acap.2016.11.016

Objective
We compared the effectiveness and cost-effectiveness of: 1) centralized reminder/recall (C-R/R) using the Colorado Immunization Information System (CIIS) versus practice-based reminder/recall (PB-R/R) approaches to increase immunization rates; 2) different levels of C-R/R intensity; and 3) C-R/R with versus without the name of the child's provider.
Methods
We conducted 3 sequential cluster-randomized trials involving children aged 19 to 25 months in 15 Colorado counties in March 2013 (trial 1), October 2013 (trial 2), and May 2014 (trial 3). In C-R/R counties, the intensity of the intervention decreased sequentially in trials 1 through 3, from 3 to 1 recall messages. In PB-R/R counties, practices were offered training using CIIS and financial support. The percentage of children with up-to-date (UTD) vaccinations was compared 6

months after recall. A mixed-effects model assessed the association between C-R/R versus PB-R/R and UTD rates.
Results
C-R/R was more effective in trials 1 to 3 (relative risk = 1.11; 95% confidence interval 1.01–1.20; *P* = .009). Effectiveness did not decrease with decreasing intervention intensity (*P* = .59). Costs decreased with decreasing intensity in the C-R/R arm, from $18.72 per child brought UTD in trial 1 to $10.11 in trial 3. Costs were higher and more variable in the PB-R/R arm, ranging from $20.63 to $237.81 per child brought UTD. C-R/R was significantly more effective if the child's practice name was included (*P* < .0001).
Conclusions
C-R/R was more effective and cost-effective than PB-R/R for increasing UTD rates in young children and was most effective if messages included the child's provider name. Three reminders were not more effective than one, which may be explained by the increasing accuracy of contact information in CIIS over the course of the trials.

8.1.15 **GOOD PRACTICE -** Regan, A. K., Bloomfield, L., Peters, I., & Effler, P. V. (2017). **Randomized Controlled Trial of Text Message Reminders for Increasing Influenza Vaccination**. Annals of Family Medicine, 15(6), 507–514. https://doi.org/10.1370/afm.2120

PURPOSE Seasonal influenza vaccine is recommended and funded for groups at higher risk of serious infection, but uptake is suboptimal. We conducted a randomized controlled trial of short message service (SMS) reminders for influenza vaccination.
METHODS Six weeks after seasonal influenza vaccinations began, we identified high-risk patients who had a mobile telephone number on record at 10 practices in Western Australia. Thirty-two percent of the selected patients had already been vaccinated in the current year and were ineligible. Of the remaining 12,354 eligible patients at each practice one-half were randomly assigned to receive a vaccination reminder by SMS (intervention) and the rest received no SMS (control). Approximately 3 months after the SMS was sent (the study period), vaccination data were extracted from the patients' electronic medical records. Log-binomial regression models were used to calculate the relative risk (RR) of vaccination between the intervention and control group.
RESULTS Twelve-percent (769 of 6,177) of the intervention group and 9% (548 of 6,177) of the control group were vaccinated during the study period, a 39% relative increase attributable to the SMS (RR = 1.39; 95% CI, 1.26–1.54). For every 29 SMSs sent, costing $3.48, 1 additional high-risk patient was immunized. The greatest effect was observed for children younger than 5 years, whose parents were more than twice as likely to have their child vaccinated if they received a SMS reminder (RR = 2.43; 95% CI, 1.79–3.29).
CONCLUSION We found SMS reminders to be a modestly effective, low-cost means to increase seasonal influenza vaccine coverage among high-risk patients.

8.1.16 Suppli, C. H., Rasmussen, M., Valentiner-Branth, P., Mølbak, K., & Krause, T. G. (2017). **Written reminders increase vaccine coverage in Danish children—Evaluation of a nationwide intervention using The Danish Vaccination Register, 2014 to 2015.** Euro Surveillance: Bulletin Europeen Sur Les Maladies Transmissibles = European Communicable Disease Bulletin, 22(17), 30522. https://doi.org/10.2807/1560-7917.ES.2017.22.17.30522

We evaluated a national intervention of sending written reminders to parents of children lacking childhood vaccinations, using the Danish Vaccination Register (DDV). The intervention cohort included the full birth cohort of 124,189 children born in Denmark who reached the age of 2 and 6.5 years from 15 May 2014 to 14

May 2015. The reference cohort comprised 124,427 children who reached the age of 2 and 6.5 years from 15 May 2013 to 14 May 2014. Vaccination coverage was higher in the intervention cohort at 2.5 and 7 years of age. The differences were most pronounced for the second dose of the measles-mumps-rubella vaccine (MMR2) and the diphtheria-tetanus-pertussis-polio vaccine DTaP-IPV4 among the 7-year-olds, with 5.0 percentage points (95% confidence interval (CI): 4.5–5.4) and 6.4 percentage points (95% CI: 6.0–6.9), respectively. Among the 2.5 and 7-year-olds, the proportion of vaccinations in the preceding 6 months was 46% and three times higher, respectively, in the intervention cohort than the reference cohort. This study indicates a marked effect of personalised written reminders, highest for the vaccines given later in the schedule in the older cohort. In addition, the reminders increased awareness about correct registration of vaccinations in DDV.

8.1.17 Herrett, E., Williamson, E., van Staa, T., Ranopa, M., Free, C., Chadborn, T., Goldacre, B., & Smeeth, L. (2016**). Text messaging reminders for influenza vaccine in primary care: A cluster randomised controlled trial (TXT4FLUJAB)**. BMJ Open, 6(2), e010069. https://doi.org/10.1136/bmjopen-2015-010069

Objectives (1) To develop methods for conducting cluster randomised trials of text messaging interventions utilising routine electronic health records at low cost; (2) to assess the effectiveness of text messaging influenza vaccine reminders in increasing vaccine uptake in patients with chronic conditions.
Design Cluster randomised trial with general practices as clusters.
Setting English primary care.
Participants 156 general practices, who used text messaging software, who had not previously used text message influenza vaccination reminders. Eligible patients were aged 18–64 in 'at-risk' groups.
Interventions Practices were randomly allocated to either an intervention or standard care arm in the 2013 influenza season (September to December). Practices in the intervention arm were asked to send a text message influenza vaccination reminder to their at-risk patients under 65. Practices in the standard care arm were asked to continue their influenza campaign as planned.
Blinding Practices were not blinded. Analysis was performed blinded to practice allocation.
Main outcome measures Practice-level influenza vaccine uptake among at-risk patients aged 18–64 years.
Results 77 practices were randomised to the intervention group (76 analysed, n at-risk patients=51 121), 79 to the standard care group (79 analysed, n at-risk patients=51 136). The text message increased absolute vaccine uptake by 2.62% (95% CI −0.09% to 5.33%), p=0.058, though this could have been due to chance. Within intervention clusters, a median 21.0% (IQR 10.2% to 47.0%) of eligible patients were sent a text message. The number needed to treat was 7.0 (95% CI −0.29 to 14.3).
Conclusions Patient follow-up using routine electronic health records is a low cost method of conducting cluster randomised trials. Text messaging reminders are likely to result in modest improvements in influenza vaccine uptake, but levels of patients being texted need to markedly increase if text messaging reminders are to have much effect.

Grey literature

8.1.18 Emborg H-D, European Joint Action on Vaccination — EU-JAV; WP5 - Report on reminder systems (2022)

No abstract available

8.2 Psychological and behavioural reactance to vaccine or preventive health-related communication

8.2.1 Verpaalen, I. A. M., Ritter, S. M., van Hooff, M. L. M., van Stekelenburg, A., Fransen, M. L., & Holland, R. W. (2025). **Psychological reactance and vaccine uptake: a longitudinal study**. Psychology & Health, 40(1), 84–104. https://doi.org/10.1080/08870446.2023.2190761

Objective
In most countries, vaccine uptake is a voluntary decision. If people experience threats to this freedom, for example, by pro-vaccination media campaigns or government pressure, psychological reactance may be induced. To regain freedom, the opposite behaviour (vaccine refusal) may become more attractive, forming a vaccination barrier. It remains unclear how state reactance fluctuates and how it relates to vaccination intention versus behaviour. Therefore, this pre-registered longitudinal study aimed to gain insight in the changes in state reactance during a COVID-19 vaccination programme and its relationship with vaccine uptake.
Methods
A representative sample of Dutch adults under 60 completed questionnaires before being eligible for vaccination, shortly before they were invited for vaccination, and after the opportunity for vaccination.
Results
Data were analysed using regression analyses ($N = 1411$). Reactance did not change as hypothesised, but remained stable over time. As hypothesised, reactance predicted lower subsequent vaccination intention. Controlling for intentions, however, reactance did not predict vaccine uptake. Furthermore, reactance predicted lower decision confidence about vaccination, except for people who strongly opposed vaccination.
Conclusion
Reactance has a sustained role in anticipation of a vaccination decision. Although reactance seems to affect the process towards the decision, this does not determine the final choice.

8.2.2 Claessens, T., Krouwer, S., Vandebosch, H., & Poels, K. (2023). **Pathways to informed choices: The impact of freedom of choice and two-sided messages on psychological reactance and vaccination intentions among individuals who express concerns**. Vaccine, 41(42), 6272–6280. https://doi.org/10.1016/j.vaccine.2023.08.016

Background
Reducing the spread of infectious diseases through vaccination faces the challenge of vaccine hesitancy: referring to questions, concerns and doubts arising when making a vaccine-related decision. A motivational state often arising within people exposed to health messages supporting informed decision making is *psychological reactance,* functioning as a driver to behavior opposed to the one recommended through the health message. Hence, there is a pressing

need for communication strategies effective in counteracting reactance to health messages.
Methods
This study tested two communication strategies that can potentially reduce psychological reactance and ameliorate evaluations of the message and subsequent behavioral vaccination intentions in the context of COVID-19. These were: (1) explicitly reminding individuals of their freedom of choice (to either accept or refuse the vaccine) and (2) providing a two-sided message, including, apart from evidence-based information on the necessity of vaccines, a set of concerns, and questions (about the vaccines) which are refuted immediately. A total of 234 participants who indicated having concerns about the COVID-19 vaccine participated in a 2 (freedom of choice: no choice vs. choice) × 2 (message sidedness: one-sided vs. two-sided) between-subjects online experiment where they received an informational brochure about COVID-19 vaccination.
Results
The results show that emphasizing freedom of choice significantly increased perceived credibility of the message, perceived information utility, and ultimately, vaccination intentions. A decrease in psychological reactance mediated these effects. Message sidedness did only show a significant direct effect on perceived information utility. No interaction effect was found.
Conclusion
These findings indicate the importance of freedom of choice in reducing psychological reactance, which in its turn can lead to an increase of positive message evaluations and vaccination intentions among individuals who express concerns. The opportunities of message sidedness as an efficacious vaccination communication strategy should be further investigated.

8.2.3 Morbée, S., Waterschoot, J., Yzerbyt, V., Klein, O., Luminet, O., Schmitz, M., Van den Bergh, O., Van Oost, P., De Craene, S., & Vansteenkiste, M. (2022). **Personal and contextual determinants of COVID-19 vaccination intention: a vignette study**. Expert review of vaccines, 21(10), 1475–1485. https://doi.org/10.1080/14760584.2022.2105212

Background: This vignette study explores which factors contribute to higher COVID-19 vaccination intentions.
Methods: Between the 4th-11 January 2021, we recruited 15,901 Belgian citizens (M_{age} = 50.11 years, range 18-100) through convenience sampling to participate in a vignette study. In each vignette, we manipulated contextual determinants consisting of different factors. Each participant rated six vignettes in terms of the outcomes 'vaccination intention' and 'recommendation to others.' Finally, we explored the benefits of tailored communication by examining whether these ratings depended upon citizens' initial motives for vaccination.
Results: Participants are most likely to accept a vaccine when they expect no or only small side effects, when the vaccine offers a 95% protection, and when people can no longer infect others ($p < 0.001$). The possibility to receive the vaccine at home or at the GP's office, highlighting that most citizens are willing to get vaccinated, and emphasizing the protective benefits for others yielded additional positive effects ($p < 0.001$). Results showed that tailored communication has a small but significant effect, especially for individuals high on distrust-based amotivation ($p < 0.01$).
Conclusion: In addition to vaccine characteristics, there is room for policymakers to respond to those determinants that fall under their control and can thus be highlighted within communication campaigns.

8.2.4 **GOOD PRACTICE -** Richards, A. S., Bessarabova, E., Banas, J. A., & Bernard, D. R. (2022). **Reducing Psychological Reactance to Health**

Promotion Messages: Comparing Preemptive and Postscript Mitigation Strategies. Health Communication, 37(3), 366–374. https://doi.org/10.1080/10410236.2020.1839203

This study compared the relative efficacy of two strategies designed to mitigate psychological reactance in health campaigns by using reminders of behavioral autonomy: preemptive scripts, which appear before the appeal, and restoration postscripts, which appear after. Employing a mixed-model experiment with a 2 (threat to freedom: low vs. high) × 3 (reactance-mitigation strategy: control vs. preemptive script vs. restoration postscript) × 2 (health campaign topic: exercise vs. nutrition) between-subjects design and a within-subjects factor of time (immediate posttest measurement followed by a one-week delay), this study (*N* = 394) compared the effects of the two mitigation strategies on reactance, attitude, and behavioral intention at two points in time. Moderated mediation models indicated that the reactance-mitigation strategies equivalently reduced the degree to which reactance was experienced in response to increasingly threatening health appeals (relative to the control). This effect indirectly influenced behavioral intention via attitude change and remained after one week.

8.2.5 Vandeberg, L., Meppelink, C. S., Sanders, J., & Fransen, M. L. (2022). **Facts Tell, Stories Sell? Assessing the Availability Heuristic and Resistance as Cognitive Mechanisms Underlying the Persuasive Effects of Vaccination Narratives.** *Frontiers in psychology*, *13*, 837346. https://doi.org/10.3389/fpsyg.2022.837346

Online vaccine-critical sentiments are often expressed in appealing personal narratives, whereas vaccine-supporting information is often presented in a non-narrative, expository mode describing scientific facts. In two experiments, we empirically test whether and how these different formats impact the way in which readers process and retrieve information about childhood vaccination, and how this may impact their perceptions regarding vaccination. We assess two psychological mechanisms that are hypothesized to underlie the persuasive nature of vaccination narratives: the availability heuristic (experiment 1, N = 418) and cognitive resistance (experiment 2, *N* = 403). The results of experiment 1 showed no empirical evidence for the availability heuristic, but exploratory analyses did indicate that an anti-vaccination narrative (vs. expository) might reduce cognitive resistance, decrease vaccination attitudes and reduce attitude certainty in a generally pro-vaccination sample, especially for those who were more vaccine hesitant. Preregistered experiment 2 formally tested this and showed that not narrative format, but prior vaccine hesitancy predicts cognitive resistance and post-reading attitudes. Hesitant participants showed less resistance toward an anti-vaccine text than vaccine-supporting participants, as well as less positive post-reading attitudes and attitude certainty. These findings demonstrate belief consistency effects rather than narrative persuasion, which has implications for scientific research as well as public health policy.

8.2.6 **GOOD PRACTICE -** Petersen, M. B., Bor, A., Jørgensen, F., & Lindholt, M. F. (2021). **Transparent communication about negative features of COVID-19 vaccines decreases acceptance but increases trust**. *Proceedings of the National Academy of Sciences of the United States of America*, *118*(29), e2024597118. https://doi.org/10.1073/pnas.2024597118

During the rapid development and rolling out of vaccines against COVID-19, researchers have called for an approach of "radical transparency," in which vaccine information is transparently disclosed to the public, even if negative information can decrease vaccine uptake. Consistent with theories about the psychology of conspiracy beliefs, these calls predict that a lack of transparency

may reduce trust in health authorities and may facilitate the spread of conspiracy theories, which may limit the long-term capabilities of health authorities during and after the pandemic. On the basis of preregistered experiments conducted on large, representative samples of Americans and Danes (*N* > 13,000), the current study contrasts the effects of vague vaccine communication with transparent communication, which discloses either positive or negative vaccine features. The evidence demonstrates that transparent negative communication may indeed harm vaccine acceptance here and now but that it increases trust in health authorities. Furthermore, the alternative of vague, reassuring communication does not increase vaccine acceptance either and leads to both lower trust and higher endorsement of conspiracy theories.

8.2.7 Schmitt J.B., et al. **Two sides of the same coin? The persuasiveness of one-sided vs. two-sided narratives in the context of radicalization prevention** Studies in Communication and Media, 10 (1) (2021), pp. 48-71, 10.5771/2192-4007-2021-1-48

Societal organizations aim at challenging online extremist messages by counter-posing with different narratives such as alternative narratives (one-sided narrative) and counter-narratives (two-sided narratives). The current study examined which type of narrative is more efficient in changing attitudes accounting for narrative involvement and reactance regarding the narrative. We employed a 2(one-sided vs. two-sided narrative) × 2 (ease of identification vs. no ease of identification) between-subjects design (N = 405) using a controversial topic: the ongoing debate about how to deal with the number of refugees in Germany. We found an indirect effect of the narrative on attitude change. People who read the two-sided narrative showed less reactance. The smaller the reactance, the more they felt involved in the narrative, which, in turn led to more positive attitudes towards refugees. We discuss these findings regarding their theoretical contribution to create customized narratives challenging extremist messages.

8.2.8 Sprengholz P, Betsch C, Böhm R. **Reactance revisited: Consequences of mandatory and scarce vaccination in the case of COVID-19**. Appl Psychol Health Well-Being. 2021;13:986–995. https://doi.org/10.1111/aphw.12285

Psychological reactance theory assumes that the restriction of valued behaviors elicits anger and negative cognitions, motivating actions to regain the limited freedom. Two studies investigated the effects of two possible restrictions affecting COVID-19 vaccination: the limitation of non-vaccination by mandates and the limitation of vaccination by scarce vaccine supply. In the first study, we compared reactance about mandatory and scarce vaccination scenarios and the moderating effect of vaccination intentions, employing a German quota-representative sample (*N* = 973). In the preregistered second study, we replicated effects with an American sample (*N* = 1394) and investigated the consequences of reactance on various behavioral intentions. Results revealed that reactance was stronger when a priori vaccination intentions were low and a mandate was introduced or when vaccination intentions were high and vaccines were scarce. In both cases, reactance increased intentions to take actions against the restriction. Further, reactance due to a mandate was positively associated with intentions to avoid the COVID-19 vaccination and an unrelated chickenpox vaccination; it was negatively associated with intentions to show protective behaviors limiting the spread of the coronavirus. Opposite intentions were observed when vaccination was scarce. The findings can help policy-makers to curb the spread of infectious diseases such as COVID-19.

8.2.9 Krouwer, S., Poels, K., & Paulussen, S. (2019). **Exploring readers' evaluations of native advertisements in a mobile news app**. Journal of Media Business Studies, 16(2), 77–94. https://doi.org/10.1080/16522354.2019.1573396

Mobile news consumption is rising quickly, just as the appearance of native advertisements on mobile news platforms, yet little is known about readers' mobile native advertising recognition and perceptions. This qualitative study, therefore, explores how readers recognise and perceive in-feed native advertisements in a mobile news app. Usability tests combined with interviews with 24 users of a national news app showed that in the mobile environment, readers are generally able to recognise native advertisements. The findings suggest four key factors that influence readers' evaluations: (1) perceived utility, (2) source credibility of the advertiser, (3) perceived control, and (4) recognisability. The results suggest that besides readers' advertising recognition, the advertisements' content and context play an important role in explaining readers' perceptions of native advertising.

8.2.10 **GOOD PRACTICE -** Nan, X., Daily, K., Richards, A., & Holt, C. (2019). **Parental Support for HPV Vaccination Mandates Among African Americans: The Impact of Message Framing and Consideration of Future Consequences**. Health Communication, 34(12), 1404–1412. https://doi.org/10.1080/10410236.2018.1493419

Is parents' support for mandating human papillomavirus (HPV) vaccination for their adolescent children influenced by how the policy advocacy message is framed? In this research, we conducted an experiment in which a group of African-American parents were exposed to messages advocating HPV vaccination mandates that were framed in either gains or losses. Our results demonstrate the importance of considering the personality trait – consideration of future consequences – when assessing the efficacy of gain- and loss-framed health advocacy. We found that parents responded more positively to gain-frames if they focused on the distant future and to loss-frames if they focused on the immediate future. Thus, it is important to recognize that public support of HPV vaccination policy is not only contingent on the message-based educational strategy employed to parent, but on the degree to which parents consider how present behaviors influence future well-being.

8.2.11 **GOOD PRACTICE -** Miller, C.H. (2015). **Persuasion and Psychological Reactance: the Effects of Explicit, High-Controlling Language.** In: Schulze, R., Pishwa, H. (eds) The Exercise of Power in Communication. Palgrave Macmillan, London. https://doi.org/10.1057/9781137478382_11

Communicating unambiguous commands using controlling language tends to alienate young audiences, which often results in message rejection, boomerang effects and source derogation. Psychological Reactance Theory (Brehm 1966) accounts for how individuals become aversively aroused when perceived freedoms are threatened by overtly persuasive messages. The theory suggests reactance may be minimized through the use of implicit, autonomy-supportive language and message forms designed to protect and restore threatened freedoms, which can emphasize self-determination, effectance and choice. This chapter explores the psychological consequences associated with high-controlling language, and discusses how reactance may also be affected by regulatory fit (Higgins 2000) associated with concrete vs abstract language. Psychological reactance theory offers valuable guidance, particularly when addressing sensitive, reactant populations.

8.3 Lessons learned from cancer screening notification or reminder systems

8.3.1 Gorini, G., Mallardi, B., Campanino, C., Betti, E., Falini, P., Sali, L., Battisti, F., Stoffel, S. T., & Mantellini, P. (2026). **A randomized controlled trial testing behavioral economics messages and screening choices to increase participation among previous non-attenders in florence's colorectal cancer screening program.** Digestive and liver disease : official journal of the Italian Society of Gastroenterology and the Italian Association for the Study of the Liver, 58(4), 534–540. https://doi.org/10.1016/j.dld.2026.01.206

Background
Behavioural economics (BE)-inspired messages within invitations for immunochemical faecal tests (FIT), or offering alternative tests such as sigmoidoscopy (FS) or CT-colonography (CTC), are strategies to re-engage non-respondents in subsequent colorectal cancer (CRC) screening rounds. This study evaluated their impact on screening participation.
Methods
In 2022–2023, a randomized controlled trial was conducted involving 20,225 non-respondents to the CRC Florence screening program. Individuals aged 54–70 were randomized into six groups: a control group receiving the standard invitation letter (SL); three groups receiving SL plus a feedback message (F), a social norm message (MN), or both (F+MN); and two groups offered FS or CTC as alternatives to FIT among invitees aged 58–60. The primary outcome was participation within 90 days. The trial was registered with ISRCTN (ISRCTN11841256).
Results
Participation was 5.7% in controls, and 7.4%, 6.7%, 6.6%, 2.0%, and 4.1% in the F, MN, F+MN, FS, and CTC groups. Invitees in the F group were more likely to participate (aOR=1.32; 95%CI:1.10–1.57), while FS invitees were less likely (aOR=0.39; 95%CI:0.27–0.54). CTC participation resembled controls aged 58–60 and was twice that of FS.
Conclusion
BE-inspired interventions can increase CRC screening participation, whereas more invasive alternative tests did not. Future studies should explore preferences for different screening tests to identify more acceptable modalities and optimise participation.

8.3.2 Ferrari, A., Van Bos, L., Talboom, S., van de Veerdonk, W., D'haenens, W., Pak, M., Descan, M., Parmentier, S., Van Collie, L., Sibiet, P., Goossens, M., & Van Hal, G. (2025). **From barriers to participation: co-creating an effective reminder letter for breast cancer screening among underserved women in Flanders**. Archives of public health = Archives belges de sante publique, 83(1), 132. https://doi.org/10.1186/s13690-025-01591-7

Background
With over 2 million cases diagnosed annually, breast cancer is a leading cause of cancer-related disability and mortality worldwide. Despite global efforts to implement screening programs, uptake rates vary widely across settings due to socioeconomic factors and accessibility challenges. In 2022 in Flanders (Belgium), breast cancer screening participation in municipalities with an income below the poverty line was 15% lower than average.
Methods
To tackle the limited participation of underserved women in the breast cancer screening program in Flanders, a culturally sensitive approach was used to investigate factors influencing screening participation and to realize a tailored reminder letter to be tested in a later phase. Working closely with community organizations, 33 women aged 50–69 (29 of whom were non-native Dutch

speakers) with low-socioeconomic status were identified to participate in the study. Through an iterative process comprising 3 focus group discussions, 3 Delphi-consultations with sector experts, 1 co-creation session and a final member check, critical insights were gathered.
Results
Key barriers included low health literacy and limited understanding of preventive care concepts. Once participants were effectively informed about the breast cancer screening program, they displayed increased help-seeking behaviors in relation to health, underscoring the importance of clear communication in fostering willingness to consider screening. An evaluation of the standard invitation letter employed in the program revealed several challenges related to readability and comprehension. These included the excessive text length, the use of complex vocabulary and grammar beyond an A2 level, slogans unrelated to the mammography appointment (e.g., 'We do it and what do you do?'), and the use of generic visuals. At the same time, simplifying the vocabulary to A1-A2 levels, employing straightforward sentence structures, and incorporating relevant visuals enhanced understandability and fostered interest in breast cancer prevention. Utilizing a color palette associated with breast cancer and featuring logos of local authorities instilled a sense of credibility and trustworthiness. Based on this feedback, a revised reminder letter was developed. The final communication was concise and included essential details such as time and place for screening and a QR code providing translation into 12 languages.
Conclusions
Simplifying vocabulary, grouping related information, and providing direct links and language options improved the clarity and accessibility of the reminder letter, thereby fostering help-seeking behaviors related to breast cancer screening.

8.3.3 Gorini, G., Betti, E., Stoffel, S., Falini, P., Iossa, A., Senore, C., Baiocchi, D., Zappa, M., Battisti, F., & Mantellini, P. (2023). **Testing behavioral economics messages to increase non-responders' participation in organized colorectal cancer-screening programs: A randomized controlled trial**. Preventive medicine, 174, 107615. https://doi.org/10.1016/j.ypmed.2023.107615

This study aimed to evaluate the impact of behavioral economic-inspired messages on participation in colorectal cancer (CRC) screening programs. We conducted a randomized-controlled trial involving 11,505 non-responders to the CRC screening programs in Florence, Rome, and Turin in 2020.
Participants aged 54–70 years were randomly assigned to four conditions. Individuals in the control conditions received a standard invitation letter while the three intervention groups included an additional paragraph featuring either i. normative feedback [F] message (giving feedback that invited subjects did not participate); ii. Minority norm [MN] message (only a minority did not participate); iii. F+ MN message (combining both messages). The primary outcome was the screening participation rate 90 days after the invitation was completed.
A multivariate analysis was conducted adjusting for gender, age and birthplace. Overall, screening participation rates were 5.3% in the control condition, 7.0% in the F, 8.2% in the MN, and 7.4% in the F + MN arms (p = 0.002). Invited subjects in the MN arm were more likely to participate (adjusted Odds Ratio[aOR] = 1.38; 95% Confidence Interval [95%CI,1.13–1.68]), particularly those aged 54–59 years (aOR = 1.52; 95%CI:1.16–1.98), and 60–64 (aOR = 1.57; 95%CI:1.62-; 95%CI: 1.06–2.48). Additionally, individuals aged 60–64 invited in F and F + MN arms demonstrated a higher likelihood of participation (aOR for F arm = 1.60; 95%CI: 1.06–2.41; aOR for F + MN arm = 1.99; 95%CI: 1.35–2.92).

The inclusion of MN and/or F messages in the invitation letter increased participation among previous non-responders <65 years. Behavioral economics is a promising area of interest for enhancing CRC screening participation.

8.3.4 Stoffel, S., Kioupi, S., Ioannou, D., Kerrison, R. S., von Wagner, C., & Herrmann, B. (2021). **Testing messages from behavioral economics to improve participation in a population-based colorectal cancer screening program in Cyprus: Results from two randomized controlled trials**. Preventive medicine reports, 24, 101499. https://doi.org/10.1016/j.pmedr.2021.101499

Despite the benefits of colorectal cancer (CRC) screening, participation compares poorly to other screening programs. This study assessed the effectiveness of adding different behavioral economic-based messages, to the invitation letter, to increase uptake in the Cypriot CRC screening program. We performed two randomized controlled trials. In the first trial ('Trial 1'), 3212 individuals, aged 50 to 69 years, were randomly allocated (1:1:1:1:1:1:1) to one of six intervention groups, or the control. The intervention groups received the standard invitation letter received by the control, with the addition of one of six messages based on the following behavioral economics principles: (1) social responsibility, (2) anticipated regret, (3) financial opportunity costs (of non-attendance), (4) benefit (of early detection), (5) scarcity effect (limited duration of the offer) and (6) social norms. The second trial ('Trial 2') tested the most efficacious message (social responsibility) against the control in a larger sample (N = 3074). In both trials, the primary outcome was uptake eight weeks after the screening invitation. In trial 1, overall uptake was 20.6%. There were no significant differences between the control and the intervention conditions for the overall sample or men (all p's > 0.05).
Highlighting the social consequences of cancer did, however, increase uptake rates among women (25.6% vs. 17.1%, aOR 1.67; 95% CI 1.05–2.66, p = 0.031). We, therefore, tested this message in Trial 2. Uptake was similar to trial 1 with 20.7% (intervention: 20.8% vs control: 20.6%) and there was no impact on overall or uptake of men and women separately (all p's > 0.05).