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Review

Assessing the impact of shared decision making processes on influenza vaccination rates in adult patients in outpatient care: A systematic review and *meta*-analysis

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ABSTRACT

Background: Shared decision making (SDM) is a promising approach, to bridge major barriers concerning vaccination by patient education and personal interaction of health care provider (HCP) and patient. SDM affects patient adherence, enhances patient knowledge, decreases decisional conflict and improves trust in the physician in most areas of health care. The shared decision making process (SDM process) is characterised by three key components: patient activation, bi-directional exchange of information and bi-directional deliberation of options.
Objectives: To assess the impact of SDM processes on influenza vaccination rates in outpatient care patients.
Methods: A systematic literature search in MEDLINE, CENTRAL, EMBASE, PsycINFO and ERIC was conducted (2020–02-05). Randomized controlled trials (RCTs) and cluster RCTs, that aimed to improve influenza vaccination rates in adult patients in outpatient care were included. We examined effects of SDM processes on influenza vaccination rates by *meta*-analysis, and considered the extent of SDM processes in the analysed interventions and possible effect modifiers in subgroup analyses.
Results: We included 21 studies, with interventions including face-to-face sessions, telephone outreach, home visits, Health Care Practitioner (HCP) trainings and supporting educational material. In 12 studies, interventions included all elements of a SDM process. A *meta*-analysis of 15 studies showed a positive effect on vaccination rates (OR of 1.96 (95% CI: 1.31 to 2.95)). Findings further suggest that interventions are effective across different patients groups and could increase effectiveness when the interaction is facilitated by multidisciplinary teams of HCP in comparison to interventions delivered by individual HCP.
Discussion: This systematic review and *meta*-analysis provide evidence that SDM processes can be an effective strategy to increase influenza vaccination rates. Further research with more detailed descriptions of SDM implementation modalities is necessary to better understand which components of SDM are most effective.
Trial Registration: PROSPERO: CRD42020175555

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1. Background

Seasonal influenza is a major global health threat affecting an estimated 1 billion people per year, leading to increased morbidity and mortality, as well as hospital admissions and absenteeism [1,2]. The most serious courses of illness are expected for elderly or chronically ill, which are therefore considered as vulnerable patients. Influenza vaccination is an effective measure for communities to prevent transmission and to protect vulnerable patients during seasonal epidemics, and has been used for over 60 years [1,2].

Despite proven effectiveness [3,4], safety and widespread accessibility in high- and middle income countries, vaccination rates are low in almost all OECD (Organisation for Economic Co-operation and Development) states, with Influenza vaccination rates ranging from 32.8% in Germany to 72% in UK for instance [5].

The most common reasons for abstaining from the influenza vaccine among vulnerable patients are assumptions that influenza vaccinations are unnecessary or ineffective or they have concerns regarding side effects or clear healthcare recommendations are missing [6–8].

These reasons are often attributable to insufficient informedness that may also result of suboptimal communication between patients and health care providers (HCP) [9,10]. Unparticipatory communication styles fail to inform patients sufficiently, to deliberate risks and benefits or to make a decision jointly. Consequently, communication needs to be a two-way process. Notions of empowerment and individual patient choice are crucial in medical care. The patients concerns and questions have to be heard, considered and addressed. A communication style that is trustbased and scienceinformed has to be developed [11].

As outpatient care is the main setting for influenza vaccinations, HCP in this setting are in a crucial position to address patients concerns and uncertainty [12].

Shared decision making (SDM) comprises the involvement of the patient in the entire decision making process in which HCP and patient take health care decisions based on partnership. SDM emphasises patients rights and autonomy and is a strategy to reduce practice variations and promote evidencebased medicine [13].

The concept was first developed by Charles et al in 1997 [14] and further specified in the upcoming years [13,15,16]. Although there is no precise general definition today [17], it is commonly described as including the following three core elements: information, deliberation, and taking a decision. In the present work, we defined SDM as a participative decision-making process, which is characterized by "decision antecedents", "decision process" and "decision outcomes" [18]. We focused on the domain "decision process", as we considered the core element "taking a decision" at least reflected in the vaccination rates. In many definitions of SDM another element is comprised before "information" and "deliberation" (e.g. "two participants are involved" [14], "announcement, that there is a decision to be made" [13,19] or "encouragement to talk" [20]), which we additionally assessed and categorised as the element "patient activation".

As our systematic review and *meta*-analysis aims to assess the impact of the "(shared) decision (making) process" on influenza vaccination rates, the term "SDM process" comprises patient activation, bi-directional exchange of information and bi-directional deliberation. To compare the analysed interventions, an assessment of the extent of the SDM process was conducted subsequently.

The SDM approach aims to increase patientś confidence in vaccination by addressing established vaccination barriers through patient-HCP interaction, including gaps in knowledge and understanding about how vaccines work, the disease they prevent, and concepts of risks and causality [21].

Due to the recurring high number of infections with influenza, it is important to identify strategies to improve vaccination rates. A variety of studies is focused on interventions to enhance influenza vaccination rates in adult patients, by increasing the demand for vaccination, access to vaccination services, or targeting HCPs [22]. Many studies have examined interventions that passively inform or remind patients about vaccinations, or target organizational aspects or HCP knowledge and attitudes. However, the aspect of patient-HCP interaction, the activation and involvement

of the patient (exchange of information and preferences) has received less attention [23–26]. With the SDM approach integrating these aspects by valuing the patientś autonomy, it is important to explore its impact on influenza vaccination rates systematically.

2. Objectives

To assess the impact of sharing the decision making process on influenza vaccination rates in adult patients in outpatient care.

3. Methods

This review followed the PRISMA statement for systematic reviews. An extended description of methods used is available in our study protocol on PROSPERO (registration number: CRD42020175555).

3.1. Search strategy

Literature search was conducted in MEDLINE and EMBASE (both via Ovid), The Cochrane Library, PsycINFO and ERIC. Furthermore, we searched for grey literature using individual clinical trial registers as clinicaltrials.gov, ICTRP (International Clinical Trials Registry Platform, WHO), the WHO NITAG resource center (https://www.nitag-resource.org/), CENTRAL and PROSPERO. Additional studies were identified by screening the reference lists of included studies of relevant systematic reviews, and by contacting the authors of potentially eligible abstracts for which the full text could not be located. The applied search strategy with details on textword and thesaurus search can be found in the *supplements section* of this document. We have considered all studies for inclusion regardless of their publication date.

Search results were collected using a reference management software (Endnote X8) and duplicates were removed. Titles and abstracts were screened independently by two review authors (LS, FK) for inclusion criteria and inconsistencies were discussed. Procurement of potentially relevant articles included contacting authors of ongoing trials and abstracts. To confirm the final selection of studies for inclusion, discussion and consensus among three review authors (LS, FK, JG) was achieved.

3.2. Selection criteria

We included studies targeting adult patients (at least 18 years old) from high-income countries for whom influenza vaccination is recommended. We excluded studies, that focused on vaccinations for HCP, medical students, children and adolescents below 18 years (or their parents), pregnant women, cognitively impaired patients and drug users.

Only RCTs or Cluster-RCTs were included. Control groups had to receive usual care, no intervention or an actively implemented alternative intervention. Studies were eligible for inclusion without any restrictions concerning the year of publication.

Interventions should aim at an active participation of both patient and HCP and at least an assumable bi-directional deliberation within the decision making process to be included in the analysis. For assessment, we examined the interventioń s description, its content and mode of delivery. In addition we used the EPOC (Cochrane Effective Practice and Organisation of Care) taxonomy for implementation strategies [27] to categorise the interventions. Provider- or system-based interventions were eligible if there was at least one component targeting patients directly by personal contact. Interventions that informed or educated patients in a passive way and without encouragement to interact actively with the HCP were therefore excluded. Interventions targeting HCP could target either physicians or non-phyisican health care providers who are allowed to vaccinate, like nurses or phamacists depending on the health care system.

The investigated setting for interventions was outpatient care. Consequently, interventions in hospitals, nursing homes, homeless shelters or workplaces were not included. In order to enhance comparability of studies and to be able to formulate concise implications for the clinical setting, we decided to focus only on interventions aiming to enhance influenza vaccination rates.

3.3. Types of outcome measures

Studies had to indicate influenza vaccination rates for all groups to be included. Effect sizes in studies were reported as odds ratios (OR), relative risk (RR) and mean difference (MD).

We compared the extent of the SDM process within the intervention, and if reported patients‘ satisfaction with the consultation, patients‘ knowledge concerning influenza vaccinations, the patients‘ quality of life as well as the patients‘ decisional conflicts of the included studies. Measures for these outcomes included dichotomous and continuous data, presented in OR or MD.

3.4. Data extraction

Data was extracted independently by two review authors (FK, LS) using a custom-made data extraction form (Excel® and Word®). Disagreements were resolved by discussion between three review authors (LS, FK, JG).

The Cochrane Risk of Bias Tool 2 was used to assess the risk of bias in included studies independently by two authors (LS, FK). In the assessment of cluster RCTs potential biases specific to that study design were incorporated [30].

Quality of evidence was assessed for the primary outcome by two authors (FK, LS) independently using the GRADE approach [32].

3.5. Analysis

We conducted a narrative synthesis of the included studies, characteristics of the interventions and their effects on influenza vaccination rates. We assessed the extent of SDM processes in the interventions and possible effect modifiers in subgroup analyses.

As mentioned above, SDM comprises decision antecedents, the decision process as well as decision outcomes [18]. According to our definition, a complete SDM process has to include the three elements “patient activation”, “bi-directional exchange of information” and “bi-directional deliberation”. The extent of a SDM process was assessed by using an established and modified rating scheme [20]. We classified the interventions as full SDM (all three criteria met) and partial SDM (unclear deliberation and/or information).

We performed a *meta*-analysis for influenza vaccination rates to estimate the effectiveness of interventions on influenza vaccination uptake. As cluster-RCTs were included, we chose the inverse variance method and a random effects model. We used OR as effect size for quantitative data synthesis and, where necessary, calculated ORs with Review Manager 5.3 from absolute numbers and without adjustments. For cluster-RCTs adjusted ORs and CIs were used and standard errors calculated by Review Manager 5.3.

We performed descriptive and quantitative analyses of partially pre-specified subgroups to describe variations of possible effect modifiers in interventions. Studies were compared according to the extent of SDM, place (at home vs. health care facility) and timing of the intervention before vs. during the appointment). Furthermore, we differentiated between interactions that were conducted by individual HCP or a multidisciplinary team of HCP. Additionally

Table 1
Characteristics of included studies.

	Country	Patients/Age	Intervention	Extent of SDM Process	n (IG)	n (CG)	p-value/ effect size for vaccination rates	vaccination rate (IG)	vaccination rate (CG)	Follow up
Arthur 2002	UK	75+	Home visit integrated in usual health check	Full SDM process	680	1372	MD (95% CI): 6.4% (2.2%-10.4%) p = 0.003	74.3%	67.9%	3 months
Black 1993	Canada	65+	Home visit by nurse	Full SDM process	198	152	MD (95% CI): −0.5%: (-11.0–10.0%)	56.1%	56.6%	Not reported
Brimberry 1988	USA	65 + or chronic disease	Telephone outreach	Unclear deliberation in SDM process	258	262	p < 0.02 (IG and IG2 in relation to CG)	9.3%	3.8%	Not reported
Coenen 2017	Belgium	Inflammatory bowel disease patients	Face-to-face education on vaccination	Full SDM process	50	52	p = 0.001	36%	10%	8 months
Dapp 2011	Germany	60+	Computer generated feedback for patient and provider, provider training, additional group session or home visit	Full SDM process	574	CG: 1353	OR (95% CI): 1.7 (1.4–2.1), p < 0.001	68.8%	56.8%	1 year
Harari 2008	UK	65+	Computer generated feedback for patient and provider, provider training	Unclear deliberation + information in SDM process	940	CG: 1066	OR (95% CI): 0.8 (0.6–1.1), p = 0.12	83.9%	85.8%	1 year
Humiston 2011	USA	65+	Telephone outreach	Full SDM process	1748	2004	OR (95% CI): 6.25 (5.41–7.22); p < 0.0001 (unadjusted) OR (95% CI): 6.27 (5.42–7.26); p < 0.001 (adjusted)	64%	22%	2 months
Klassing 2018	USA	18 + with asthma/COPD	Telephone outreach	Full SDM process	77	70	p = 0.019	72.7%	88.6%	5 months
Leung 2017	Hong Kong	65+	Face-to-face health education and brochure	Full SDM process	265	264	Adjusted RR (95% CI): 1.34 (1.04–1.72), p = 0.021	33.6%	25%	3 days
Lukasik 1987	Canada	65+	Telephone outreach	Full SDM process	120	123	p = 0.0002	50.8%	26.8%	6 weeks – 3 months
Marra 2014	Canada	65 + or chronic disease	On site education about vaccination for patients, provider training, letter reminder for patients	Unclear deliberation in SDM process	2009: 8845 patients in 14 communities 2010: 10,390 patients in 14 communities	2009: 5970 patients in 10 communities 2010: 22,015 patients in 15 communities	2010: MD (95% CI): –23.8% (–41.4%- –5.0%), p = 0.01	2009: 83.8% 2010: 80.1%	2009: 85.6% 2010: 56.9%	2 years
McDowell 1986	Canada	65+	Telephone outreach	Unclear deliberation in SDM process	226	230	IG, IG2, IG3 compared to CG: p < 0.001 Difference between IG, IG2, IG3: p < 0.005	42%	15.6%	3 months
Moran 1996	USA	High risk by age/medical diagnosis	Educational brochure to empower discussion	Unclear deliberation + information in SDM process	198	202	p = 0.0004, OR (95% CI): 2.29 (1.45–3.61)	36%	20%	3 months
Nuttall 2013	UK	65–90 years	Home visit and letter reminder	Full SDM process	30	CG: 30	p = 0.329 (between 3 groups)	40%	27%	9 months
Parker 2018	USA	18 + lymphoma survivors	New face-to-face consultation and provider communication skills training	Full SDM process	117	81	p = 0.02 logistic HLM: OR (95% CI): 2.42 (1.16–5.02) PH model, HR (95% CI): 1.69 (1.04–2.77)	59%	38%	3, 6, 9, 12 months
Stuck 2015	Switzerland	65+	Computer generated feedback for patient and provider,	Full SDM process	827	1320	p = 0.005, OR (95% CI): 1.35 (1.09–1.66)	65.8%	59.2%	2 years

Table 1 (*continued*)

	Country	Patients/Age	Intervention	Extent of SDM Process	n (IG)	n (CG)	p-value/ effect size for vaccination rates	vaccination rate (IG)	vaccination rate (CG)	Follow up
			provider training, telephone and home visit outreach for patients							
Turner 1994	USA	Not reported Patients of family practicioners/general internists, eligible for influenza vaccination if 65 + or chronic disease	Patient-carried prompt card and personal instruction how to use this	Unclear deliberation + information in SDM process	22 physicians	15 physicians	p = 0.51 (MD)	24% (baseline: 17%)	26% (baseline: 20%)	1 year
Usami 2009	Japan	65+	Face-to face counselling by pharmacist and educational brochure	Unclear deliberation in SDM process	911	952	IG: p < 0.001 (vaccinated) IG: p < 0.008 (MD) CG: p < 0.001 (vaccinated) CG: p < 0.008 (MD)	81.6%	64.9%	2–3 months
Wilkinson 2002	USA	Patients sheduled for primary care team visits (average age 60 y, primary diagnoses mostly chronic)	Appointment guidebook empowering discussion	Unclear deliberation + information in SDM process	141	106	IG: p = 0.340 CG: p = 0.236 Z: −1.772 significance 0.10 Note: z score for two-tailed significance +/- 1.65 at alpha 0.10; +/- 1.96 at alpha 0.05.	34%	23.6%	Not reported
Wright 2012	USA	Patiens of primary care practices with access to online portal, influenza/ pneumococcal: according to guidelines *Probably 65 + or chronic disease*	Patient education, reminder and empowerment through online patient portal	Unclear deliberation + information in SDM process	227	285	Unadjusted: p = 0.018 (p < 0.05) Adjusted: p = 0.016 (p < 0.05), OR: 1.83	22%	14%	2 months
Zwar 2012	Australia	40–80 years COPD patients	Home visit by nurse	Full SDM process	161	169	p = 0.13, OR (95% CI): 1.88 (0.88–4.02)	81.4%	77.2%	12 months

Cluster RCTs are listed in cursive letters.

we examined the effectiveness of interventions directed at elderly, chronically ill and mixed patient groups.

4. Results

4.1. Description of studies

4.1.1. Results of the search

We identified 5688 studies, with 4677 remaining after removing duplicates. After titles and abstracts were screened, 135 articles remained for full text assessment. Full texts were available for 111 of these studies. Of these full-text articles, 21 studies matched our selection criteria and were included in our systematic review, and 15 of which were suitable for quantitative synthesis and were included in the *meta*-analysis. With the remaining 6 studies using a per-protocol approach, [28,29] displaying problematic estimation methods for vaccination rates [30,31] or insufficient adjustments for clustering effects in cluster-RCTs [32,33].

4.2. Included studies

4.2.1. Study design

Of all included studies, 15 studies were randomized at individual level (by patient, family or household) [28,29,34–46], whereas six studies had a cluster-randomized study design (by HCP, practice, pharmacy or community) [30–33,47,48]. Studies were published between 1986 and 2018.

4.2.2. Characteristics of settings and participants

The studies were conducted in practices of general practitioners (GPs) (n = 14) [30,32,34,36–42,44–46,48], pharmacies [29,31,33], specialized outpatient practices [28,47] or other outpatient practices, such as community health centers [43] or public health clin-

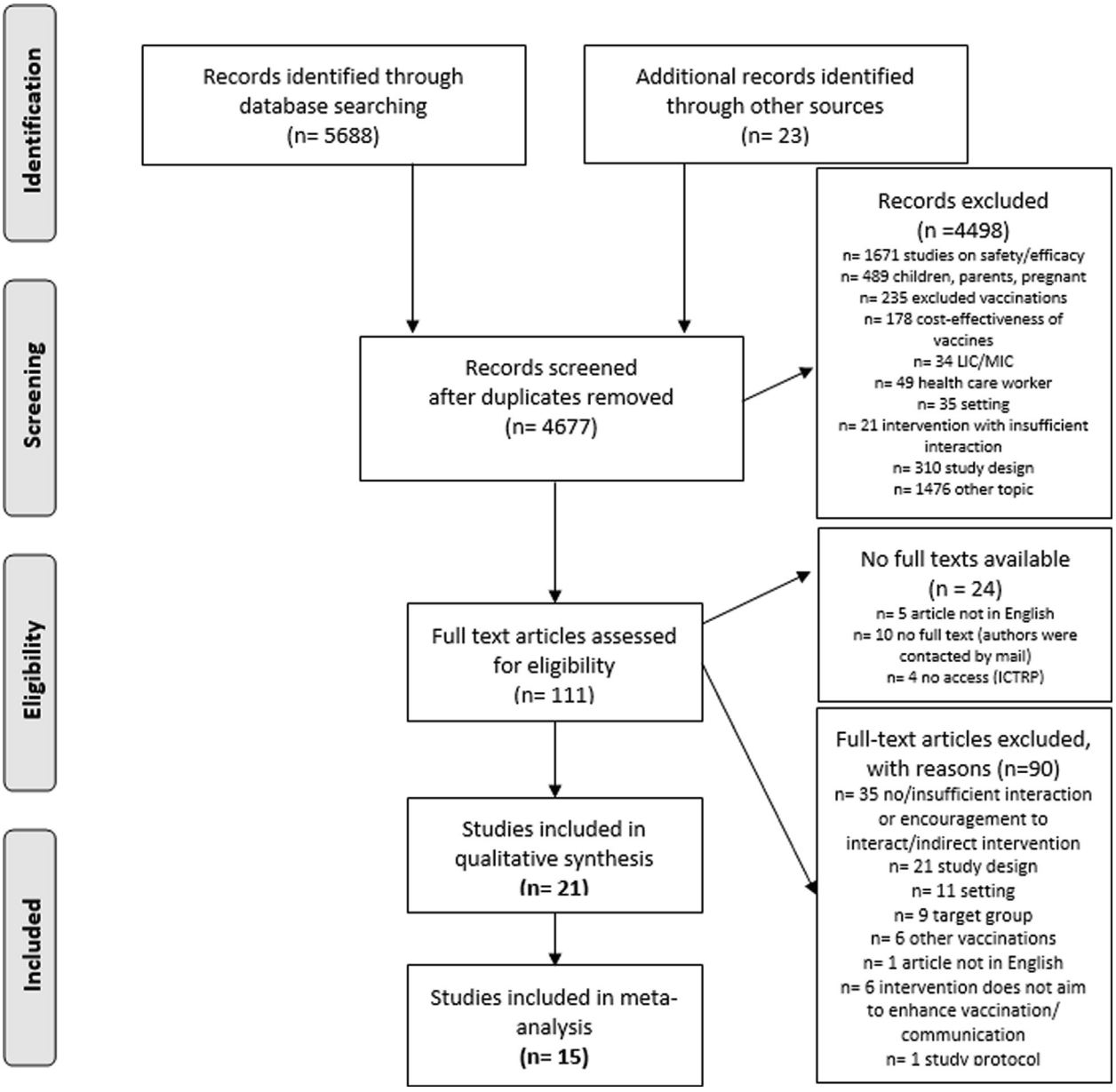

Fig. 1. PRISMA study flow diagram.

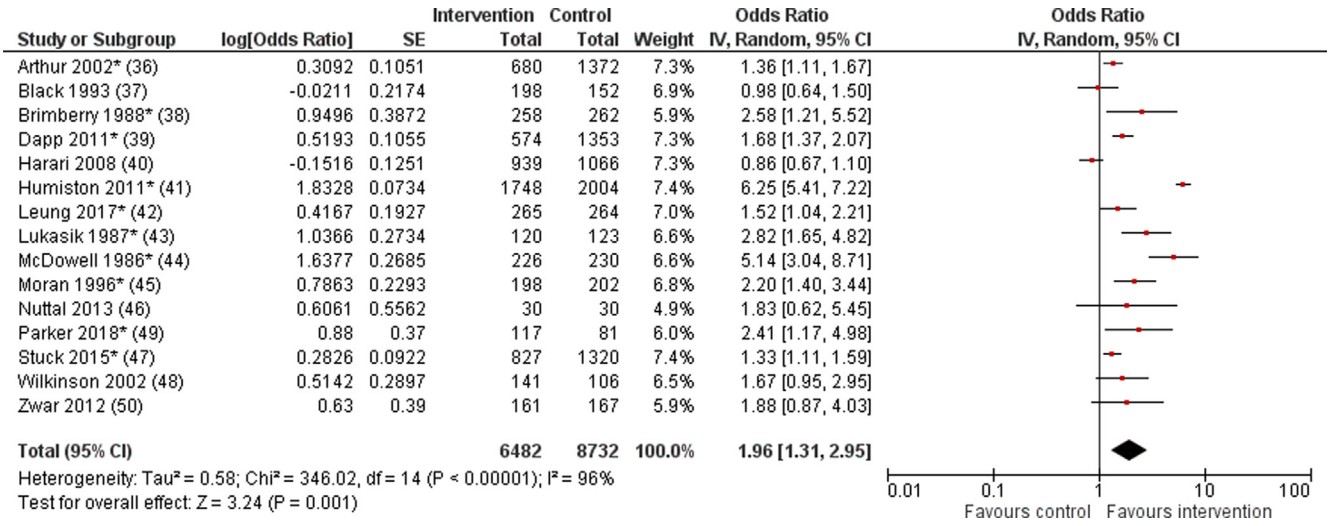

Fig. 2. Effects of analysed interventions on vaccination rates. CI: confidence interval; SE: standard error; IV: inverse-variance method; *: p < 0.05.

ics [35]. They focused mainly on chronically ill and elderly patients (Table 1).

4.2.3. Characteristics of interventions and control conditions

We used the *Effective Practice and Organisation of Care* (EPOC) taxonomy of implementation strategies [27] to categorize interventions of included studies. Of all included studies, 13 were assessed as "patient mediated interventions" [30,32,36–46,48]. In six studies, "educational meetings" for HCP was a component of the intervention [31,37,38,45,47,49]. Trainings for HCP often included education on vaccination indications, delivery, and/or communication skills, but varied largely in intensity, administration and content. Other studies applied "reminders" [32,38,39,41,46,47], "educational material" [37,38,45], "educational games" [47] and "audit and feedback" [37,38,45,47] directed at HCP, targeted "organisational culture" [47], or "continuous quality improvement" [45].

The intervention in 12 studies was compared to "usual care", as administered routinely in the respective setting [28,29,31,33,36–43]. In three studies, the control group was provided with an alternative intervention (e.g. education for patient or HCP on other topics than vaccination) [32,35,47]. Control groups in another five studies recieved an active control intervention: letter reminder for patients [34,44,46], reminder notification for HCP [30] or copies of guidelines for HCP [48].

4.3. Effect of interventions

4.3.1. Primary outcome: Influenza vaccination uptake

Vaccination rates were assessed by medical records [29,30,32,34,39,41,42,44,46], trial specific recording forms [36,40,43], health authorities [31], or patient reported [32,33,35,37,38,45,47,48]. Effect sizes were presented in OR, RR and MD (Table 1).

A significant increase of vaccination rates was reported in 14 studies. In four studies, vaccination rates increased without statistical significance [30,44,46,48]. However, three studies indicated a decreased vaccination rate after the intervention [35,38], in one case even significantly [29]. Achieved vaccination rates varied remarkable between studies and ranged from 3.8% to 88.6% (Fig. 1).

Meta-analysis of interventions enabling SDM processes showed an increase of influenza vaccination rates by OR (95% CI): 1.96 (1.31–2.95) compared to controls. (Fig. 2).

4.4. Secondary outcomes

4.4.1. Extent of SDM-P in interventions

Out of the 21 included studies, 12 studies featured interventions meeting our criteria for a *full SDM-P* [28,29,34,35,37,39–41,44,45,47,48], meaning there were indications for patient activation, bi-directional exchange of information and deliberation in the description of the intervention, its content and/or delivery procedure.

The *deliberation in the SDM process* was unclear in four studies [31,33,36,42], and additionally both a bi-directional exchange of *information and the deliberation in the SDM process* was unclear in five studies [30,32,38,43,46] (Table 1).

Additional secondary outcomes could be identified in some studies as follows.

Patient knowledge was increased significantly in the intervention groups (MD of knowledge scores; p = 0.01 [47]; p = 0.02 [48]). Items to assess vaccination knowledge were included in disease specifc questionnaires, measuring primarily overall knowledge on lymphoma and COPD respectively.

Patient quality of life did not differ significantly between groups (measured by "Quality of life cancer survivor" [50,47] and "SF-12®" [48]. The self percieved health status assessed with the HRA-O questionnaire [51] revealed fewer patients in the intervention group perceiving fair or poor health status (OR 0.7 (95% CI: 0.5–0.9); [37]) and (p = 0.04; [45]).

Patient satisfaction or **decisional conflict** was not measured in any of the included studies.

We differentiated the effectiveness of interventions according to possible effect modifiers and patient groups who benefited most from SDM (Table 2).

The two interventions with *unclear deliberation* increased vaccination rates most [36,42]. Both studies compared mailed letter reminders vs. personal/ telephone reminders. We defined "unclear deliberation" as an SDM process in which the element "deliberation" was not precisely described or reported. Therefore, we could not estimate if patients had the opportuinity to weigh pros and cons together with their HCP. Interventions with unclear information and deliberation seemed to be less effective then interventions classified as full SDM process.

In most studies, there was an interaction by a team of HCP and interventions showed to increase vaccination rates more than interventions with an interaction by an individual HCP. For instance, the patient was reminded and informed about the vaccination by a nurse prior to the consultation with the doctor, where

Table 2
Subgroup analyses of effect modifier in interventions.

Subgroup	Studies	number of patients	I^2	Effect size: OR (95% CI) statistical method: inverse variance, random effects
Total	n = 15	15,214	96%	**1.96 (1.31–2.95)**
Extent of SDM process: Full SDM process	n = 10 **(34), (35), (37), (39), (40), (41), (44), (47), (45), (48)**	11,586	97%	**1.91 (1.15–3.18)**
Extent of SDM process: Unclear deliberation in SDM process	n = 2 (36), (42)	976	53%	**3.86 (1.98–7.50)**
Extent of SDM process: Unclear information + deliberation in SDM process	n = 3 (38), (43), (46)	2652	87%	1.43 (0.75–2.73)
Interaction by team of HCP	n = 11 (36), **(37)**, (38), **(39), (40), (41),** (42), (43), **(44), (45), (48)**	12,367	97%	**2.17 (1.30–3.63)**
Interaction by single HCP	n = 4 **(34), (35), (47),** (46)	2847	42%	**1.39 (1.05–1.84)**
Target of intervention: patient	n = 8 **(34), (35)**, (36), **(40),** (42), (43), **(44),** (46)	4614	77%	**1.85 (1.32–2.59)**
Target of intervention: patient + HCP	n = 7 **(37)**, (38), **(39), (41), (47), (45), (48)**	10,600	98%	**2.05 (1.03–4.04)**
Place and timing of intervention: before appointment, at home	n = 9 (36–38, 42–46, 48) (36), **(37)**, (38), (42), (43), **(44), (45),** (46), **(48)**	8090	84%	**1.80 (1.32–2.47)**
Place and timing of intervention: during appointment, at the health care facility	n = 4 **(34), (35), (40), (47)**	3129	40%	**1.38 (1.08–1.76)**
Place and timing of intervention: before (home) + during appointment (health care facility)	n = 2 **(39), (41)**	3995	87%	**4.39 (2.02–9.52)**
Patients: chronically ill	n = 3 (43), **(47), (48)**	649	0%	**2.30 (1.44–3.67)**
Patients: elderly	n = 11 **(34), (35), (37)**, (38), **(39)**, **(40), (41)**, (42), (43), **(44), (45)**	13,798	97%	**1.91 (1.17–3.12)**
Patients: chronically ill + elderly (mixed)	n = 2 (36), (46)	767	0%	**1.96 (1.24–3.08)**

Calculated with Review manger 5.3.
RCTs: ORs calculated by absolute, unadjusted data.
Cluster-RCTs: adjusted ORs, as stated in paper, SE calculated.
Studies with citations in bold letters were assessed as "*full SDM process.*"
ORs in bold letters with $p < 0.05$.

sequentially the patients' preferences and needs were discussed and options deliberated.

About half of the examined interventions targeted both the patient and HCP to promote SDM. The effect size was slightly higher, but with a wider CI in interventions targeting both participants of the SDM processes in contrast to interventions which focused exclusively on the patients or HCP.

Interventions that took place at home and before the appointment showed more effectiveness than interventions that were implemented at the healthcare facility during the appointment. Studies with interventions targeting both settings and points of time showed the highest effect on vaccination rates, though this analysis only included two studies. While all interventions taking place during the appointment displayed *full SDM processes* according to our criteria, only part of the studies implemented before an appointment was assessed as *full SDM-P*.

Studies directed at chronically ill patients displayed a higher pooled effect size than for elderly or mixed patients groups, though most studies were directed at elderly patients.

4.4.2. Risk of bias in included studies

We identified a possible high risk of bias arising from the randomization process in studies that did not use automatically generated randomization sequences or showed major differences in baseline characteristics between the intervention group (IG) and control group (CG). [28,39,41 30,32,33,48].

Due to the type of interventions, blinding of participants was not possible in many cases. Other bias attributable to deviations from intended interventions comprised providing the intervention only for a part of the intervention group [39,41], patients changing assigned groups [28] or risk of contamination at physician [45,46] or patient/household [43] level.

In 7 studies reporting major proportions of missing data, patient losses or estimation methods leading to incomplete outcome data were attributed a high risk of bias [29–32,36,46,47].

Risk of bias in measurement of the outcome was mainly attributable to self-reporting by participants [32,33,35,37,38,45,47,48], which can be prone to bias, for instance social desirability bias or inaccuracy of data. One study [30] used an inappropriate sample method to estimate vaccination rates.

As all included studies reported influenza vaccination uptake the domain "reporting bias" was estimated as low risk. However, protocols were not available for most studies and reporting bias concerning other (secondary) outcomes cannot be precluded.

A high risk of other bias was assessed for five studies, due to incorrect analysis *(no adjustments for cluster design)*[31–33], external influences, questionable selection of particiants [28] or insufficient differences between interventions [41] (Fig. 3; Fig. 4).

5. Discussion

5.1. Summary of main results

Interventions enabling SDM in adult influenza vaccination enhanced vaccination rates by OR (95% CI): 1.96 (1.31–2.95) (with moderate to low quality of evidence (GRADE [52]). When examin-

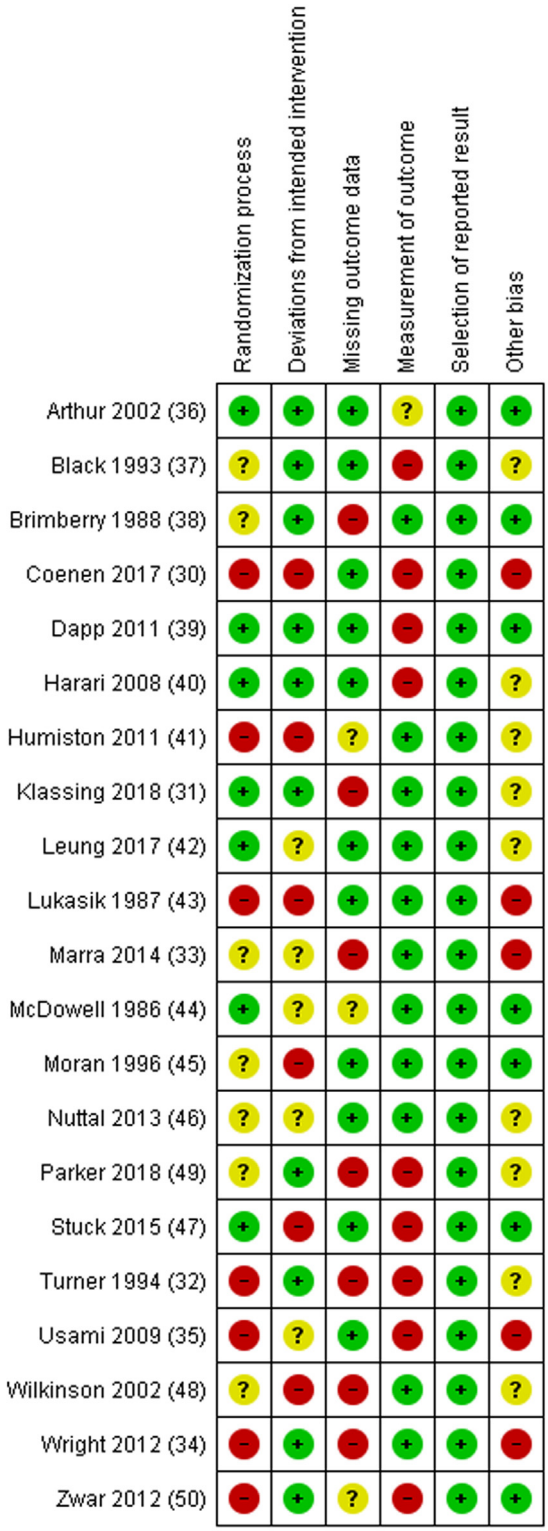

Fig. 3. Risk of biaś summary.

ing all studies in qualitative analyses, the majority of interventions significantly increased influenza vaccination rates, but negative effects on vaccination rates were found in three of 21 studies as well. These three studies displayed major limitations in study design or implementation, which could explain greater deviations from true intervention effects. These limitations included dissimilar implementation of interventions between groups [35], analysis per protocol though substantial dropout rates occured [29] or a possible dilution of intervention effect [38] due to study design and/or free choice of intensity of intervention. For those studies showing distinctive positive effects -predominantly telephone outreach interventions (five studies)- time of publication must be taken into consideration. Some of these studies [36,41,42] have been conducted over 30 years ago. We presume that influenza awareness in the population and in HCP as well as framework conditions and priorities in health systems for influenza vaccination differed substantially at that time and thus limiting comparability and generalizability of results.

The extent of SDM processes varied remarkably between studies. All of them displayed at least some kind of patient activation, but a full SDM process was only found in about half of the trials (57.1%). Interventions that involved the patient actively in the entire decision making process *(full SDM process)* showed to be more effective than interventions where only patient activation was reliably implemented. As the two studies displaying *unclear deliberation in SDM process* showed even higher effect sizes, we could not determine a relation of extent of SDM process and effect on influenza vaccination rates. However, this relation cannot be precluded definitively, because these studies [36,42] displayed limitations dicussed before (published 1986 and 1988).

Subgroup analyses showed effectiveness of interventions on vaccination rates across patients groups comprising elderly patients or chronically ill. Though the pooled effect seemed to be somewhat higher in groups of chronically ill, the majority of studies was directed at elderly patients. Furthermore the findings suggest a higher effectiveness, when implemented by teams of HCP. We suspect that sharing responsibilities in enabling SDM enhances feasibility of interventions in clinical practice, for example due to reduced effort and time for each single HCP.

Furthermore, interventions displayed higher effect sizes when they implemented components before (at home) and during the appointment (at the health care facility), albeit only *meta*-analysed with two studies. Apart from that, varying extents of SDM must be considered, with a remarkable low proportion of studies enabling *full SDM processes* in interventions implemented before an appointment and a high proportion of those implemented during the appointment.

Patient satisfaction, knowledge, quality of life and decisional conflict were addressed rarely in included studies. Although improvements in patient knowledge and self perceived health status have been reported, informative value of results might be limited due to other components of the interventions that aim at other clinical parameters than vaccination (e.g. breathe training for COPD patients or regular lymphoma check-ups).

Previous reviews have shown comparable results in terms of intervention strategies based on personal contact between adult patients and HCP in primary care and influenza vaccination uptake. For example, patient outreach visits as well as telephone reminders were more effective if personal contact was involved [25,26]. The likelihood of accepting influenza vaccinations could be increased, if they were recommended personally by teams of HCP [53].

A review of studies examining the effectiveness of home visits has shown positive results in increasing vaccination rates [54]. As enhancing access to vaccination services is an obvious aspect in these interventions, the face-to-face intervention between patient and HCP might be a less recognized component contributing to the effectiveness of home visits. Face-to-face interventions to enhance vaccination uptake in children suggested to slightly enhance knowledge in parents [55].

A systematic review of 2018 showed positive effects on influenza vaccination rates especially among elderly patients in home visits and interventions with nurses or pharmacists educating

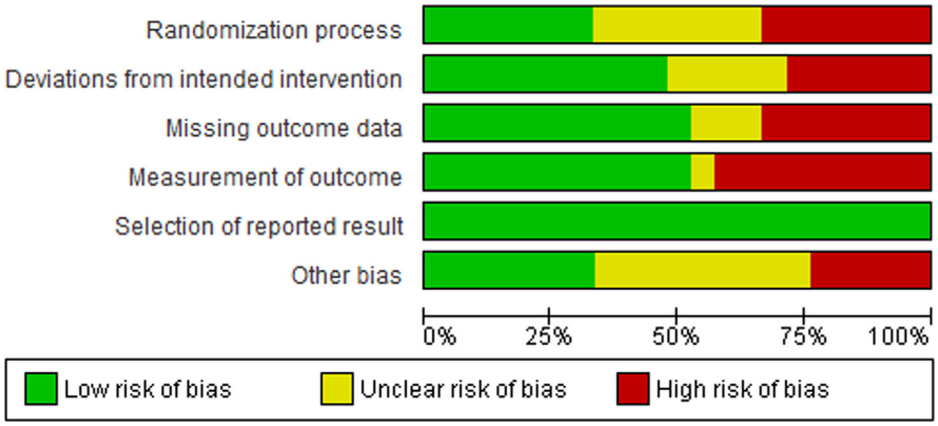

Fig. 4. Risk of biaś graph.

patients and concurrently administering the vaccines [24]. Although the term SDM was not mentioned in the description of the intervention, it can be assumed that (due to the type of intervention) at least the core elements of this consultation style were applied.

5.2. Strenghts and limitations

Our search strategy was very broad including various terms related to SDM, dimishing the risk of missing out relevant literature. However, only including publications in English or German language potentially limited the number of reviewed studies.

A limitation of our review is the considerable heterogeneity of included studies regarding characteristics of interventions and study design. In terms of control conditions, studies received alternative or active control interventions, apart from that receiving "usual care". We suppose remarkable differences in "usual care" as delivered e.g. in GP practices, specialist practices or pharmacies, as well as in different countries, health systems and cultural settings. Attained vaccination rates differed substantially between studies, suggesting dissimilar baseline vaccination rates in the observed settings or populations. In this context a ceiling effect must be taken into consideration when interpreting results of studies with a very high achieved vaccination uptake. For example studies with baseline vaccination rates (or attained vaccination rates in CG) over 70% reported smaller or even partly negative effects of interventions [29,38,48].

Heterogeneity should be considered for interpreting results of the *meta*-analysis particularly, which was remarkably high in most comparisons, measured by I^2. Heterogeneity was also present in terms of publication years (ranging from 1986 – 2018), with older clinical trials conforming less to standardized reporting styles [56] and also potentially affecting generalisability and reproducabilty of findings. Therefore, results of included studies must be interpreted in consideration of their timely execution and external influences (e.g. changes in national immunization recommendations and reimbursement policies) and epidemiological events. For example, the H1N1 pandemic in 2009 was found to affect seasonal influenza awareness and attitudes towards vaccination [57,58].

To enable comparability of effect sizes in a forest plot and *meta*-analyis, we used unadjusted data for all RCTs and calculated ORs. When compared to adjusted ORs as stated in the respective papers, we found ORs being slightly lower in some of our calculations. However, imprecision observed in some studies may be contributable to other factors as well, for instance small sample sizes. For cluster-RCTs we used adjusted ORs for the *meta*-analysis, thus ORs were not only adjusted for clustering effects but also for baseline variables [48] hypothetically affecting results.

Another limitation of our study is that we were not able to use a validated tool to objectify SDM. As included studies did not utilize any kind of standardised measurement for SDM, we relied on the studieśreporting to evaluate the extent of SDM process in interventions using an adapted custom made rating scale. The possibility that a criterion assessed as "unclear" was actually either met or not met in the implementation must be considered, possibly affecting the accuracy of our SDM process assessment. However, this is the first systematic review shedding light on the topic of SDM in the field of vaccination.

5.3. Further research

In the field of adult (influenza) vaccination we did not identify many RCTs adressing SDM as per description and no studies using SDM specific measurement methods. Further clinical trials should apply validated measurement tools with ideally a dyadic approach to better reproduce the dimensions of SDM. Effects on other aspects like patient satisfaction with the consultation, patient knowledge on vaccination and decisional conflict could be addressed and explored further.

More research could contribute to substantiate findings of impact of effect modifiers and effectiveness of interventions for certain patient subgroups. Additionally, further research is necessary to analyze the effect of SDM processes in interventions targeting uptake of non-seasonal vaccines or vaccinations for children.

5.4. Implications for policy and practice

Our findings suggest that the potential of SDM to enhance influenza vaccination rates is not yet fully used. Furthermore, we conclude that interventions by multidisciplinary HCP teams can be more effective than by individual HCP when implementing SDM interventions. The team approach would have the advantage to decrease time ressources per HCP at the same time. Certain tasks of direct patient interaction (e.g. activate and inform or educate patients), can be performed by non-physician HCP, who might act as communication facilitators between patient and physician [59]. Apart from that, non-physician HCP can be responsible for case management, with the physician providing the clinical leadership [60]. SDM seems to be effective in increasing influenza vaccination rates. Clinicians can already increase the use of SDM in their practice by encouraging their patients to present any reasons for vaccine hesitancy including concerns about the immune system, vaccine safety, risk balance, uncertain efficacy, religious and cul-

tural norms, alternative concepts of disease, and concepts of individual responsibility and power relations. HCP should be made aware that experts and non-experts perceive risk differently. Effective training of physicians is crucial including methods of risk communication and communication skills. If a physician is unfamiliar with or uncertain about vaccinations, communication will probably be avoided or inaccurate, generating mistrust. Therefore, obligatory vaccinology and vaccine safety courses should be introduced into medical school and residency training curricula. Communication and vaccine advocacy must be encouraged by patient groups acting together with HCP and policy makers to bring about change [11].

5.5. Conclusion

Though varying extent of SDM processes in interventions, overall interventions aligning with an SDM approach have shown to be effective in increasing influenza vaccination rates in adult patients and across subgroups comprising elderly patients or chronically ill. Interaction facilitated by teams of HCPwere associated with higher vaccination rates. This collaborative approach involving different HCP in SDM processes therefore appears promising in increasing effectiveness and feasibility in clinical practice.

Ethical approval

An ethical approval for the present research was not required.

CRediT authorship contribution statement

Linda Sanftenberg: Conceptualization, Formal analysis, Investigation, Writing - original draft. **Flora Kuehne:** Methodology, Software, Formal analysis, Investigation, Data curation, Writing - original draft, Visualization, Project administration. **Charlotte Anraad:** Writing - review & editing, Methodology, Supervision. **Caroline Jung-Sievers:** Conceptualization, Writing - review & editing, Supervision. **Tobias Dreischulte:** Methodology, Writing - review & editing, Supervision. **Jochen Gensichen:** Methodology, Conceptualization, Resources, Writing - review & editing, Supervision.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.vaccine.2020.12.014.

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