

Part 1: Screening titles and abstracts for relevance

Objective:

To practise the procedure of application of selection criteria to titles and abstracts in two steps:

1) independently, and 2) comparison with co-author's decisions and arriving at final a decision.

We use the (simplified) selection criteria described in:

Kaufman J, Ryan R, Walsh L, Horey D, Leask J, Robinson P, Hill S. Face-to-face interventions for informing or educating parents about early childhood vaccination. Cochrane Database of Systematic Reviews 2018, Issue 5. Art. No.: CD010038. DOI: 10.1002/14651858.CD010038.pub3.

Study objective: To assess the effects of face-to-face interventions for informing or educating parents about early childhood vaccination on vaccination status and parental knowledge, attitudes and intention to vaccinate.

Types of studies

Randomised controlled trials (RCTs) and cluster-RCTs.

Types of participants

- Children: infants (less than 1 year) or preschool-aged children (1 to 5 or 6 years).
- Parents: parents, guardians, or others fulfilling the parental role, alone or in groups.
- Vaccine program organisers: anyone involved in the planning or implementation of vaccination programmes or interventions

Types of interventions

- Face-to-face communication interventions directed to parents to inform or educate them about routine childhood vaccinations.
- Content includes information about:
 - vaccine-preventable diseases (e.g. symptoms, prevalence, transmission, severity)
 - vaccines (e.g. delivery method, dose, ingredients, schedule, risks or side effects, benefits)
 - vaccine service delivery (e.g. where to go to receive vaccinations, costs, clinic opening hours, services to assist with access)
- Interventions delivered by anyone, including physicians, nurses, midwives, health visitors, or other healthcare professionals; trained volunteers; lay health workers; members of the community; or peers.
- Comparisons:
 - Face-to-face interventions directed to parents versus control (usual care or passive intervention, i.e. non-face-to-face information or education, or no intervention),
 - Face-to-face intervention A versus face-to-face intervention B.

Types of outcome measures

Primary outcomes

- Children: vaccination status of child (i.e. vaccination status up-to-date, or receipt of one or more vaccines, as defined by study authors); outcome domain: vaccination status and behaviours
- Parents: knowledge or understanding of vaccination; outcome domain: knowledge or understanding
- Parents: attitudes or beliefs about vaccination; outcome domain: attitudes or beliefs
- Parents: intention to vaccinate child; outcome domain: attitudes or beliefs
- All categories: adverse effects; outcome domain: any

1) Andersson N, Cockcroft A, Ansari NM, Omer K, Baloch M, Ho Foster A, Shea B, Wells GA, Soberanis JL (2009). **Evidence-based discussion increases childhood vaccination uptake: a randomised cluster controlled trial of knowledge translation in Pakistan.**

Childhood vaccination rates are low in Lasbela, one of the poorest districts in Pakistan's Balochistan province. This randomised cluster controlled trial tested the effect on uptake of informed discussion of vaccination costs and benefits, without relying on improved health services. Following a baseline survey of randomly selected representative census enumeration areas, a computer generated random number sequence assigned 18 intervention and 14 control clusters. The intervention comprised three structured discussions separately with male and female groups in each cluster. The first discussion shared findings about vaccine uptake from the baseline study; the second focussed on the costs and benefits of childhood vaccination; the third focussed on local action plans. Field teams encouraged the group participants to spread the dialogue to households in their communities. Both intervention and control clusters received a district-wide health promotion programme emphasizing household hygiene. Interviewers in the household surveys were blind of intervention status of different clusters. A follow-up survey after one year measured impact of the intervention on uptake of measles and full DPT vaccinations of children aged 12-23 months, as reported by the mother or caregiver. In the follow-up survey, measles and DPT vaccination uptake among children aged 12-23 months (536 in intervention clusters, 422 in control clusters) was significantly higher in intervention than in control clusters, where uptake fell over the intervention period. Adjusting for baseline differences between intervention and control clusters with generalized estimating equations, the intervention doubled the odds of measles vaccination in the intervention communities (OR 2.20, 95% CI 1.24-3.88). It trebled the odds of full DPT vaccination (OR 3.36, 95% CI 2.03-5.56). The relatively low cost knowledge translation intervention significantly increased vaccine uptake, without relying on improved services, in a poor district with limited access to services. This could have wide relevance in increasing coverage in developing countries.

2) Gust DA, Kennedy A, Wolfe S, Sheedy K, Nguyen C, Campbell S (2008). **Developing tailored immunization materials for concerned mothers.**

The objectives of this study were to (i) identify 'Worried' and 'Fencesitter' mothers through the use of screening questions; (ii) obtain detailed information from participants about their attitudes and beliefs regarding vaccines and their interactions with their child's main health care provider, including availability of immunization information; (iii) solicit comments on draft educational materials that were developed specifically for this study and (iv) solicit comments on revised educational materials. Focus groups of mothers were conducted in two phases (Phase 1: n = 17 groups; Phase 2: n = 12 groups) and in three cities across the United States. Phase 1 focus group discussions suggested that perceived necessity and safety of vaccines contributed to mothers' attitudes about having their child receive immunizations. Participants relied on their children's main health care provider for immunization information; however, mothers often perceived that providers did not supply enough information about vaccinations. In Phase 2, comments on the revised educational materials (brochures) were generally positive, with many mothers noting that the new brochures provided more relevant information and conveyed it in a respectful way. Science-based tailored immunization materials may assist health care providers in addressing unique information needs and may improve vaccine acceptance among specific types of mothers.

3) Tulchinsky T, al Zeer AM, Abu Mounshar J, Subeih T, Schoenbaum M, Roth M, Gamulka B, Abenueze M, Acker C (1997). **A successful, preventive-oriented village health worker program in Hebron, the West Bank, 1985-1996.**

Village health rooms (VHRs) were established in villages with no on-site health facilities in the Hebron District of the West Bank, beginning in 1985. By 1991, the program served a total population of 40,000 in 49 VHRs and by the end of 1996 covered 69 villages in Hebron and 20 in other districts that were previously served by visiting vaccination teams and nearby clinics. The VHRs provide close contact with the population of mothers for well child and pregnancy care, health education and provide visiting doctor/nurse teams for backup services and supervision. Data on coverage, utilization, costs, and outcome measures are presented. The program is accepted and grows despite adverse social and political conditions.

4) Virtanen M, Peltola H, Paunio M, Heinonen OP (2000). **Day-to-day reactogenicity and the healthy vaccinee effect of measles-mumps-rubella vaccination.**

Revaccination policies adopted in many countries to control measles have raised various safety issues including those concerning the second vaccine dose. We performed a prospective, double-blind, crossover trial among twins receiving a measles-mumps-rubella (MMR) vaccine. The study comprised 1162 monozygous and heterozygous twins, each of whom randomly received placebo and then vaccine, or vice versa, 3 weeks apart, at 14 to 83 months of age. Most of the oldest children had previously been vaccinated against measles, and one half of the remainder of children had had the disease. Symptoms and signs were recorded daily on structured forms. Statistical methods included a complex analysis of the vaccine attributability of the symptoms and conditional logistic regression. Vaccination-attributable events occurred in 6% overall. At 14 to 18 months of age, reactions developed between days 6 and 14, peaking at day 10. The clearest vaccine-attributable effect was fever exceeding 101.3 degrees F (38.5 degrees C; odds ratio: 3.28; 95% confidence interval: 2.23-4.82; P <.001), but the same trend was found for rash, arthralgia, conjunctivitis, staying in bed, drowsiness, and irritability. At 6 years of age, systemic reactions occurred 5 to 15 times less frequently, only arthralgia being associated with vaccination. Zygosity, gender, history of allergy, or infections did not modify reactions. Instead, respiratory symptoms developed within days postinjection to a level of 15% to 20% without subsequent decline and with no difference between vaccinees and placebo recipients. Vaccination was avoided during infections, but many small children became mildly ill within a week or so with no relation to vaccination (the healthy vaccinee effect). MMR vaccine was virtually nonreactogenic when given at 6 years of age. vaccine, measles, mumps, rubella, reactogenicity, adverse events, zygosity, healthy vaccinee effect.

5) Usman HR, Rahbar MH, Kristensen S, Vermund SH, Kirby RS, Habib F, Chamot E (2011). **Randomized controlled trial to improve childhood immunization adherence in rural Pakistan: redesigned immunization card and maternal education.**

A substantial dropout from the first dose of diphtheria-tetanus-pertussis (DTP1) to the 3rd dose of DTP (DTP3) immunization has been recorded in Pakistan. We conducted a randomized controlled trial to assess the effects of providing a substantially redesigned immunization card, centre-based education, or both interventions together on DTP3 completion at six rural expanded programme on immunization (EPI) centres in Pakistan. Mother-child pairs were enrolled at DTP1 and randomized to four study groups: redesigned card, centre-based education, combined intervention and standard care. Each child was followed up for 90 days to record the dates of DTP2 and DTP3 visits. The study outcome was DTP3 completion by the end of follow-up period in each study group. We enrolled 378 mother-child pairs in redesigned card group, 376 in centre-based education group, 374 in combined intervention group and 378 in standard care group. By the end of follow-up, 39% of children in

standard care group completed DTP3. Compared to this, a significantly higher proportion of children completed DTP3 in redesigned card group (66%) (crude risk ratio [RR] = 1.7; 95% CI = 1.5, 2.0), centre-based education group (61%) (RR = 1.5; 95% CI = 1.3, 1.8) and combined intervention group (67%) (RR = 1.7; 95% CI = 1.4, 2.0). Improved immunization card alone, education to mothers alone, or both together were all effective in increasing follow-up immunization visits. The study underscores the potential of study interventions' public health impact and necessitates their evaluation for complete EPI schedule at a large scale in the EPI system.

6) Brugha RF, Kevany JP (1997) **Maximizing immunization coverage through home visits: a controlled trial in an urban area of Ghana.**

A strategy of home visits to maximize children's immunization coverage was implemented in three towns in Ghana. The strategy was tested in town 1 in a controlled trial where clusters of children were allocated to the intervention and control groups. A total of 200 mothers in the intervention group were visited at home by non-health workers and their children were referred to a routine under-fives' clinic. Subsequent home visits targeted at those who failed to complete immunization schedules were made by nurses. After 6 months, coverage had risen from 60% to 85%, which was 20% higher than in the town 1 control group of 219 age-matched children ($P < 0.005$). A similar home-visiting strategy in a neighbouring town resulted in a rise in coverage from 38% to 91% ($n = 55$), mainly through home immunizations. Children were more likely to complete the schedule if their fathers were interviewed and participated in the decision to send them to the clinic. Countries with national service programmes can use a home-visiting strategy to supplement and strengthen their routine immunization programmes. A wide range of other community-based primary health care interventions could also be tested and implemented using this methodology. The strategy of home visits to maximize children's immunization coverage was evaluated in three towns in Eastern Ghana in 1991-92. Mothers were visited by a non-health worker and referred to an under-fives clinic; if they failed to follow through, a second home visit was made by a nurse. After 6 months, the proportion of completed schedules was significantly higher among the 200 intervention group children than the 219 controls, whether measured by card only (85.5% vs. 62.6%) or by card and history (86.0% vs. 66.7%). Complete coverage was most likely when the mother followed the advice of the interviewer and, without further prompting, brought the child to the health clinic (relative risk (RR), 1.43; 95% confidence interval (CI), 1.17-1.75), when a nurse met the mother at a subsequent home visit (RR, 0.40; 95% CI, 1.00-1.96), and if fathers were interviewed and participated in the decision to send the child to the clinic (RR, 1.85; 95% CI, 1.10-3.12). During the home visit period, 70.2% of previously uncompleted immunization schedules were completed. Other potential advantages of home visits include disaggregated data collection, identification of pockets of low immunization coverage, information on health service users' perspectives, and the involvement of fathers in health care decision making. However, home visiting should be viewed as a means of strengthening routine primary health care service provision and not as a substitute for clinic services.

Part 2: Study selection from full text publication

Objective: To practise the procedure of application of selection criteria to a full text publication in two steps 1) independently, and 2) comparison with co-author's decisions and arriving at a final decision.

Please refer to the selection criteria described on page 1 of this text when you assess the full text publication.

Please use the checklist on page 8 to document your decisions.

Example of questions to include or exclude publications after reading full text

First author, year _____

Decision (after completing checklist):

Include (All questions answered «Yes»)

Discuss (Some questions answered «Unclear»)

Exclude (Some questions answered «No»)

Final decision (after discussion):

Include (All questions answered «Yes»)

Exclude (Some questions answered «No») → Reason /#: _____

1. Is it an empirical study published in a full text format?

Yes

No

Unclear

2. Is the aim to assess the effects of face-to-face interventions for informing or educating parents about early childhood vaccination?

Yes

No

Unclear

3. Is the study design one of:

Randomised controlled trial

Yes

No

Unclear

Cluster-randomised controlled trial

Yes

No

Unclear

4. Is the population infants (less than 1 year) or preschool-aged children (1 to 5 or 6 years), parents, guardians, or others fulfilling the parental role, alone or in groups?

Yes

No

Unclear

5. Is the intervention face-to-face communication directed to parents to inform or educate them about routine childhood vaccinations, that includes information about: vaccine-preventable diseases, vaccines, or vaccine service delivery, and delivered by anyone, including physicians, nurses, midwives, health visitors, or other healthcare professionals; trained volunteers; lay health workers; members of the community; or peers.

Yes

No

Unclear

6. Is the intervention compared to: either usual care or passive intervention, i.e. non-face-to-face information or education, or no intervention), or another face-to-face intervention?

Yes

No

Unclear

7. Is the outcome one or more of:

Vaccination status of child

Yes

No

Unclear

Adverse effects of vaccination

Yes

No

Unclear

STUDY SELECTION EXERCISE

Comments: _____
