Enhancing access to vaccination services

Reducing out of pocket costs

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
(Joyce & Racine 2005) **Citation:** CHIP Shots: Association Between The State Children's Health Insurance Programs And Immunization Rates **Aim of study:** To compare changes in up-to-date immunisation status before and after implementation of State Children's Health Insurance Program (SCHIP) in all 50 states and the District of Columbia	**Source population/s:** US **Eligible population:** Children aged 19-35 months and their parents from all 50 states and 28 selected metropolitan areas. **Selected population:** Children aged 19-35 months and their parents from all 50 states and 28 selected metropolitan areas who provided data for the National Immunisation Survey (NIS). **Excluded population/s:** NR **Setting:** 50 States and 28 Immunisation Action Plan areas in the US. **Vaccines:** Receiving the 4:3:1 4 doses of DTP, 3 doses of OPV, I dose of MMR or 4:3:1:3:3 4 doses of DTP, 3 doses of OPV, I dose of MMR, 3 doses	**Method of allocation:** NR **Intervention/s description:** SCHIP established in1997 to make available health insurance to children in poor or near-poor families who are ineligible for Medicaid. SCHIP allows states to raise the income eligibility thresholds above the Medicaid thresholds to any level. **Control/comparison/s description:** Before and after data compared. The intervention was evaluated using data from the NIS, a national probability sample of children aged 19-35 months from all states and 28 selected metropolitan areas. **Sample sizes:** **Total n=** >34,000	**Primary Outcomes** Proportion of children up-to-date for the 4:3:1, 4:3:1:3:3 vaccine series pre and post SCHIP. **Secondary outcomes** NR **Follow-up periods:** Data from 1995-96 compared to 2001-2002 **Method of analysis:** Frequencies and percentages	**Primary outcomes:** Vaccinations for the 4:3:1 series were unchanged: Poor 71.5% (pre) vs. 73.5% post, Near poor 77.0% (pre) vs. 76.9% post, Non poor 82.9% (pre) vs. 84.4% post, Unknown income 73.0% (pre) vs. 77.5% post SCHIP. For the 4:3:1:3:3 series the changes were greater. Poor 57.0% (pre) vs. 67.9% post, Near poor 60.5% (pre) vs. 72.7% post, Non poor 68.0% (pre) vs. 79.7% post, Unknown income 57.5% (pre) vs. 71.4% post SCHIP. **Secondary outcomes:** NR	**Limitations identified by author:** Inability of NIS to provide detail about household demographics. NIS not able to determine eligibility for SCHIP or whether children had health insurance. Differences in immunisation status may not have been detected by poverty status Although no significant change was observed does not mean that no change has occurred or that widening of differences has not been prevented.

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stratified by poor, near-poor and non-poor children. **Study design:** Before and after study **Internal validity score:** + **Applicability:** B	Hib, 3 doses Hep B by 19 months.	households per year provided data **Intervention n=** NR **Control n=** NR Poor n= 42,546 defined as 100% of FPL Near-Poor n= 73,057 defined as an income of greater of equal to 100% of FPL Non-Poor n= 96,040 defined as an income of greater of equal to 250% of FPL Unknown income n= 52,571 **Baseline comparisons:** Yes between poor, Near-poor, non-poor and unknown. Percentages presented only no comparisons made between groups or p-values or CIs reported. **Study sufficiently powered?** NR		**Attrition details:** NR	**Limitations identified by review team**: Time span may mean that outside factors may have contributed to the results. Little information is provided on the numbers of families receiving SCHIP. The intervention is not described in great detail. **Evidence gaps and/or recommendations for future research:** Studies exploring broader populations and settings **Source of funding:** Robert Wood Johnson Foundation

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					Changes in Health Care Financing Organisation Initiative

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(Kirschke et al. 2004) **Citation:** Childhood Immunization Rates Before and After the Implementation of Medicaid Managed Care **Aim of study:** To evaluate trends in childhood immunization coverage after implementation of Medicaid managed care in Tennessee (TennCare) in 1994. **Study design:** Before and after	**Source population/s:** Tennessee, US **Eligible population:** Parents and their infants (aged of 30 days through 24 months) in Tennessee, US. **Selected population:** Parents and their infants who had continuous enrolment from the age of 30 days through 24 months in TennCare (1994-1999 cohort) or fee-for-service Medicaid (1986-1994 cohort). **Excluded population/s:** Infants who did not have continuous enrolment from the age of 30 days through 24 months in TennCare (1994-1999 cohort) or fee-for-service Medicaid (1986-1994 cohort). **Setting:** Tennessee, US no further demographic details provided.	**Method of allocation:** Year of birth **Intervention/s description:** Not clearly described. A state-wide Medicaid managed care plan. It required that all children have a defined primary care physician from within a managed care organisation (MCO). The MCO were required submit data on the federal Screening, Diagnosis and Treatment Program, that mandated that children receive immunisations according to the Advisory Committee on Immunisation Practices. **Control/comparison/s description:** Before and after study	**Primary Outcomes:** The proportion of children up-to-date following TennCare. The difference between black versus white children immunised **Secondary outcomes:** NR **Follow-up periods:** 1986 to 1999 five years after TennCare was introduced. **Method of analysis:** Descriptive and multivariate logistic regression.	**Primary outcomes:** The results are presented graphically. The proportion of children enrolled in fee-for-service Medicaid or TennCare receiving all of their immunisations in the private sector increased during the study period from 32% for the 1986-1993 birth cohorts to 44% under TennCare ($P<.001$). Use of private providers for immunisations increased for each of the first 6 cohorts of children born under TennCare (1994-1999), and 77% of children born in 1999 received at least some of their immunisations in the private sector. A corresponding decrease in the proportion of children receiving	**Limitations identified by author:** The unknown effect of other immunisation initiatives on immunisation rates during the study period. **Limitations identified by review team:** Limited information on the study setting, how the survey sample compared to the study population. Effect of outside influences. Limited information on the intervention and how it was

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study **Internal validity score:** - **Applicability:** C	**Vaccines:** DTP, OPV and MMR	The intervention was evaluated using the Tennessee Department of Health's annual survey of the immunisation status of 24 month old children born 1986-1999. The survey reported on a random sample selected from the birth certificates of all children born in Tennessee exactly 2 years earlier. Each year's sample represents approximately 30% of all births in the state during the sample month. The sample size of births selected from each of 13 health department regions was determined based on a standard population size formula, including corrections to account for expected exclusions, such as migration out of state. Only official written provider records or data from the computerised Tennessee Immunisation Registry are accepted as valid. **Sample sizes:** **Total n=** 23044 (mean 1663 per year)		immunisations in the public sector occurred, precise numbers are not reported. Among children enrolled in TennCare, the gap between completion rates for white children and black children markedly decreased; black race became a marginal risk factor for not completing the 4:3:1 series (17% vs. 14%; RR, 1.25; 95% CI, 1.04-1.49). After TennCare, enrolled children immunised in the private sector were still slightly more likely to be incomplete, but the difference was not significant (RR, 1.04; 95% CI, 0.93-1.18). **Secondary outcomes:** NR **Attrition details:** NR	delivered. The results for the proportion of children up-to-date following TennCare is only presently graphically. **Evidence gaps and/or recommendations for future research:** Studies exploring broader populations and settings **Source of funding:** NR

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		Intervention n= NR **Control n=** NR **Baseline comparisons:** The proportion of children continuously enrolled in Medicaid increased from 21% for fee-for-service Medicaid (1986-1993 birth cohorts) to 34% under TennCare (1994-1999 birth cohorts) (P<.001). Among children enrolled in fee-for-service Medicaid or TennCare, the proportion of white children increased during the study period (from 41% to 67%), with a corresponding decrease in the proportion of black children (from 59% to 32%). It is not reported if this is significant or not. The proportion of children enrolled in fee-for-service Medicaid or TennCare receiving all of their immunizations in the private sector increased during the study period from 32% for the 1986-1993 birth cohorts to 44% under TennCare (P<.001). Use of private providers for immunizations increased			

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		for each of the first 6 cohorts of children born under TennCare (1994-1999), and 77% of children born in 1999 received at least some of their immunizations in the private sector. A corresponding decrease in the proportion of children receiving immunizations in the public sector occurred. It is not reported whether this was significant or not. **Study sufficiently powered?** NR			

Expanding Access in medical or public health clinical settings

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(Larcher et al. 2001) **Citation:** Overcoming barriers to Hepatitis B immunisation by a dedicated Hepatitis B immunisation service **Aim of study:** To determine the effectiveness of a selective hospital based hepatitis B immunisation programme and the barriers needed to be overcome to obtain a successful outcome. **Study design:** Cohort study **Internal**	**Source population/s:** United Kingdom **Eligible population:** Babies born to hepatitis B infected women (HBsAg positive) identified at booking during universal antenatal screening at Homerton Hospital, Hackney, London. **Selected population:** Babies born to women with hepatitis B identified at booking during universal antenatal screening delivered at Homerton Hospital, Hackney, London during the study period. **Excluded population/s:** Babies born to HBsAg negative women at Homerton Hospital, Hackney, London. **Setting:** Homerton Hospital, Hackney, London. Which in 1992-1993, babies born to ethnic minorities comprised 48% of live births and 31% were black African or Caribbean. **Vaccine:**	**Method of allocation:** NR **Intervention/s description:** The intervention comprised a hospital based immunisation service to vaccinate babies (born to women with hepatitis B) at birth, 1 and 6 months. The immunisation clinic was held in the hospital at the same time as the neonatal follow up clinic, with nursing and reception staff from the special care baby unit (SCBU). All babies who failed to attend one of their vaccinations were notified to their general practitioner, health visitor, and community paediatrician and given the next available appointment. If they failed to attend a second time, hospital based liaison health visitors contacted the family's health visitor and attempted to contact the family themselves to reinforce the need for	**Primary Outcomes** Proportion of babies receiving hepatitis B vaccinations. **Secondary outcomes** Proportion of babies receiving hepatitis B vaccinations compared to a neighbouring area (Tower Hamlets) Effect of residence on uptake Babies lost to follow-up Attendance for routine immunisation (1995 only) **Follow-up periods:** 1, 2, and 3 months **Method of analysis:** NR	**Primary outcomes:** For the study period, 91% of eligible (242/265) infants received three doses of vaccine. **Secondary outcomes:** <u>Proportion of babies receiving hepatitis B vaccinations compared to a neighbouring area (Tower Hamlets)</u> 91% of infants were vaccinated compared to 32% of the neighbouring area (Tower Hamlets) (p <0.01), although 41% of the Tower Hamlets group had been lost to follow up. <u>Effect of residence on uptake</u> 25% of infants moved out of Hackney during the study Compared to non-residents, a higher proportion of those who were residents were vaccinated (190/199) compared to non residents (52/66)	**Limitations identified by author:** None **Limitations identified by review team**: The authors have not described the method used for determination of sample size. The baseline characteristics of participants is limited. **Evidence gaps and/or recommendations for future research:** Studies exploring broader populations and settings **Source of funding:** NR

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validity score: - **Applicability:** B	Hep B	attendance. **Control/comparison/s description:** Compared to a neighbouring area (Tower Hamlets) who did not receive the intervention. **Sample sizes:** Total n= 265 Intervention n= NR Control n= NR **Baseline comparisons:** The two areas are described as being broadly similar with high indices of social deprivation. **Study sufficiently powered?** NR		(p<0.001). <u>Babies lost to follow-up</u> A significant number of those lost to follow-up lived outside Hackney (p<0.001) and a significant proportion were African (p<0.02). <u>Attendance for routine immunisation (1995 only)</u> <u>Hackney residents</u> Uptake of routine immunisations was higher in the hepatitis B eligible infants compared to non-hepatitis B eligible babies for Hackney residents. 3 doses DTP 100% (hepatitis B eligible infants) versus 91% (non-hepatitis B eligible babies) MMR 97% (hepatitis B eligible infants) versus 86% (non-hepatitis B eligible babies) (no p values or CI reported). <u>Non-Hackney residents</u> Uptake of routine immunisations was lower the hepatitis B eligible	

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				infants compared to non-hepatitis B eligible babies for Hackney residents. 3 doses DTP 50% (hepatitis B eligible infants) versus 59% (non-hepatitis B eligible babies) MMR 39% (hepatitis B eligible infants) versus 49% (non-hepatitis B eligible babies) (no p values or CI reported). **Attrition details:** Twenty three (9%) infants were lost to follow up and presumed to have failed to complete a full course of vaccine. Of these one did not receive the vaccine, seven received only one dose, and 15 received two doses.	

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(Mayer, Housemann, & Piepenbrok 1999) **Citation:** Evaluation of a	**Source population/s:** United States. **Eligible population:** The eligible participants were children (average age 1year	**Method of allocation:** NA **Intervention/s description:** The intervention consisted of expanded hours of	**Primary Outcomes:** Immunisation rates of DTP, OPV and MMR after 1year. **Secondary outcomes:**	**Primary outcomes:** Significant increase for DTP-2 (11.3% vs. 30.5%, DTP-3 (11.1% vs. 36.2%), DTP-4 (3.8% vs. 66.5%), OPV-2 (14.9% vs. 31.7%), OPV-3 (11.3%	**Limitations identified by author:** NR **Limitations identified by**

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campaign to improve immunization in a rural head start program **Aim of study:** To evaluate an intervention to improve immunization rates in a high poverty, medically underserved rural area employing a pretest-posttest design. **Study design:** Before and after study **Internal validity score:** - **Applicability:** B	and 11 months) from Head start programme. For the pre-intervention data for 1992-1993 demographic and immunisation records of students in the Head start programme were collected. For the post-intervention data for 1993-1994 all younger siblings of Head start students were collected. **Selected population:** A total of 1149 children were identified from the Head start administrative data. Removal of first-borns and children who had a sibling in the post-intervention sample left 567 children. Immunisation data was available for 551 children (97%). 519 children were identified for the post-prevention sample. Following a removal of children who had a pre-intervention sample, 331 remained. Of these, immunisation records were obtained for 246 (73%). **Excluded population/s:** Not students of the Head start programme.	operation at clinics, with immunisation services beyond traditional business hours, including evenings and/or weekends; opening additional vaccination sites ; modification of appointment policies, with walk-in immunisations provided without a prior formal appointment; and parent outreach and education, with use of outreach workers to reinforce appointments and health communications. **Control/comparison/s description:** NA **Sample sizes:** **Total n=** 551 (pre-intervention) n=246 (post-intervention) **Intervention n= NA** **Control n**= NA **Baseline comparisons:** Yes. The pre and post-intervention group were similar in all respects. Two-	Not relevant to the review **Follow-up periods:** One year. **Method of analysis:** Descriptive statistics.	vs. 66.3%) and MMR (23.8% vs. 61%) after the implementation of the intervention (p<0.001). Non-significant improvements were detected for DTP1 and OPV1 (CI not reported) **Secondary outcomes:** Not relevant to the review **Attrition details:** NR	**review team**: Not reported method used for calculation of sample size. No characteristics are reported for the study setting. **Evidence gaps and/or recommendations for future research:** Studies exploring broader populations and settings **Source of funding:** NR

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	Setting: Head start programmes in Bootheel, Missouri, United States. **Vaccines:** DTP,OPV,MMR	thirds were single parent families. Maternal unemployment was about 80% and a large majority had less than a high school education. **Study sufficiently powered?** NR			

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(Stroffolini & Pasquini 1990) **Citation:** Five years of vaccination campaign against hepatitis B in Italy in infants of hepatitis B surface antigen carrier mothers **Aim of study:** The impact of five years of a vaccination campaign against hepatitis B in	**Source population/s:** Italy **Eligible population:** Newborns of hepatitis B surface antigen (HBsAg) positive mothers. **Selected population:** Newborn babies born to women screened for HBsAg (who were positive) during the third trimester of pregnancy in Italy. **Excluded population/s:** Newborn babies born to hepatitis B surface antigen (HBsAg) negative women. **Setting:** Hospitals in all Italian regions,	**Method of allocation:** NR **Intervention/s description:** The intervention was introduced in 1984. All newborn babies born to HBsAg positive women (screened for HBsAg during the third trimester of pregnancy) regardless of the mother's status of hepatitis Be antigen (HBsAg), were given a single intramuscular injection of hepatitis B immune globulin within 24h after birth and the first dose of hepatitis B vaccine within 7 days of birth.	**Primary Outcomes** Percentage of eligible newborn babies vaccinated against Hepatitis B. **Secondary outcomes:** NR **Follow-up periods:** Annually from 1984 to 1988. **Method of analysis:** Descriptive statistics	**Primary outcomes:** The proportion of eligible babies immunised against hepatitis B increased from 24% in 1984, 39% in 1985, 41% in 1986, 45% in 1997 to 62% in 1988. The increase was significant when compared to baseline (29% in 1984 versus 62% in 1988) ($P < 0.01$). **Secondary outcomes:** NR **Attrition details:** NR	**Limitations identified by author:** The authors have reported that pregnant women who were aware of being HBsAg carriers were more likely to undergo screening than those who were unaware of their HBsAg status; this may have resulted in performance bias in the study. **Limitations identified by review team:**

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infants of hepatitis B surface antigen carrier mothers in increasing the screening and up take of hepatitis B vaccination in Italy. **Study design:** Interrupted Time Series (ITS) **Internal validity score:** - **Applicability:** B	no further information reported. **Vaccine:** Hep B	**Control/comparison/s description:** Before and after data **Sample sizes:** **Total n= NR** **Intervention n= NR** **Control n=NR** **Baseline comparisons:** NR **Study sufficiently powered?** NR			Exact numbers of participants not reported No baseline characteristics of participants reported. The time fame over which the study was conducted may mean that other influences also contributed to the increase in uptake. There are very limited details reported on the intervention, such as precisely what it comprised, who delivered it and in what setting. **Evidence gaps and/or recommendations for future research:** Well designed studies should be conducted in this

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					topic area **Source of funding:** NR

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(Szilagyi et al. 1997) **Citation:** Effect Of 2 Urban Emergency Department Immunization Programs On Childhood Immunization Rates **Aim of study:** To assess the ability of two emergency immunisation programmes to vaccinate children **Study design:**	**Source population/s:** New York City , USA **Eligible population:** Project nurses and emergency department (ED) patients **Selected population:** Project nurses hired and trained specifically for the study working in two urban EDs in New York City, USA. ED patients from two urban hospitals in New York City, USA from whom all vaccinated pre-school children (no ages given) were sampled over a 10 week period between Autumn 1992 and summer 1994 **Excluded population/s:** NR **Setting:**	**Method of allocation:** NR **Intervention/s description:** The intervention comprised: 1. A project nurse identifying preschool-age children 2. The project nurse interviewing parents regarding their immunisation status and other health questions 3. Offering pre-school immunisations without cost 4. Follow up involved review of medical records at primary care and ED **Control/comparison/s description:** NA **Sample sizes:**	**Primary Outcomes** Percentage of patients up to date for immunisations -Vaccinated -Not vaccinated At time points: -first visit -one day later -6 months later **Secondary outcomes** NR **Follow-up periods:** Six months after ED visit **Method of analysis:** Data from the two ED were analysed separately. Percentages	**Primary outcomes:** The numbers of children vaccinated from the two EDs were 106/577 & 129/724 (no further details provided). Of the remaining unvaccinated children 104/471 and 145/595, respectively were assessed after one day and after six months to see if they had received any vaccinations. There are no further details on how is number of children was arrived at or the selection process for this. Thus in total, 210/577 and 274/724 patients assessed one day later and again six months later (including those vaccinated at the ED visit. Assessment included a	**Limitations identified by author:** Immunisation records were provided by parents (portable notes) or medical records from primary care. It is possible immunisations could have occurred at other health care settings and were missed Follow up was not possible in 21% and 28% of cases from each ED thus calculation of immunisation rate could be inaccurate Not an RCT;

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Prospective cohort study **Internal validity score:** + **Applicability:** C	Two ED of hospitals in New York City, USA **Vaccines:** Diphtheria, tetanus, pertussis, Haemophilus influenzae type B, poliovirus, MMR and hepatitis B	**Total n=** 577 and n=724 at each ED respectively **Intervention n=** NR **Control n=** NR 106/577 & 129/724 of the two ED samples were vaccinated Of the remaining unvaccinated patients 104 and 145 respectively were included for follow up. Thus 210 and 274 patients in total were followed up from the two ED The number of project nurses involved is not specified **Baseline comparisons:** Populations were equal in demographics except for the fact that vaccinated children were more likely to have portable medical records **Study sufficiently powered?** NA	calculated and chi square and t-tests were used for comparisons	review of medical records at their primary care and the ED. The primary outcome was the percentage of patients up-to-date for immunisations. The authors found that at the Manhattan ED, one day after the initial ED visit there was a significant increase in the percentage of children up-to-date (75%) compared to at the first visit (64%) ($p< 0.001$), however after 6 months there was no difference in the proportion of patients up-to-date (66%) compared to the first. At the Bronx ED, one day after the initial ED visit there was a significant increase in the percentage of children up-to-date (71%) compared to at the first visit (63%) ($p< 0.05$), after 6 months there were significantly less patients up-to-date (54%) compared to the first visit ($p<0.05$). A comparatively	selection bias as study was voluntary These two ED had previous experience of immunisation programmes and highly motivated staff and therefore probably produced the best result possible **Limitations identified by review team:** None to add **Evidence gaps and/or recommendations for future research:** The authors conclude that in spite of a modest increase in immunisation rate this approach was labour-intensive and therefore not cost-effective. Future research on cost effectiveness

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				large number of eligible children were lost to follow-up (21% at ED1 and 28% at ED2). **Secondary outcomes:** NR **Attrition details:** Outcome assessment was successful in 79% and 72% in each of the ED respectively Reasons for not completing: Primary care provider had never seen child. Immunisations were received out of town Children were placed in foster care Unable to reach parents or obtain medical records	is needed. **Source of funding:** New York State Department of Health

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(Fitzpatrick, Molloy, & Johnson 1997) **Citation:** Community mothers' programme: extension to the travelling community in Ireland **Aim of study:** To see whether the community mothers' programme, using lay volunteer mothers to deliver a childhood development programme could be extended successfully to the travelling community in Ireland.	**Source population/s:** Ireland. **Eligible population:** The eligible participants were all travelling mothers delivering within Dublin or entering the region within four months of delivery over an 18 month period were offered the help and support of a community mother by the family development nurse. **Selected population:** The participants comprised 39 traveller and 127 settled intervention mother/infant pairs (randomised controlled trial (RCT) intervention); settled community mothers; 105 settled control pairs (RCT control). **Excluded population/s:** Non–travelling mothers within Dublin, Ireland. **Setting:** A regional health authority in Dublin, Ireland. **Vaccines:**	**Method of allocation:** NR **Intervention/s description:** The intervention comprised of services of a community mother offered by the family development nurse. Potential community mothers were identified by the local public health nurses and then interviewed by the family development nurse to assess suitability. Once these community mothers were accepted they had to undergo a pre-service training course. Each community mother had to work under the guidance of a family development nurse who served as a resource person, confidante, and monitor, working in partnership with 15-20 community mothers. Each community mother aimed to support 5-15 parents. **Control/comparison/s**	**Primary Outcomes:** Proportion of children who received all three all three of their primary immunisations by their 1st birthday. **Secondary outcomes:** Proportion of children who received DTP by their 1st birthday. **Follow-up periods:** Baseline and 12 months. **Method of analysis:** Descriptive statistics	**Primary outcomes:** 22/39 traveller children (56.4%) versus 67/105 RCT control children (63.8%) versus 108/ 127 RCT intervention children (85.0%) ($p<0.001$) received all three of their primary immunisations by their 1st birthday. **Secondary outcomes:** 55.9% of traveller children 72.7% of the RCT control children versus 79.2 5 of the RCT intervention group had received DTP ($p<0.05$). **Attrition details:** NR	**Limitations identified by author:** NR **Limitations identified by review team:** No formal power calculation used to determine sample size. **Evidence gaps and/or recommendations for future research:** Well-conducted RCT for evaluating the effectiveness of community mothers programme in improving the immunisation uptake among infants. **Source of funding:** NR

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Study design: Prospective cohort study; comparisons were made with results of a previous randomised controlled trial of settled mothers. **Internal validity score:** + **Applicability:** B	Primary immunisation (not specified).	**description:** Only standard support. The standard support was available from their own local public health nurse, consisting of visits at birth, six weeks, and other times as required. All groups received invitations to attend for primary immunisations and for a developmental assessment at nine months. **Sample sizes:** **Total n=** 271 **Intervention n=** 39 (traveller group) **RCT intervention group n=** 127 **Control n=**105 **Baseline comparisons:** Traveller mothers were significantly older than RCT control ($p<0.05$) but not than RCT intervention mothers; they left school at a significantly younger age than settled mothers. Twenty one travellers (53.8%) had left school before the age of 14;			

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		another had never attended school. Significantly more traveller mothers were married. **Study sufficiently powered?** NR			

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(Koniak-Griffin et al. 2003) **Citation:** Nurse visitation for adolescent mothers: two-year infant health and maternal outcomes **Aim of study:** To evaluate the effectiveness of early intervention programme (EIP) of home visitation by public health nurses (PHNs), for improving	**Source population/s:** USA **Eligible population:** **P**regnant adolescents (aged 14–19 years) planning to keep their baby. **Selected population:** Pregnant adolescents (aged 14–19 years), at 26 weeks or less gestation, planning to keep their infant, and had had no prior live births who were recruited from referrals to the county health department. The age range was 14-19 years; the majority were Latina 64%, followed by Non-Hispanic White 19%, African American 11% and other ethnicities 6%.	**Method of allocation:** NR **Intervention/s description:** The intervention (EIP) comprised of Intense home visitation by the public health nurses (PHNs) extending from pregnancy through 1 year postpartum. Approximately 17 prenatal and postnatal home visits, each lasting 1–1/2 to 2 hours were provided to the participants. During these visits, PHNs provided nursing case management, individualized life planning and counselling, health education, social support, and referrals for family planning, child care, and	**Primary Outcomes:** Immunisation rates of infants at 24 months of age. Data on infant immunisations were confirmed by medical records or by review of immunisation cards issued by the county health department or direct care provider, as verified by the evaluator nurse. Immunisations were considered adequate if four or more doses of diphtheria-tetanus-pertussis vaccine, three or more doses of poliovirus vaccine, and one or more	**Primary outcomes:** 77% of infants in the EIP compared to 87% of infants in the comparison group were adequately immunised. (CI and p-values not reported). **Secondary outcomes:** Not relevant to the review. **Attrition details:** Number of participants lost-to-follow-up n= 43. No significant group difference was found in the subject attrition rate between the EIP and TPHNC groups	**Limitations identified by author:** NR **Limitations identified by review team:** Not reported method of randomisation and concealment of allocation. Not reported blind assessment of primary outcome. Confidence Interval and p-value not reported for the results.

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immunisation rates among infants at 24 months of age. **Study design:** RCT **Internal validity score:** + **Applicability:** B	91% were single, 8% married and 1% divorced. 47% were attending high school or were enrolled buy not attending 13%. **Excluded population/s:** Pregnant adolescents who were dependent on narcotics, IV drug users, or had a serious medical or obstetric problem documented in their health referral. **Setting:** Homes in Los Angeles, California, USA. **Vaccines:** DTP, Polio.	mental health services. The EIP group also received four preparation-for-motherhood classes focusing on behaviours to promote health during pregnancy, parent-child communication, and the transition to motherhood. Unique EIP features included demonstration of selected components of the Neonatal Behavioural Assessment Scale (NBAS) by PHNs [18], videotape instruction and feedback to improve parenting behaviours, examination of educational and vocational goals and options, and problem-solving exercises **Control/comparison/s description:** The control group received one or two prenatal home visits by the PHNs, with a focus on assessment and counselling related to prenatal health care (source and adequacy), self-care, childbirth preparation, future educational plans, and well-baby care. During the	doses of measles-containing vaccine were received by 24 months of age, as recommended by the Centres for Disease Control and Prevention (CDC) (1995). **Secondary outcomes:** Not relevant to the review. **Follow-up periods:** 24 months of age. **Method of analysis:** Descriptive statistics.		Not reported intention to treat analysis. **Evidence gaps and/or recommendations for future research:** Studies exploring broader populations and settings **Source of funding:** National institute of Nursing Research (NINR) and the Office of Research on Women's Health.

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		one postpartum home visit, PHNs provided general information about child care, postpartum recovery, maternal and infant nutrition, home safety, and family planning. **Sample sizes:** **Total n=** 102 **Intervention n=** 55 **Control n**=47 The authors have not provided the exact numbers of participants randomised in to each group; they have only provided the number of participants for each group for those who have completed the study. **Baseline comparisons:** Sociodemographic characteristics of groups were compared, no significant differences were found. **Study sufficiently powered?** Formal power calculation used for determination of sample size.			

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
(Koniak-Griffin et al. 2002) **Citation:** Public health nursing care for adolescent mothers: impact on infant health and selected maternal outcomes at 1 year post birth **Aim of study:** To compare effects of an early intervention programme (EIP) of intense home visitation by public health nurses (PHNs) with effects of traditional public health nursing care (TPHN) on infant health and selected maternal outcomes of	**Source population/s:** USA **Eligible population:** Pregnant adolescents (aged 14–19 years) planning to keep their baby. **Selected population:** Pregnant adolescents (aged 14–19 years), at 26 weeks or less gestation, planning to keep their infant, and had had no prior live births who were recruited from referrals to the county health department. The age range was 14-19 years; the majority were Latina 64%, followed by Non-Hispanic White 19%, African American 11% and other ethnicities 6%. 91% were single, 8% married and 1% divorced. 47% were attending high school or were enrolled buy not attending 13%. **Excluded population/s:** Pregnant adolescents who were dependent on narcotics, IV drug users, or had a serious medical or obstetric problem documented in their health referral.	**Method of allocation:** Participants randomised by computer in to experimental (EIP) or control group (TPHN). **Intervention/s description:** The intervention (EIP) comprised of Intense home visitation by the public health nurses (PHNs) extending from pregnancy through 1 year postpartum. Approximately 17 prenatal and postnatal home visits, each lasting 1–1/2 to 2 hours were provided to the participants. During these visits, PHNs provided nursing case management, individualized life planning and counselling, health education, social support, and referrals for family planning, child care, and mental health services. The EIP group also received four preparation-for-motherhood classes focusing on behaviours to promote health during pregnancy, parent-child communication, and the	**Primary Outcomes:** Proportion of infants in each group adequately immunised (2 doses of DTP and 2 doses of OPV by 12 months of age). **Secondary outcomes:** Not relevant to the review. **Follow-up periods:** Baseline, 6 weeks, 6 months and 12 months postpartum. **Method of analysis:** Data from 71% (n = 102) of the enrolled participants (144) who remained in the study through 12 months postpartum were used in all analyses. Intention to treat analysis not used.	**Primary outcomes:** 96% of the EIP children were adequately immunised in comparison to 86% of those receiving TPHN care. The group difference was statistically significant ($\chi 2 = 5.11$, $p < .05$). **Secondary outcomes:** Not relevant to the review. **Attrition details:** Randomised n= 144 Analysed n= 102. No. of drop outs= 42 The drop outs were compared to those who completed the program to 1 year postpartum on the following; ethnicity, socio economic status, martial status, education level, length of gestation, acculturation level and physical and sexual abuse history) and no significant differences were found.	**Limitations identified by author:** Maternal report used to supplement a small portion of missing medical record data (on infant hospitalisations and immunisation status) and the measurement of substance use through self-report rather than urine assays. Both of the above will not help in collection of reliable results. **Limitations identified by review team:** The authors have not have provided exact number of participants randomised to group. Intention to treat analysis not used.

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
adolescent mothers. **Study design:** RCT **Internal validity score:** + **Applicability:** B	**Setting:** Homes in Los Angeles, California, USA. **Vaccines:** DTP, Polio.	transition to motherhood. Unique EIP features included demonstration of selected components of the Neonatal Behavioural Assessment Scale (NBAS) by PHNs [18], videotape instruction and feedback to improve parenting behaviours, examination of educational and vocational goals and options, and problem-solving exercises **Control/comparison/s description:** The control group received one or two prenatal home visits by the PHNs, with a focus on assessment and counselling related to prenatal health care (source and adequacy), self-care, childbirth preparation, future educational plans, and well-baby care. During the one postpartum home visit, PHNs provided general information about child care, postpartum recovery, maternal and infant nutrition, home safety, and family planning**.**			**Evidence gaps and/or recommendations for future research:** Studies exploring broader populations and settings **Source of funding:** National Institute of Nursing Research and the Office of Research on Women's Health.

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
		Sample sizes: **Total n=** 102 **Intervention n=** 55 **Control n=**47 The authors have not provided the exact numbers of participants randomised in to each group; they have only provided the number of participants for each group for those who have completed the study. **Baseline comparisons:** Sociodemographic characteristics of groups were compared, no significant differences were found. **Study sufficiently powered?** Formal power calculation used for determination of sample size.			

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
(Johnson, Howell, & Molloy 1993) **Citation:** Community mothers' programme: randomised controlled trial of non-professional intervention in parenting **Aim of study:** To see whether non-professional volunteer community mothers could deliver a child development programme to disadvantaged first time mothers for children aged up to 1 year**.** **Study design:** RCT **Internal**	**Source population/s:** Ireland **Eligible population:** Women who gave birth 1989 and lived in Dublin. **Selected population:** 262 women from low socio-economic status who gave birth 1989 (during the 6 month study period) for the first time and lived in a defined deprived area of Dublin. **Excluded population/s:** All first time mothers who did not deliver in 1989 and did not live in a defined deprived area of Dublin. **Setting:** A regional health authority in Dublin, Ireland. **Vaccines:** Primary immunisations (not specified)	**Method of allocation:** Randomisation was achieved by preparing 280 cards from a table of random numbers assigning families to the intervention group (odd numbers) or the control group (even numbers). The cards were sealed in consecutively marked envelopes, which were drawn in order as required. The study reports further that when the family development nurse explained the programme, either the help of a community mother was offered or the mother was asked whether she would serve as a control. **Intervention/s description:** All mothers received standard support from the public health nurse, which included, visits at birth and six and at other times as required (not further specified). Those in the intervention group also received the services of a community mother, who was	**Primary Outcomes:** Receiving all 3 primary immunisations by the infants first birthday. **Secondary outcomes:** NA **Follow-up periods:** 1 year **Method of analysis:** Descriptive statistics.	**Primary outcomes:** A higher proportion of the intervention group received all three shots of the primary immunisation 85% versus 65% of the control group: 1.31, 95%CI 1.12 to 1.54: p <0.001. **Secondary outcomes:** NA **Attrition details:** 30 women (and their infants) were lost to follow-up. 15 (six in the intervention group, nine controls) had moved away; 10 (six in the intervention group, four controls) had dropped out; three children (all controls) were taken into protective custody because of child abuse; one mother in the intervention group had died; and one child in the intervention group had spent the whole year in hospital.	**Limitations identified by author:** Lack of blinding of the nurses **who administered the year of year questionnaires.** **Limitations identified by review team**: No intention to treat analysis. Randomisation not truly random. **Evidence gaps and/or recommendations for future research:** Well-designed RCT's. **Source of funding:** Bernard van Leer Foundation, The Hague.

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
validity score: + **Applicability:** B		scheduled to visit monthly during the first year of the child's life to provide support and encouragement to first time parents in rearing their children using the child development programme, (developed at the Early Childhood Development Unit, University of Bristol) developed in which health visitors give parents of young children support and guidance on health and development matters. Parents are regarded as the experts on their own child and are encouraged to solve their own problems in child rearing. Potential community mothers are identified by the local public health nurse and interviewed by a regional family development nurse to assess suitability. Community leaders and self promoting individuals are generally not regarded as suitable. Once accepted, the community mother undergoes four			

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
		weeks of training, during which the concepts of the programme are explained. She also meets other community mothers, and they exchange ideas and explore ways of delivering the programme. After training, each community mother works under the guidance of a family development nurse, who serves as a resource person, confidante, and monitor. Each community mother aims at supporting five to 15 first time parents. **Control/comparison/s description:** Standard support from a local public health nurse, which consisted of visits at birth and six weeks and at other times as required. **Sample sizes:** **Total n=** 262 **Intervention n=** 141 **Control n=**121 **Baseline comparisons:** There were no significant differences between the groups, except for both			

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
		mother's and father's employment status which was higher in the intervention group (p <0.05). **Study sufficiently powered?** NR			

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
(Johnson et al. 2000) **Citation:** Community mothers programme-seven year follow-up of a randomised controlled trial of non professional intervention in parenting. **Aim of study:** To evaluate the community mothers programme in	**Source population/s:** Ireland **Eligible population:** The eligible participants were children 8 years of age. The authors have not provided any information on eligibility criteria and selection process for participants in the study. **Selected population:** A total of 232 children were included in the study with 127 in the intervention group and 105 in the control group in the RCT conducted in1990. The present RCT attempted to follow-up the original cohort 7 years after the original trial and carry out the face-to-face to interview. A total	**Method of allocation:** NR **Intervention/s description:** The community mother's programme used experienced volunteer mothers in disadvantaged areas to give support and encouragement to first-time parents in rearing their children using a child development programme. Potential community mothers were identified by the local public health nurse, and assessed and trained by a family development nurse. Each community mother	**Primary Outcomes:** Immunisation uptake among children after 7 years. **Secondary outcomes:** Not relevant to the review. **Follow-up periods:** 7 years **Method of analysis:** Descriptive statistics.	**Primary outcomes:** In the intervention group 94.7% (36/38) of the children had MMR immunisation compared with the control group (RR 0.95, 95% CI 0.88 to 1.02, p=0.15). Children in the intervention group were more likely to have completed Haemophilus influenzea (RR 1.26, 95% CI 1.06 to 1.51) and polio immunisation (RR 1.19, 95% CI, 1.02 to 1.40) compared to the control group. The entire intervention	**Limitations identified by author:** NR **Limitations identified by review team:** Not reported method used for calculation of sample size. Not reported method of randomisation and concealment of allocation. Not reported blind assessment of

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
improving immunisation uptake among children. **Study design:** RCT **Internal validity score:** + **Applicability:** B	of 77 mothers (38 in the intervention group and 39 in the control group) were located and in included in the study in 1997. **Excluded population/s:** NR **Setting:** Community mothers programme, Dublin, Ireland. **Vaccines:** MMR, Haemophilus Influenzae, Polio, School booster.	supported 5-15 first time parents, whom she visited once a month. **Control/comparison/s description:** No community mothers programme **Sample sizes:** **Total n= 232** **Intervention n=127** **Control n= 105** **Baseline comparisons:** Baseline comparisons made for the two groups for age, mothers employment, mothers marital status and housing, but none of these differences were statistically significant. **Study sufficiently powered?** NR		group received a school booster compared with 94.6% (35/37) of the control group (RR 1.06, 95% CI 0.98 to 1.14, p=0.15). **Secondary outcomes:** Not relevant to the review. **Attrition details:** 32.8% of the original sample randomised were analysed after 7 years. *Analysed* n=77 Intervention group n=38 Control group n=39	primary outcome. Not reported of Intention to treat analysis. **Evidence gaps and/or recommendations for future research:** Studies exploring broader populations and settings **Source of funding:** NR

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
(Johnston et al. 2006) **Citation:** Healthy Steps in an Integrated Delivery System. **Aim of study:** To test the effects of the Healthy Steps for Young Children programme (HS) (which supports parents managing children's developmental and behavioural issues)—with and without a prenatal component—on child health and development, parenting practices, and parental well-being.	**Source population/s:** USA **Eligible population:** The eligible participants were pregnant mothers in the second trimester in one of the five primary care clinics in an integrated delivery system in the Pacific Northwest, USA. The participants were recruited by review of obstetrical records, followed by a letter of invitation, telephone screening, and an enrollment visit with study staff. To be eligible, pregnant women had to be at less than 22 weeks' gestation at study enrollment, younger than 45 years, English speaking, and planning to use a study clinic for paediatric care. Enrollment occurred from July 20, 1998, through September 29, 2000. **Selected population:** A total of 80% of the eligible participants agreed to take part in the study. A total of 439 participants were included in the study.	**Method of allocation:** Individual randomisation was performed centrally, stratified by clinic, and blocked in groups of 4**.** Not reported method of concealment of allocation. **Intervention/s description:** Three clinics received the intervention. Four masters's-level trained Healthy Steps Specialists (HSSs) provided most of the intervention programmes services. Two HSSs had backgrounds in nursing, one in clinical social work and one in mental health practice. All received additional training and ongoing education in early child development and in specific aspects of HS. Key clinicians and other personnel from intervention clinic sites also received intervention-related training. The HSS provided postnatal home visits; developmental advice and parent-initiated	**Primary Outcomes:** Proportion of infants up-to-date at 24 months. **Secondary outcomes:** Not relevant to the review. **Follow-up periods:** When the infants were 30 months old. **Method of analysis:** Intention to treat analysis used.	**Primary outcomes:** At 24 months, more intervention recipients than comparison enrollees were up to date for immunisations (90% vs. 85%; adjusted RR, 1.06 [95% CI, 1.02-1.09]). **Secondary outcomes:** Not relevant to the review. **Attrition details:** Baseline n= 439 Analysed n= 343 Loss to follow up n= 92	**Limitations identified by author:** Significant differences in the demographic composition of nonrespondents in the intervention group compared with the control group and within the randomized treatment groups as well. **Limitations identified by review team:** Not reported method of allocation concealment. Not reported blind assessment of primary outcome. **Evidence gaps and/or recommendations for future research:** Studies exploring broader

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
Study design: Nested RCT **Internal validity score:** + **Applicability:** B	**Excluded population/s:** Participants more than 22 weeks gestation, non- English speaking, more than 45v years of age and not panning to use any of the five study clinics. **Setting:** Five primary care clinics in an integrated delivery system in the Pacific Northwest, USA. **Vaccine**: Not specified	telephone support; developmental assessments, the Reach Out and Read literacy programme, and other risk-based screening services; and parenting classes. **Control/comparison/s description:** Two geographically distant clinics served as comparison sites. Comparison clinic enrollees received the health plan's standard package of well-child paediatric care, outreach, and support services. **Sample sizes:** **Total n=** 439 **Intervention n=** 303 **Control n=** 136 **Baseline comparisons:** NR **Study sufficiently powered?** Formal power calculation used for determination of sample size.			populations and settings **Source of funding:** Kaiser Foundation Health Plan

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
(Kitzman et al. 1997) **Citation:** Effect of prenatal and infancy home visitation by nurses on pregnancy outcomes, childhood injuries, and repeated childbearing **Aim of study:** To test the effect of prenatal and infancy home visits by nurses on pregnancy-induced hypertension, preterm delivery, and low birth weight; on children's injuries, immunisations, mental development	**Source population/s:** USA **Eligible population:** Women (and their babies) born to African-American women at the Regional Medical Centre in Memphis from June 1, 1990, through August 31, 1991. **Selected population:** 1139 consecutive African-American women (and their babies) who gave birth at the Regional Medical Centre in Memphis from June 1, 1990, through August 31, 1991 who were less than 29 weeks gestation, with no previous live births, and who had at least 2 socio demographic risk characteristics (unmarried, <12 years of education, unemployed) and who provided consent to participate in the study. Of the selected population 92% were African American 98% were unmarried 64% were aged 18 or under 85% come from households at or below the federal poverty	**Method of allocation:** Computer generated randomisation. **Intervention/s description:** There were four treatment groups. Women in treatment 1 (n = 166) were provided with free, round-trip, taxicab transportation for scheduled prenatal care appointments; they did not receive any postpartum services or assessments. Women in treatment 2 (n = 515) were provided with the free transportation for scheduled prenatal care appointments plus developmental screening and referral services for the child at 6, 12, and 24 months of age. Women in treatment 3 (n = 230) were provided with the same services as in treatment 1 plus intensive nurse home-visiting services during pregnancy,	**Primary Outcomes:** Completely immunised by 24 months for 4DTP, 3OPV, 1MMR, 1Hib for group 2 compared to group 4. **Secondary outcomes:** Not relevant to the review **Follow-up periods:** 24 months **Method of analysis:** Intention to treat analysis used.	**Primary outcomes:** There was no programme effect on immunisation rates for infants in group 2 (those for received free transportation for scheduled prenatal care appointments plus developmental screening and referral services for the child at 6, 12, and 24 months of age) compared to infants in group 4 (those who received free, round-trip, taxicab transportation for scheduled prenatal care appointments; plus intensive nurse home-visiting services during pregnancy, 1 postpartum visit in the hospital before discharge, and they continued to be visited by nurses through the child's second birthday). No further details reported. **Secondary outcomes:** Not relevant to the review. **Attrition details:**	**Limitations identified by author:** NR **Limitations identified by review team:** Not reported blind assessment of primary outcome. **Evidence gaps and/or recommendations for future research:** Studies exploring broader populations and settings **Source of funding:** National Institute of Nursing Research, the Bureau of maternal and child health, the administration for children and families, the Office of the Assistant

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
and behavioural problems; and on maternal life course. **Study design:** RCT **Internal validity score:** - **Applicability:** C	guidelines **Excluded population/s:** Not attending obstetrical clinic at the Regional Medical Centre in Memphis. **Setting:** Public system of obstetric care in Memphis, Tennessee, USA. **Vaccines**: DTP, OPV, MMR, Hib	1 postpartum visit in the hospital before discharge, and 1 postpartum visit in the home. Women in treatment 4 (n = 228) were provided with the same services as in treatment 3; in addition, they continued to be visited by nurses through the child's second birthday. The experimental home-visiting program was conducted by the Memphis/Shelby County Health Department. Nurses completed a mean of 7 home visits (range: 0–18 visits) during pregnancy and 26 home visits (range: 0–71 visits) during the first 2 years after the birth. They followed detailed visit-by-visit guidelines in their efforts (1) to improve the outcomes of pregnancy by promoting women's healthy prenatal behaviors, (2) to improve the health and development of children by promoting parents' competent care of their children, and (3) to			secretary for Planning and evaluation, the National centre for child abuse and neglect.

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
		enhance parents' life-course development by encouraging parents to plan subsequent pregnancies, complete their education, and find work. The nurses helped families make use of needed health and human services and attempted to involve other family members and friends (particularly the children's fathers and grandmothers) in the pregnancy, birth, and early care of the child. Program protocols were grounded in epidemiologic findings and theories of human ecology, human attachment, and self-efficacy. For evaluation of postnatal outcomes, treatment 2 was compared with treatment 4. Only these 2 groups were assessed after delivery of the child, to limit the cost of the study. **Control/comparison/s description:** See above			

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
		Sample sizes: **Total n=** 1139 **Intervention** Treatment group 1 n=166 Treatment group 2 n=515 Treatment group 3 n=230 Treatment group 3 n=228 **Baseline comparisons:** Yes **Study sufficiently powered?** Yes. Sample size was established from a series of power calculations.			

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
(El-Mohandes et al. 2003) **Citation:** The effect of a parenting education programme on the use of preventive paediatric health care services among low-Income, minority mothers: A	**Source population/s:** USA **Eligible population:** Pregnant women of Washington, DC, receiving inadequate or no prenatal care. **Selected population:** Pregnant women (at least 18 years old) receiving inadequate or no prenatal care, who spoke English, had no history of psychiatric illness, were not incarcerated or otherwise	**Method of allocation:** Block randomisation. **Intervention/s description:** The intervention comprised home-visits, parent-infant developmental play groups (DPG), parent support groups (PSG) and monthly support calls from a PIP (Pride in parenting) family resource specialist. The home visits initially	**Primary Outcomes:** Proportion of infants receiving their first immunisation by 4 months. Proportion of infants receiving their first immunisation by 6 months. Proportion of infants completing their immunisation schedule (3 DTP/ 2	**Primary outcomes:** By 4 months 66.7% of infants in the intervention group and 54.3% of infants in the control group received their first immunisation (1DTP/ 1 polio and 1 Hib) (p=0.0463). At 6 months (49.5% of infants in the intervention group vs. 34.9% in the control group, p=0.0307) received 2 polio	**Limitations identified by author:** NR **Limitations identified by review team:** Concealment of allocation not addressed. Intention to treat analysis not reported.

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
Randomised controlled study **Aim of study:** To determine if a community based intervention programme focusing on parenting education will have an impact on preventive health care utilization behaviours among low-income, minority mothers in Washington,DC. **Study design:** RCT **Internal validity score:** + **Applicability:** C	institutionalised, and were not planning to place their baby for adoption . who were residents of Washington, DC, Recruitment of the participants was from 4 hospitals in Washington, DC. Inadequate care was defined as care initiated in the third trimester, or < 5 prenatal visits. Nearly all mothers were black (98%), never married (90.6%), more than half had completed at least high school education (54%) and were living below poverty line (60.1%)**.** **Excluded population/s:** Mothers were excluded if their infants were delivered before 34 weeks of gestation, weighed below 1500g, or had congenital abnormalities. **Setting:** Home and hospital sites Washington D. C (USA). **Vaccines:** DPT, Oral polio, HIB.	occurred weekly and were conducted by a lay home visitor who had participated in a 9 week training programme. Home visitors followed a standardised curriculum during the visits, including instruction on various parenting health and child care topics that coincided with the age and development of the infant. They also provided health and development information and facilitated parental usage of community health and health service resources. When the infants reached 5 months of age, home visits were interchanged with biweekly group sessions consisting of a 45 minute DPG followed by a 45 minute PSG. Group sessions were conducted at each of the hospital sites and were lead by an experienced infant developmental specialist. **Control/comparison/s description:** Standard social services.	OPV and 3 Hib) by 9 months. Proportion of infants completing their immunisation schedule (3 DTP/ 2 OPV and 3 Hib) by 12 months. **Secondary outcomes:** NR **Follow-up periods:** 4, 8, and 12 months post hospital discharge. **Method of analysis:** Non parametric statistical inferences were applied and StatXact statistical software was used.	vaccinations, infants in the intervention group had also received at least 2 DTP vaccinations (48.6%) compared to 33.7% of the control group, (p=0.0277). 41.1% of infants in the intervention group received at least 2DTP/ 2 polio and 2 Hib compared to control 28.9% of control (P= 0.0556). By 9 months (37.4% of infants in the intervention group vs. 20.8% in the control group, p=0.0143) had a completed primary immunisation schedule. By 9 months infants in the intervention group were found to be more likely to complete their scheduled immunisation (odds ratio=2.2, 95%confidence interval: 1.09-4.53). By 12 months (40.7% of infants in the intervention group vs. 35.1% in the control group, p=0.2797) had a completed primary immunisation schedule.	Not reported blind assessment of primary outcome. Data was only available on 65.4% of the sample at 8 months. **Evidence gaps and/or recommendations for future research:** Studies exploring broader populations and settings **Source of funding:** National Institute of Child Health and Human Development (NICHD) and the National Institutes of Health (NIH) Office of Research on Minority Health**.**

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
		Sample sizes: **Total n=** 286 **Intervention n=** 146 **Control n=** 140 **Baseline comparisons:** Control and intervention groups were not significantly different for with respect to demographic and socio economic differences. **Study sufficiently powered?** NR		**Secondary outcomes:** NR **Attrition details:** Baseline:286 After 4 months: 207 (72.4%) After 8 months: 187 (65.4%) After 12 months: 167 (58.4%). The main causes of attrition were moving out of Washington, DC or placement of infants outside their mothers care.	

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
(Norr et al. 2003) **Citation:** Maternal and Infant Outcomes at One Year for a Nurse-Health Advocate Home Visiting Program Serving African	**Source population/s:** USA **Eligible population:** Pregnant women and their infants, who self identified as African-American or Mexican American in Chicago. **Selected population:** The eligible participants were pregnant mothers and their	**Method of allocation:** NR **Intervention/s description:** The intervention comprised of REACH-Futures programme (Resources, Education and Care in the Home). This programme included home visits by a team of	**Primary Outcomes:** Completion of all recommended immunisations at 12 months. Documented by: mothers report and immunisation card or medical record. **Secondary outcomes:**	**Primary outcomes:** By 12 months of age, 79% of the infants in the study were up to date on all four required immunisation series (76.4% of infants in the intervention group vs. 74.6% in the control group were up-date on immunisation series as documented by the mother or medical record;	**Limitations identified by author:** NR **Limitations identified by review team:** Not reported method of randomisation and allocation concealment.

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
Americans and Mexican Americans **Aim of study:** To evaluate the effects of REACH-Futures programme at 12 months after birth. **Study design:** RCT **Internal validity score:** - **Applicability:** B	infants, who self identified as African-American or Mexican American and were recruited from two prenatal clinics of the University of Illinois at Chicago Medical Centre. All were low-income, inner-city women who lived in community areas with high infant mortality rate. African Americans were more likely to be adolescents (43 vs. 33%) compared to Mexican Americans and were more likely to have graduated from high school (57% vs. 38%) and to be employed or in school (43% vs. 30%). African-Americans were far more likely to be living with their mothers (63% vs. 29%), where as Mexican-Americans were more likely to be living with a male partner (59% vs. 14%). Mexican Americans were significantly more likely to be members of household with at least one current or recent worker (74% vs. 52%). All of these differences between African Americans and Mexican Americans were statistically significant.	trained community residents led by a nurse. The programme had a bilingual team serving Mexican American families and, African American teams serving African Americans. All programme educational materials were available in English and Spanish. Each team had one nurse and two health advocates. Each family was contacted once a month and more often if necessary. The advocate always paid the first visit in the home within 2 weeks after discharge. The nurse accompanied the advocate at 1, 6, and 12 month visits and conducted an infant health and development screening. After 2 months, if mother and infant were doing well telephone calls were substituted for alternate monthly visits. The average participant received around 5 home visits and seven contacts over the first 12 months.	Not relevant to the review **Follow-up periods:** 12 months **Method of analysis:** Descriptive statistics.	83.2% of infants of in the intervention group vs. 79.3% in the control group were up-to date on immunisation series as reported by the mother; 61.4% of infants in the intervention group vs. 48.6% in the control group were up-date on immunisation series as documented from the mother's interview) (CI and p-value not reported). Mexican American infants were significantly more likely to be fully immunised than African American infants. There were no differences in the proportion of infants fully immunised at 1 year for the REACH-Futures and control groups for African Americans. Among Mexican Americans, the control group had a higher immunisation rate than the REACH-Futures group. **Secondary outcomes:** Not relevant to the review.	Not reported method used for calculation of sample size. The authors have not reported the exact number of participants randomised in to intervention and control group. Not reported blind assessment of primary outcome. CI and p-value not reported. Intention to treat analysis not used. **Evidence gaps and/or recommendations for future research:** Well designed studies should be conducted in this topic area **Source of**

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
	Excluded population/s: Not attending the two prenatal clinics in the University of Illinois at Chicago Medical Centre. **Setting:** Homes in Chicago, USA. **Vaccines:** Not specified.	**Control/comparison/s description:** No REACH-Futures intervention. **Sample sizes:** **Total n=** 588 **Intervention n=** NR **Control n=** NR The authors have not reported the exact number of participants randomised. **Baseline comparisons:** NR **Study sufficiently powered?** NR		**Attrition details:** At 12 months, 81% of the sample remained in the study. A total of 477 completed the study (258 in the intervention group and 219 in the control group).	**funding:** The agency for Health Care and Policy Research, the National Centre for Nursing Research and the Dean's Fund, College of Nursing, University of Illinois at Chicago.

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
(O'Sullivan & Jacobsen 1992) **Citation:** A randomized trial of a health care programme for first-time adolescent mothers and	**Source population/s:** USA **Eligible population:** Adolescent mothers who gave birth at a large urban teaching hospital in the eastern United States	**Method of allocation:** NR **Intervention/s description:** Both groups received routine care which comprised well-baby visits at the hospital at 2 weeks, 2 months, 4 months, 6 months, 9 months, 12 months, 15 months and 18 months as recommended by the American Academy of Paediatrics. New copies of immunisation cards were given to	**Primary Outcomes:** Immunisation up-take after 18 months. **Secondary outcomes:** NR **Follow-up periods:** 18 months. **Method of analysis:**	**Primary outcomes:** 33% of the infants in the intervention group (37 /113) compared to 18% of the infants in the control group were fully immunised (20/111) ($p<0.02$). **Secondary outcomes:** Not relevant to the review	**Limitations identified by author:** NR **Limitations identified by review team:** Not reported method of randomisation and allocation

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
their infants **Aim of study:** To test the effectiveness of a special healthcare programme for adolescent mothers and their infants in improving the immunisation up-take. **Study design:** RCT **Internal validity score:** - **Applicability:** C	**Selected population:** Black adolescent first time mothers (aged 17 years or under) who gave birth at a large urban teaching hospital in the eastern United States. **Excluded population/s:** Mothers who intended to place their children for adoption **Setting:** Urban teaching hospital in the eastern United States. **Vaccines:** not specified.	mothers if they had lost or forgotten the cards The intervention comprised a teen baby clinic in the hospital and directed by a master's prepared nurse practitioner. The programme focussed on up-to-date immunisations for the infant. Reminder phone calls and letters were used for 6 weeks after a missed programme appointment, at the 2-week visit and for 8 weeks after a missed appointment at subsequent visits. Mother's were charged $2.00 if record card's were lost, but required at non-visits **Control/comparison/s description:** Routine care only. **Sample sizes:** **Total** n= 243 **Intervention** n=120 **Control** n= 123 **Baseline comparisons:** There were no statistically significant differences between the intervention and the control group in maternal age, length of prenatal care, whether or not the adolescent had a previous pregnancy and complications of the mother or infant at delivery. **Study sufficiently powered?** NR	Chi-squared analysis	**Attrition details:** 224 of the 243 randomised completed the study. *Analysed:* n=224 intervention group n= 113 Control group n=111 Loss to follow-up n= 13 No reasons for loss to follow-up reported.	concealment. Not reported method used for determination of sample size. Not reported on blind outcome assessment. Intention to treat analysis not used. Charging control mothers for lost immunisation cards may bias findings No demographic characteristics reported. **Evidence gaps and/or recommendations for future research:** Well designed studies should be conducted in this topic area **Source of funding:**

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
					Robert Wood Johnson Foundation

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
(Steele & O'Keefe 2001) **Citation:** A Program Description of Health Care Interventions for Homeless Teenagers **Aim of study:** To determine the effectiveness of a broad-spectrum health intervention program for homeless and runaway youth. **Study design:** Cohort study **Internal validity score:**	**Source population/s:** USA **Eligible population:** Homeless and runaway youth in New Orleans. **Selected population:** All new homeless and runaway youth who were residents between June 1, 1999 and July 31, 1999 at Covenant House, New Orleans. **Excluded population/s:** NR **Setting:** Covenant House New Orleans a residential comprehensive care centre for homeless and runaway youth aged 16-21 years and their children.	**Method of allocation:** NR **Intervention/s description:** The intervention called, 'Bright Futures' comprised diagnosis, treatment, and counseling for drug use, sexually transmitted diseases (STDs), other health issues and education. Efforts were made to obtain immunisation status from childhood healthcare providers but as these were unavailable immunisation status relied upon individuals. If there was any uncertainty about hepatitis B status a complete 3 dose series was planned.	**Primary Outcomes:** Completion of immunisations at 9/12 follow-up according to medical records. **Secondary outcomes:** NR **Follow-up periods:** 9 months **Method of analysis:** Descriptive statistics	**Primary outcomes:** Completion of the 3 dose hepatitis B series increased from 12% to 59% (no CI or p values reported) **Secondary outcomes:** NR **Attrition details:** NR	**Limitations identified by author:** Completion of the hepatitis B series was difficult because of 6/12 time period required. **Limitations identified by review team:** Baseline demographics not specific. The numbers of those providing data for follow-up not clearly reported. Attrition details not reported.

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
+ **Applicability:** B	**Vaccine:** Hep B	**Control/comparison/s description:** Before and after data **Sample sizes:** **Total n=** 106 **Intervention n=** 106 **Control n=** NA **Baseline comparisons:** 74 females/ 32 males **Study sufficiently powered?** NR			The cohort were voluntary residents of the facility. Precise numbers are not provided only percentages. No CI or p values reported **Evidence gaps and/or recommendations for future research:** Studies exploring broader populations and settings **Source of funding:** Pfizer, Inc and a Freedom Foundation Award

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
(Taylor, Davis, & Kemper 1997) **Citation:** Health care utilisation and health status in high-risk children randomised to receive group or individual well child care **Aim of study:** To determine if health care utilisation and health status among high-risk children is modified by the use of group well child care (GWCC) as compared with traditional one-to-one individual well child care (IWCC).	**Source population/s:** USA **Eligible population:** Infants and their mothers at two urban paediatric clinics at the University of Washington. **Selected population:** High risk infants (aged < 4 months) and their mothers at two urban paediatric clinics at the University of Washington. High risk infants were defined as infants whose mothers had at least one of the following risk factors: single marital status, education level less than completion of high school, participation in Medicaid (as a proxy of poverty), age less than 20 years at delivery, previous substance abuse, or history of abuse as a child. **Excluded population/s:** Children were excluded if their parents were non-English speaking, the primary care giver was not a biological parent, an older sibling received primary care from another provider, or there was a serious ongoing	**Method of allocation:** NR **Intervention/s description:** There were two treatment groups and infant were ramdomised to either by two study nurse practitioners. Both groups received health supervision visits at 4, 5, 6, 8, 10, 12 and 15 months of age and comprised a study nurse practitioner leading discussion on a predetermined curriculum of topics, focused on age appropriate child rearing issues and a brief physical either before or after each session. One group individually administered well child care (IWCC) (n=109) received the discussions on a one-to-one basis. A second group, group administered well child care (GWCC) received the discussions as part of a group (with other infants born with 2 months of each other). **Control/comparison/s**	**Primary Outcomes:** Up-to-date for vaccinations at 12 months defined as receiving 3 DTP/DT, 2 OPV/IPV, 3 HepB and 3 Hib. **Secondary outcomes:** Up-to-date for vaccinations at 12 months defined as receiving 3 DTP/DT, 2 OPV/IPV. **Follow-up periods:** 11 months **Method of analysis:** Chi squared test	**Primary outcomes:** 67% of the GWCC groups compared to 73% of the IWCC group received were up-to-date (had received 3 DTP/DT, 2 OPV/IPV, 3 HepB and 3 Hib by their 1st birthday) (p = 0.35). **Secondary outcomes:** 84.5% of the GWCC groups compared to 87.0% of the IWCC group received were up-to-date (had received 3 DTP/DT and 2 OPV/IPV by their 1st birthday) (p = 0.61). **Attrition details:** Data for 17 infants was not included the immunisation analysis, 3 infants were removed form their parents due to abuse or neglect and 7 parents withdrew from the study after signing consent to participate, and another 7 families moved county before the infant was aged 6 months.	**Limitations identified by author:** NR **Limitations identified by review team:** The authors have not reported the method of randomisation and concealment of allocation. Not reported of method used for calculation of sample size. Not reported blind assessment of primary outcome. **Evidence gaps and/or recommendations for future research:** Studies exploring broader populations and settings

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
Study design: RCT **Internal validity score:** + **Applicability:** B	medical condition. **Setting:** Two urban, University paediatric clinics in Seattle, Washington, USA. **Vaccines:** DTP/DT,OPV/IPV,Hib, Hep B	**description:** See above **Sample sizes:** **Total n=** 220 **Intervention n=** 111 **Control n=** 109 **Baseline comparisons:** Yes **Study sufficiently powered?** NR			**Source of funding:** Centre for the future of children at the David and Lucile Packard Foundation, and the Stuart Foundation.

Home visits

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
(Bartu et al. 2006) **Citation:** Postnatal home visiting for illicit drug-using mothers and their infants: A randomised controlled trial **Aim of study:** To investigate the effect of post natal home visiting on immunisation. **Study design:** RCT **Internal validity score:** ++ **Applicability:** B	**Source population/s:** Australia **Eligible population:** The eligible participants were illicit drug using mothers in Perth, Australia. Women were recruited at the Antenatal Chemical Dependency Clinic (ACDC) at King Edward Memorial Hospital (KEMH). Those included were illicit drug users and English speaking so that informed, written consent could be given. Recruitment commenced in April 2000 and the six-month follow ups ceased in April 2003. The women were recruited at approximately 35–40 weeks gestation by experienced research midwives and randomised after delivery to either the intervention group or the control group. **Selected population:** A total of 311 women were assessed for eligibility, 115 (37%) did not meet the inclusion criteria (very preterm infant, adolescent mother, in	**Method of allocation:** Randomisation was conducted using opaque sealed envelopes. **Intervention/s description:** The intervention comprised of home visitation by the research mid-wife at weeks one, two and four, then monthly until six months post-partum. Each visit lasted from 1 to 2 h. Any difficulties encountered by the mother were addressed at each visit. Immunisation was discussed during the home –visits. The intervention group received eight home visits. At the last contact, mothers in both groups received $A20 for their time for each home visit. At recruitment they were unaware that they would be paid for this, hence it was not an inducement for involvement in the study. **Control/comparison/s description:**	**Primary Outcomes:** Immunisation status after 2, 4, 6 months post partum **Secondary outcomes:** Not relevant to the review. **Follow-up periods:** 2, 4, 6 months post partum. **Method of analysis:** Analysis was performed on an intention-to-treat basis	**Primary outcomes:** No significant differences were detected in immunisations at two months and four months (P = 0.757 and P = 0.477, respectively) or six months post-partum (P = 0.283). **Secondary outcomes:** Not relevant to the review. **Attrition details:** Four women were lost to follow up in the intervention and nine in the control group. There were two deaths from sudden infant death syndrome (SIDS), one in each arm of the study. The baby in the control group was born to amphetamine-using parents and died 12 days post-partum. The mother of the other SIDS baby (in the intervention group) was on methadone. This child died at 11 weeks. The parents of both infants were referred for	**Limitations identified by author:** NR **Limitations identified by review team:** Well conducted and reported RCT. **Evidence gaps and/or recommendations for future research:** Studies exploring broader populations and settings **Source of funding:** Healthways no. 8027

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
	jail, foetal death in utero, relocation outside metropolitan area). A further 32 (10.1%) refused to participate and 12 (3.9%) were missed (i.e. delivered over the weekend and discharged before Monday). One hundred and fifty-two (49%) women were randomised (76 each in intervention and control group). **Excluded population/s:** Very preterm infant, adolescent mother, in jail, foetal death in utero, and relocation outside metropolitan area. **Setting:** Homes in Perth, Australia. **Vaccines:** Not specified.	The control group had a telephone contact at two months and a home visit at six months. **Sample sizes:** **Total n= 152** **Intervention n=76** **Control n=76** **Baseline comparisons:** The maternal age was similar in each group, the median and ranges being 25 (18–41) in the CG and 27 (17–39) years in the HVG (P = 0.215). Almost all were of Caucasian origin and over half in each group had some high school education. In the CG, 51% were unemployed and 41% in the HVG. A small proportion of each group (12% CG; 15% HVG, P = 0.811) had worked in the sex industry. Approximately 60% in each group had a partner. Over two-thirds in each group had an income of less than $A20 000 in the previous year. In the CG, 59% of the partners were		psychological counselling.	

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
		illicit drug users compared with 75% in the HVG (P = 0.099) **Study sufficiently powered?** Formal power calculation used for determination of sample size			

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
(Bond, Nolan, & Lester 1998) **Citation:** Home vaccination for children behind in their immunisation schedule: a randomised controlled trial **Aim of study:** To ascertain the effectiveness of a home vaccination service for children behind in their	**Source population/s:** Australia. **Eligible population:** Children living in north-west metropolitan Melbourne, Australia. **Selected population:** Children living in 10 local council areas in north-west metropolitan Melbourne (defined by 56 postcode zones) who were either born January 1996 and 90 days late for their third diphtheria-tetanus-pertussis/poliomyelitis/Haemophilus influenzae type B vaccination (DTP/OPV/Hib; 1st milestone), or born June 1995 and 120 days late for their measles-mumps-rubella vaccination (MMR; 2nd milestone). **Excluded population/s:**	**Method of allocation:** Children were allocated at random (by computer) to the intervention or the control group before any contact with the parents was made. **Intervention/s description:** The intervention comprised making contact with the intervention group by letter, then by telephone one to three weeks after randomisation to later to verify vaccination status, to organise an appointment, and to administer a pre-vaccination health check. This health check was to	**Primary Outcomes:** Proportion of children completing primary vaccinations (DPT/OPV/Hib or MMR). Proportion of children completing DPT/OPV/Hib. Proportion of children completing MMR. **Secondary outcomes:** Not relevant to the review. **Follow-up periods:** The intervention	**Primary outcomes:** 46 (57%) of the children in the intervention group and 24 (27%) of the children in the control group received either DTP/OPV/Hib or MMR (risk ratio [RR], 2.08; 95% CI, 1.4-3.1; P < 0.001). 18/32 (56.3%) of the children in the intervention group and 12/35 (33.3%) of the children in the control group received DTP/OPV/Hib (risk ratio [RR], 1.69; 95% CI, 0.97 to 2.9; P < 0.057). 28/49 (57.1%) of the	**Limitations identified by author:** Limitations of this study arise from the need to randomise the population sample before verification of immunisation status. This has the potential to introduce bias because of the possibility of differences in response between the intervention and control groups. Another limitation was the number of

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
vaccination schedule. **Study design:** RCT **Internal validity score:** ++ **Applicability:** B	Children not living in 10 local council areas in north-west metropolitan Melbourne (defined by 56 postcode zones) and overdue for the specific vaccinations. **Setting:** Melbourne, Australia. **Vaccines**: DPT/OPV/Hib , MMR	ensure that the child did not require special medical attention and could be vaccinated at home. If no telephone contact could be made, two follow-up letters were sent. As local councils and maternal and child health nurses provide a substantial number of childhood vaccinations in Victoria and maintain vaccination records, we checked these (possible) providers for vaccination details if parents could not be contacted. Children were confirmed as either overdue for vaccination or up to date with vaccination if parents, the local council or the maternal and child health nurse provided a record of the vaccination. A nurse administered vaccination in the child's home at a time convenient to the parents. Siblings were also vaccinated if they were due for vaccination. The nurse providing the vaccination had completed	lasted 6 weeks, but the precise follow-up date is not reported. **Method of analysis:** Descriptive statistics.	children in the intervention group and 12/52 (23.1%) of the children in the control group received MMR (risk ratio [RR], 2.48; 95% CI, 1.43 to 4.3; P < 0.001). **Secondary outcomes:** Not relevant to the review. **Attrition details:** NR	children in each group with whom no contact was made. However, the authors state that these limitations are unlikely to have caused substantial bias. **Limitations identified by review team:** Method of allocation not reported. Socio-demographics of children's parents not reported. **Evidence gaps and/or recommendations for future research:** Studies exploring broader populations and settings

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
		a standard Victorian Government Department of Human Services immunisation course. A resuscitation kit (including adrenalin) was taken on each home visit, and the cold chain was maintained by transporting vaccines in a temperature-monitored car refrigerator. Before vaccination, the nurse administered a pre-vaccination health checklist to confirm the child's medical history, as obtained during the initial telephone contact, and to assess the child's health on the day of vaccination. Vaccines that were due were verified from the parent-held Child Health Record. The child's temperature was taken if he or she was hot or appeared unwell (a temperature > 38.58c precluded vaccination). Paracetamol was offered to all children before vaccination. The nurse remained with the family for more than 20 minutes			**Source of funding:** National Health and Medical Research Council (NHMRC) project grant number HS371

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
		after vaccination. The visits included time for parents to complete questionnaires about immunisation service use, reasons for the delay in vaccination, education level, family size and whether the family had a Health Care Card. (A Health Care Card is a Federal Government card available to low income families, including those receiving government pensions, to obtain concessions for health and medical expenses; ie, it is an indicator of disadvantage or poverty.) The intervention period comprised six weeks from November 1996. **Control/comparison/s description:** No home vaccination service, however, two months after the intervention period, and based on updated information from the Australian Childhood			

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
		Immunisation Register, letters were sent to parents of control children for whom neither the Register nor local councils had recorded a third DTP/OPV/Hib or an MMR vaccination. Telephone calls were made to verify vaccination status and to offer, vaccination at the Royal Children's Hospital. Parents of control children were also informed of local vaccination services offered by the maternal and child health nurse or of the schedules of mobile vaccination vans provided by local councils. **Sample sizes:** **Total n=** 169 **Intervention n=** 81 **Control n=**88 **Baseline comparisons:** NR **Study sufficiently powered?** The authors have reported that sample size was estimated assuming that			

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
		35% of intervention children would accept vaccination and 6% of control children would be immunised.			

Vaccination programmes to schools

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
(Brabin et al. 2008) **Citation:** Uptake of first two doses of human papillomavirus vaccine by adolescent schoolgirls in Manchester: prospective cohort study **Aim of study:** To assess feasibility and acceptability of delivering a human papillomavirus (HPV) vaccine to adolescent girls**.** **Study design:** Prospective cohort study **Internal validity score:** (+)	**Source population/s:** Populations of ten primary care trusts in Greater Manchester, UK. Population demographics not described. **Eligible population:** Girls in attending school (year 8) from two primary care trusts in Greater Manchester. **Selected population:** 2817 girls in year 8 at 36 secondary schools in two primary care trusts in Greater Manchester, UK that agreed to participate. **Excluded population/s:** NR **Setting:** Set in 36 secondary schools in two primary care trusts in Greater Manchester, UK.	**Method of allocation:** NR **Intervention/s description:** Each trust was responsible for delivering the vaccine in its catchment area and at 0, 1 and 6 months. Filers that summarised the content of an educational film were distributed to parents, parent's evenings were organised, and a slip was distributed with indications for refusal for parents to complete, letters and reminders sent by post with a prepaid envelope for reply. Rescheduled visits were offered for missed appointments. The intervention was delivered in schools and through contact with parents. **Control/comparison/s description:** NR **Sample sizes:**	**Primary Outcomes:** Vaccine uptake of the first and second doses of HPV. **Secondary outcomes:** School type, ethnic composition and entitlement to free schools meals. **Follow-up periods:** Vaccine uptake for the first (0 months) and second (1 months) doses. Precise follow-up periods are not given. **Method of analysis:** NR	**Primary outcomes:** First dose 1989 (70.6%) received the first dose, including 1665 (59.1%) on schedule and 324 (11.5%) at a later date. Of those that were unvaccinated 29 (1.0%) had consented to vaccination. Second dose 1930 girls (68.5%) received the second dose, including 1474 (52.3) on schedule and 456 (16.2%) at a later date. 59 girls (2.1%) missed the second dose. **Secondary outcomes:** 571 provided no response to vaccination and 228 refused vaccination. Uptake was reported to be significantly lower in schools with a higher proportion of ethnic minority girls (P<0.001 for trend) and in girls entitled to free school lunches (p=	**Limitations identified by author:** Data limitations due to new vaccine. **Limitations identified by review team:** Limited demographic information provided on population. Limited information on the intervention including what was delivered, by whom, when/ where, how often and for how long. This intervention is linked with the delivery of an educational film that is not described here. Precise follow-up periods that

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
Applicability: B		**Total n=** 2817 **Intervention n=** 2817 **Control n=** NA **Baseline comparisons:** NR **Study sufficiently powered?** NR		0.029 for trend). **Attrition details:** NR	include the opportunity for catch-up are not indicated. **Evidence gaps and/or recommendations for future research:** Studies exploring broader populations and settings **Source of funding:** Funding received by the University of Manchester, vaccine delivery was the responsibility of the primary care trusts.

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
(Koniak-Griffin, Verzemnieks, Anderson, Brecht, Lesser, Kim, & Turner-Pluta 2003)	**Source population/s:** USA **Eligible population:** Pregnant adolescents (aged 14–19 years) planning to keep their baby.	**Method of allocation:** NR **Intervention/s description:** The intervention (EIP) comprised of Intense home visitation by the public	**Primary Outcomes:** Immunisation rates of infants at 24 months of age. Data on infant immunisations were confirmed by medical	**Primary outcomes:** 77% of infants in the EIP compared to 87% of infants in the comparison group were adequately immunised. (CI and p-values not reported).	**Limitations identified by author:** NR **Limitations identified by review team:**

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
Citation: Nurse visitation for adolescent mothers: two-year infant health and maternal outcomes **Aim of study:** To evaluate the effectiveness of early intervention programme (EIP) of home visitation by public health nurses (PHNs), for improving immunisation rates among infants at 24 months of age. **Study design:** RCT **Internal validity score:** + **Applicability:**	**Selected population:** Pregnant adolescents (aged 14–19 years), at 26 weeks or less gestation, planning to keep their infant, and had had no prior live births who were recruited from referrals to the county health department. The age range was 14-19 years; the majority were Latina 64%, followed by Non-Hispanic White 19%, African American 11% and other ethnicities 6%. 91% were single, 8% married and 1% divorced. 47% were attending high school or were enrolled buy not attending 13%. **Excluded population/s:** Pregnant adolescents who were dependent on narcotics, IV drug users, or had a serious medical or obstetric problem documented in their health referral. **Setting:** Homes in Los Angeles, California, USA. **Vaccines**: DTP, Polio.	health nurses (PHNs) extending from pregnancy through 1 year postpartum. Approximately 17 prenatal and postnatal home visits, each lasting 1–1/2 to 2 hours were provided to the participants. During these visits, PHNs provided nursing case management, individualized life planning and counselling, health education, social support, and referrals for family planning, child care, and mental health services. The EIP group also received four preparation-for-motherhood classes focusing on behaviours to promote health during pregnancy, parent-child communication, and the transition to motherhood. Unique EIP features included demonstration of selected components of the Neonatal Behavioural Assessment Scale (NBAS) by PHNs [18], videotape instruction and feedback to improve parenting behaviours, examination of educational and vocational goals and options, and	records or by review of immunisation cards issued by the county health department or direct care provider, as verified by the evaluator nurse. Immunisations were considered adequate if four or more doses of diphtheria-tetanus-pertussis vaccine, three or more doses of poliovirus vaccine, and one or more doses of measles-containing vaccine were received by 24 months of age, as recommended by the Centres for Disease Control and Prevention (CDC) (1995). **Secondary outcomes:** Not relevant to the review. **Follow-up periods:** 24 months of age. **Method of analysis:** Descriptive statistics.	**Secondary outcomes:** Not relevant to the review. **Attrition details:** Number of participants lost-to-follow-up n= 43. No significant group difference was found in the subject attrition rate between the EIP and TPHNC groups	Not reported method of randomisation and concealment of allocation. Not reported blind assessment of primary outcome. Confidence Interval and p-value not reported for the results. Not reported intention to treat analysis. **Evidence gaps and/or recommendations for future research:** Studies exploring broader populations and settings **Source of funding:** National institute of Nursing Research (NINR) and the Office of Research on Women's Health.

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
B		problem-solving exercises **Control/comparison/s description:** The control group received one or two prenatal home visits by the PHNs, with a focus on assessment and counselling related to prenatal health care (source and adequacy), self-care, childbirth preparation, future educational plans, and well-baby care. During the one postpartum home visit, PHNs provided general information about child care, postpartum recovery, maternal and infant nutrition, home safety, and family planning**.** **Sample sizes:** **Total n=** 102 **Intervention n=** 55 **Control n**=47 The authors have not provided the exact numbers of participants randomised in to each group; they have only provided the number of participants for each group for those who have			

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
		completed the study. **Baseline comparisons:** Sociodemographic characteristics of groups were compared, no significant differences were found. **Study sufficiently powered?** Formal power calculation used for determination of sample size.			

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
(Guay et al. 2003) **Citation:** Effectiveness and Cost Comparison of Two Strategies For Hepatitis B Vaccination of Schoolchildren **Aim of study:** To compare the effectiveness and costs of school-based and clinic-based programmes in Quebec, Canada.	**Source population/s:** Quebec, Canada **Eligible population:** Grade 4 pupils in Monteregie, Canada. **Selected population:** Grade 4 pupils at Local Community Service Centres (CLSC) in four territories in Monteregie. **Excluded population/s:** NR **Setting:** Monteregie, Canada	**Method of allocation:** NR **Intervention/s description:** (S- CLSC) Vaccination offered at school during school hours. Parents contacted via letters send with information about the hepatitis B programme and consent forms. Children not returning consent forms were followed-up by the school nurse calling parents. No hepatitis B was provided by physicians in these	**Primary Outcomes:** The proportion of children receiving three doses of the hepatitis B vaccine. **Secondary outcomes:** NR **Follow-up periods:** Survey data for 1997-1998 school year. **Method of analysis:** Descriptive statistics.	**Primary outcomes:** 772/1054 (73% of pupils were vaccinated in the region using C-CLSC compared with 92%, 93% and 95% of the school based vaccination programme cohort vaccinated. **Secondary outcomes:** NR **Attrition details:** NR	**Limitations identified by author:** NR **Limitations identified by review team:** Difficult to generalise results as limited baseline information provided. No information about were data was obtained.

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
Study design: Cohort study **Internal validity score:** **-** **Applicability:** C	**Vaccine:** Hep B	regions. **Control/comparison/s description:** (C- CLSC)Vaccination offered by appointment a three different times for each dose, two on Saturdays between 9 and 4 pm at one community site and one on Wednesday nights between 4 and 9pm at another community site. Parents were contracted via letters form school and children had to be accompanied with an adult at the time of vaccination. Consent was obtained during the first appointment, parents of children not receiving eh first dose, missed an appointment were contacted for catch-up recall was also done before clinics. **Sample sizes:** Total n= 4487 Intervention group 1 n= 1441 (24 schools) Intervention group 2 n= 1211(15 schools)			Limited intervention details provided. **Evidence gaps and/or recommendations for future research:** Well designed studies should be conducted in this topic area **Source of funding:** NR

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
		Intervention group 3 n=781 (16 schools) Control n= 1054 (18 schools) **Baseline comparisons:** School based (S-CLSC) and community based (CLSC) were compared in terms of percentage of population with low incomes, number of primary schools, number of grade 4 pupils. **Study sufficiently powered?** NR			

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
(Skinner et al. 2000) **Citation:** Randomised controlled trial of an educational strategy to increase school-based adolescent hepatitis B vaccination **Aim of study:** To evaluate a specifically designed	**Source population/s:** Melbourne, Australia **Eligible population:** Pupils in year 7 (UK equivalent) at Melbourne metropolitan secondary schools randomly selected from the metropolitan region of Melbourne to intervention (66 schools or 7,588 students) or control groups (69 schools or 9,823 students).	**Method of allocation:** Cluster randomisation by school to intervention and control groups **Intervention/s description:** A hepatitis B education/ promotion kit was developed after consultation with educational authority, local state government representatives. It was	**Primary Outcomes:** Mean school vaccination uptake for all 3 doses of hepatitis B vaccination. **Secondary outcomes:** <u>Implementation evaluation</u> The number of items taught by teachers (from a possible 12)	**Primary outcomes:** The difference in uptake of the first dose was 79.2% intervention schools versus 80.7% (-1.5% [CI -5.5 to 2.4%, p = 0.46]). The difference in uptake of the second dose was 77.3% intervention schools versus 78.9% (-1.5% [CI -5.5 to 2.4%, p = 0.44]).	**Limitations identified by author:** 155 of student did not return consent forms and this may have indicated that they were already vaccinated, intended to be vaccinated by private providers or simply lost their forms.

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
hepatitis B education/promotion curriculum package as part of a successful hepatitis B vaccination delivery system to adolescents. **Study design:** RCT **Internal validity score:** + **Applicability:** B	**Selected population:** Pupils in year 7 (UK equivalent) Schools were randomly selected from the metropolitan region of Melbourne to intervention (66 schools or 7,588 students) or control groups (69 schools or 9,823 students) who agreeed to participate 82% (NB numbers in paper do not add up). 24 reoplacemetn schools were recuirted. **Excluded population/s:** Schools with enrolment numbers under 25 Catholic schools due to programming reasons Schools with immunisation dates in the in the first month of the school year Schools where school based immunisation was not offered by the local council **Setting:** Metropolitan Melbourne secondary schools **Vaccine:** Hep B	delivered by health and physical education teachers, although could be taught by English or science teachers and this was encouraged. It was delivered to all year 7 pupils in the weeks leading up to the first immunisation. It comprised 4 lessens. There was a resource fact sheet and assessment, a video and questions designed to engage young people, a small group discussion and an activity to locate resource information on the internet. Parents received a 'homework assignment' and a student newsletter and articles to the local press were composed. Posters were created for display around the whole school. A chart monitoring return of consent cards was on display in classrooms. Reminder stickers were given for student diaries to remind pupils and parents when the immunisations	in the intervention schools <u>Impact evaluation</u> Student knowledge gain and change in attitudes about Hepatitis B before and after the intervention. **Follow-up periods:** Not clearly reported **Method of analysis:** Descriptive statistics, two-sided t-test.	The difference in uptake of the third dose was 73.8% intervention schools versus 75.6% (-1.7% [CI -5.8 to 2.3%, p = 0.39]). **Secondary outcomes:** <u>Implementation evaluation</u> 48 (73%) of schools returned questionnaires. The mean implementation score was 6.8 (SD 2.5, range 0-12). Schools were then categorised as low, medium and high implementation schools based on this score. Immunisation rates increased by between 4-10% between low and high implementation schools for all 3 doses, this was not statistically significant. <u>Impact evaluation</u> Participation rate was 68%. Intervention students had a mean pre-post	Generalisability as Catholic schools did not participate and schools with vaccination dates in the first month of the year. **Limitations identified by review team:** Method of randomisation not described in detail. The study did not include those students not immunised at the school i.e., by private providers or GPs. Precise follow-up period not reported. Attrition details not reported. **Evidence gaps and/or recommendations for future research:**

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
		were due. Specific teacher training was offered. This intervention was in addition to the standard state government student and parent information brochures. **Control/comparison/s description:** Controls schools received the standard state government student and parent information brochures. **Sample sizes:** **Total n=** 135 schools (17,411 pupils) **Intervention n=** 66 schools (7,588 pupils) **Control n=** 69 schools (9,823 pupils) **Baseline comparisons:** Schools were similar in terms of metropolitan region of Melbourne, school sector, coeducational or single sex schools, government or independent school, SES and the percentage of NESB students. The		intervention score difference of 19.4% (95%CI 17.5 to 21.2%) and control students had a mean pre-post intervention score difference of 9.23% (95%CI 4.7% to 13.8%). After adjusting for clustering within schools, the different between pre-post between intervention and control schools was 10.2% (95% CI 5.2% to 15.1%, p= 0.001). **Attrition details:** NR	Studies exploring broader populations and settings **Source of funding:** Victorian Health Promotion Foundation.

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
		only difference was that control schools had a higher mean schools enrolment than the intervention schools 142 versus 105. **Study sufficiently powered?** NR			

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
(Reeve et al. 2008) **Citation:** School-based vaccinations delivered by general practice in rural north Queensland: an evaluation of a new human papilloma virus vaccination program **Aim of study:** Presentation of data regarding implementation of HPV vaccination program in Mount Isa, Queensland, Australia.	**Source population/s:** Mount Isa, Queensland, Australia. **Eligible population:** Girls attending two local high schools in Mount Isa, Queensland, Australia. **Selected population:** 304 girls in years 10, 11 and 12 attending two local high schools in Mount Isa, Queensland, Australia eligible to receive the HPV vaccination. 94% of those eligible retuned consent forms, this may have been influenced by parents not understanding consent forms etc.	**Method of allocation:** All those eligible received the program. **Intervention/s description:** The school based program was tendered out to a local general practice. The practice manager, admin staff, and practice nurse organised the program and nurse immunisers were employed on a casual basis to provide immunisation in schools. The immunisation team delivered and collected consent forms from the schools. An immunisation day was allocated for each	**Primary Outcomes:** Uptake of vaccination. Percentage competing course. **Secondary outcomes:** NR **Follow-up periods:** NR **Method of analysis:** Descriptive statistics?	**Primary outcomes:** First dose Both schools achieved 82% coverage. Second dose 76% (which increased to 88% after GP catch-up doses included). Third dose 72% (which increased to 79% after the catch up opportunity at the GP practice). **Secondary outcomes:** NR **Attrition details:**	**Limitations identified by author:** Acknowledge lack of data on HPV coverage. **Limitations identified by review team:** Difficult to determine impact of this particular intervention as baseline data is not available. Population characteristics lack detail.

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
Study design: Feasibility study **Internal validity score:** (+) **Applicability:** C	**Excluded population/s:** NR **Setting:** Two local high schools in the Rural city of Mount Isa, Queensland, Australia. Indigenous population of 19%. The intervention was set in pubic high schools and was part of a larger immunisation program, aimed at years 8 students (two does HBV and one does varicellla-zoster) and year ten students (one dose DTPa).	age group, with follow-up days for those absent on their allocated day. Those who missed out at school could also be brought into the general practice. The program is ongoing but these are results from its first 6/12. **Control/comparison/s description:** NR **Sample sizes:** **Total n=** 304 **Intervention n=** 304 **Control n=** NA **Baseline comparisons:** NR **Study sufficiently powered?** NR		NR	Percentages are given rather than numbers. **Evidence gaps and/or recommendations for future research:** As the vaccine has only recently been introduced studies documenting interventions to increase uptake are scarce. **Source of funding:** Likely government but authors acknowledge support from Primary Care Research Evaluation and Development Fellowship in writing the paper.

Vaccination Programmes in Prisons

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
(Hutchinson et al. 2004) **Citation:** Sudden rise in uptake of hepatitis B vaccination among injecting drug users associated with a universal vaccine programme in prisons **Aim of study:** To determine the impact of the Scottish Prison Service initiative to offer HBV vaccination to the IDU population of Glasgow. **Study design:** ITS **Internal validity score:** + **Applicability:** B	**Source population/s:** UK **Eligible population:** IDU population in Glasgow, Scotland. **Selected population:** Cross sectional surveys conducted in 1993, 1994, 1999 and 2002 with respondents drawn from street, needle exchange and drug treatment settings. Sites were throughout Glasgow to cover the entire IDU population. Only IDUs who had injected in the previous two months and commenced injecting within the last five years were included in the surveys. **Excluded population/s:** IDUs that had not injected in the previous two months and commenced injecting within the last five years. **Setting:** Glasgow IDU population.	**Method of allocation:** NR **Intervention/s description:** In April 1999 the Scottish Prison Service implemented an initiative to offer HBV vaccination at zero, one and two months, followed by a booster at 12 months to all inmates of prisons and young offender institutions in Scotland irrespective of their injecting history. **Control/comparison/s description:** Before and after implementation. **Sample sizes:** **Total n=** NR **Intervention n=** NR **Control n=** NR **Baseline comparisons:** Not reported separately for included population in this review. **Study sufficiently powered?**	**Primary Outcomes** Uptake (%) of HBV in young people aged 16-20, 21-25 and >25. Only young people aged 16-20 are reported in this review. **Secondary outcomes** NR **Follow-up periods:** Pre Prison initiative (1993, 1994, 1999)(January-March)) and early initiative (April 1999) and post initiative 2002 **Method of analysis:** Descriptive statistics	**Primary outcomes:** Uptake (%) of HBV in young people aged 16-20 was 1993 (pre)14% 6/43 1994 (pre) 20% 5/25 1999 (pre- January) 22% 4/18 1999 April (early) 46% 12/26 2002 (post) 56% 23/41 Pre (1993, 1994 and 1999) versus post (2002) comparison X^2 = 18.0; P <0.0001 **Secondary outcomes:** NR **Attrition details:** NR	**Limitations identified by author:** Vaccination was self reported and therefore subject to recall and other bias. **Limitations identified by review team**: Uptake is for any uptake and not completion of the 3 dose series of hepatitis B vaccinations. Other factors may have contributed to the increase in HBV vaccinations. Small sample **Evidence gaps and/or recommendations for future research:** **Source of**

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
	Vaccine: Hep B	NR			**funding:** Chief Scientist Office, Scottish Executive

Vaccination programmes to hospitals

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
(Bell et al. 1997) **Citation:** A program to immunize hospitalised preschool-aged children: evaluation and impact **Aim of study:** To determine the impact of an immunisation programme designed to vaccinate hospitalised 0 to 2-year-old children who were under immunised at admission. **Study design:** Before and after study **Internal validity score:**	**Source population/s:** USA **Eligible population:** Eligible participants were children aged 0-2 years, hospitalised in the Children Hospital of Philadelphia after February 1994. **Selected population:** 2329 children (aged 0-2 years) admitted to the medical and surgical units at The Children's Hospital of Philadelphia during the study period (February to November 1995). All children evaluated lived in the city of Philadelphia, 71% were from west and South Philadelphia. The mean age of the evaluated group was 10 months (±6.5), 57% were boys. **Excluded population/s:** Children in the intensive care unit or on the oncology unit or patients who were admitted and discharged from the hospital on weekends. **Setting:**	**Method of allocation:** NA **Intervention/s description:** On a daily basis, the immunisation nurse co-ordinator and assistant identified all age appropriate children admitted to six different medical and surgical units. The PCP (Primary care provider) of each child was contacted to verify the child's utilisation of the primary care site as well as to retrieve the immunisation record. After discussions with the PCP and review of the child's medical status and immunisation record, the paediatric resident assigned to the patient was contacted and in the first 2 years of the programme , was told what immunisations were needed if the child was delayed. Before the immunisation, informed consent was obtained and educational information	**Primary Outcomes:** The percentage of children fully immunised on admission compared with the percentage at the time of discharge. **Secondary outcomes:** NR **Follow-up periods:** From admission to discharge. **Method of analysis:** Descriptive statistics. Intention to treat analysis used.	**Primary outcomes:** Sixty six percent (674) of eligible patients (1026) received at least one vaccination before hospital discharge. 85% of those vaccinated received multiple immunisations. Of the 2006 children evaluated, the percentage of those fully vaccinated for age increased significantly from 44% on admission to 70% on discharge ($p<0.0001$) (CI not reported). **Secondary outcomes:** NR **Attrition details:** NR	**Limitations identified by author:** NR **Limitations identified by review team:** Not reported method used for calculation of sample size. confidence intervals not reported **Evidence gaps and/or recommendations for future research:** Studies exploring broader populations and settings **Source of funding:** CDC and the Philadelphia Department of Public Health.

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
++ **Applicability:** B	The Children Hospital of Philadelphia, Philadelphia, USA. **Vaccines:** Not specified.	and teaching were provided about future immunisations by the inpatient nursing staff and or the immunisation nurse coordinator. The vaccine was distributed by the hospital pharmacy without charge under the CDC vaccine programme. Immunisations were administered by the nursing staff on the day of discharge from the hospital. Once the child received the vaccine, an updated immunisation record was mailed or faxed to the PCP. **Control/comparison/s description:** NA **Sample sizes:** **Total n=** 2006 **Intervention n=**NA Control n=NA **Baseline comparisons:** NA **Study sufficiently powered?** NR			

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
(Conway 1999) **Citation:** Opportunistic immunisation in hospital **Aim of study:** To assess potential for catch up and scheduled immunisation during hospital admission **Study design:** Cross-sectional study **Internal validity score:** **-** **Applicability:** B	**Source population/s:** Leeds, Yorkshire, UK **Eligible population:** Hospital clerks, junior doctors, and consultants. Preschool children admitted to a paediatric ward in Leeds. **Selected population:** Hospital clerks, junior doctors, and consultants in paediatric wards in an NHS hospital in Leeds, UK Consecutive preschool age (mean age 1.5 years) children admitted to a paediatric ward (no dates given) in Leeds. Immunisation status was ascertained for all 1000 children from parents and or medical records. No further details given **Excluded population/s:** NR **Setting:** NHS hospital in Leeds, UK. No further study demographics reported	**Method of allocation:** NA **Intervention/s description:** The intervention comprised: 1. The hospital clerk checking the immunisation status 2. Junior doctors offering appropriate vaccinations before discharge 3. Consultants were instructed to reinforce this policy. **Control/comparison/s description:** NA **Sample sizes:** **Total n=** 1,000 **Intervention n=** NR **Control n=**NR The number of hospital clerks, junior doctors, and consultants involved is not specified. **Baseline comparisons:** NA	**Primary Outcomes:** % children taking up offer of appropriate immunisations in hospital **Secondary outcomes:** NR **Follow-up periods:** Length of hospital stay **Method of analysis:** Results expressed as percentages. No further analysis was presented	**Primary outcomes:** 43/183 children 23% who were due an immunisation or had missed an immunisation were offered vaccination, of these 65% (n=28) accepted. n=15 carers refused immunisation for their child **Secondary outcomes:** NR **Attrition details:** NA	**Limitations identified by author:** None **Limitations identified by review team:** No details on this cohort of children other than age i.e. ethnicity , social background Therefore difficult to assess applicability of this cohort of children to the UK population in general No detail on recruitment or refusal to participate in study. Limited information is provided on the intervention and the participants e.g. the number of junior doctors and whether they

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
	Vaccines: Diphtheria, tetanus, pertussis, Hib and oral poliomyelitis and MMR	**Study sufficiently powered?** NA			received any training. No comparison **Evidence gaps and/or recommendations for future research:** Authors suggest that medical staff were reluctant to participate, further research into the why and how to change this situation is warranted. **Source of funding:** Not reported

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
(Muehleisen et al. 2007) **Citation:** Assessment Of Immunization Status In Hospitalized Children Followed By Counselling Of Parents And Primary Care Physicians Improves Vaccination Coverage: An Interventional Study **Aim of study:** to assess the effect of vaccination reminders to parents during hospitalisation and report post discharge rates of catch up immunisations **Study design:**	**Source population/s:** Basel, Switzerland **Eligible population:** Public hospital staff and children admitted into one public hospital in Basel, Switzerland **Selected population:** Hospital staff and consecutive children aged 61 days to 17 years enrolled into one public hospital in Basel, Switzerland in two cohorts: January 1st to March 25, 2003 (control group) and March 26th to April 25th 2003 (intervention group) **Excluded population/s:** Children with chronic diseases **Setting:** Public hospital in Basel, Switzerland. No further study demographics reported **Vaccines:** Diphtheria, tetanus, pertussis , poliomyelitis, MMR, Hepatitis B and Haemophilus influenzae	**Method of allocation:** Consecutive children enrolled **Intervention/s description:** The intervention comprised: 1. Hospital staff (no details) enrolling children in a consecutive manner by and obtaining informed consent 2. Assessment of Immunisation records (no details) 3. Noted if immunisation not up to date in the control group and in the intervention group advise that carers should take their child to a primary care provider to obtain immunisation. In addition a letter sent to the relevant physician. **Control/comparison/s description:** Under immunisation was noted in control group but no action taken. **Sample sizes:**	**Primary Outcomes:** Number of catch up immunisations at one month and nine months post hospital discharge **Secondary outcomes:** NA **Follow-up periods:** Nine months post hospital discharge **Method of analysis:** Data presented as percentages and p values given (test unreported)	**Primary outcomes:** Numbers of catch up immunisations at: <u>One month</u> Control 9/106 Intervention: 26/95 p= 0.016 <u>Nine months</u> Control 37/106 Intervention 43/95 No statistically significant difference. **Secondary outcomes:** NA **Attrition details:** 201/209 were followed up until nine months (no details reported)	**Limitations identified by author:** Assessment of immunisations was based on written records therefore assessment s not necessarily accurate Some immunisation records were missing Single centre study **Limitations identified by review team:** The authors report that inaccurate/missing immunisation records as reported above would probably have been similar in both groups but as this was not a RCT that can not be assumed.

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
Controlled before and after study **Internal validity score:** + **Applicability:** B		**Total n=** 430 **Intervention n=** 219 **Control n=** 211 Of these 209 were assessed as under immunised The number of hospital staff involved is not specified **Baseline comparisons:** The authors report baseline characteristics were similar in both groups (data not shown) **Study sufficiently powered?** NA			No details on the hospital staff and any training **Evidence gaps and/or recommendations for future research:** Further research into the use of multiple repeat reminders for immunisations to the parent and primary care provider. **Source of funding:** NR

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
(Rodewald et al. 1996) **Citation:** Effect Of Emergency Department Immunizations On	**Source population/s:** Monroe county, New York State, USA **Eligible population:** Emergency department (ED) staff Primary care groups	**Method of allocation:** Randomisation using a concealed envelope technique **Intervention/s description:** The intervention comprised:	**Primary Outcomes:** Measure of under immunisation rates at one month and one year after emergency department visit **Secondary outcomes:**	**Primary outcomes:** One month after emergency department visit under immunisation rates were Control group: 31% Letter group:, 28% p=0.4 Vaccination group: 23%	**Limitations identified by author:** Study population had a high baseline immunisation rate Study population

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
Immunization Rates And Subsequent Primary Care Visits **Aim of study:** To test the hypothesis that emergency department immunisation will improve immunization rates without decreasing subsequent primary care visits **Study design:** RCT **Internal validity score:** ++ **Applicability:** C	Children attending ED in Monroe county, New York State **Selected population:** ED staff in hospital in Monroe county, New York State Primary care groups of 54 primary care sites in Monroe county, New York State Children (aged 6-36 months, no further details were given) attending ED enrolled into RCT if carer consent was given between September 1st 1990 and August 31st 1991 **Excluded population/s:** NR **Setting:** Urban hospital ED and 54 primary care sites in Monroe county, New York State **Vaccines:** Diphtheria, tetanus, pertussis, poliovirus, MMR, and Haemophilus influenzae	1. Children being enrolled by hospital staff (no details) in ED, days and evenings, 7 days a week up until 11pm at night 2. Informed consent received from carers and child randomised into one of three groups: no intervention, letter to primary care group or vaccination if deemed under vaccinated. 3. A decision rule determined those likely to be under immunised and those children in the vaccination group were offered Immunisation. The decision rule was based on the age of the child, number of specific immunisations (source unknown) and time since last visit to a primary care provider. **Control/comparison/s description:** No intervention or letter sent to primary care provider regarding immunisation status	Subsequent primary care visits post emergency department visit **Follow-up periods:** One year after emergency department visit **Method of analysis:** Data presented as percentages and comparisons were made with chi square and t tests.	p=0.2 p values compared with control One year after emergency department visit under immunisation rates were Control grp: 28% Letter grp:, 25% p=0.2 Vaccination grp: 25% p=0.2 p values compared with control **Secondary outcomes:** Subsequent primary care visits post emergency department visit were unaffected **Attrition details:** n=14, of which n=8 had a primary care provider outside of the area and n=6 had no medical records	had a primary care provider therefore results can not be applied to children without a primary care provider **Limitations identified by review team:** Immunisation status was determined by a decision rule not medical records. Two thirds of the children were not even considered for catch up immunisation. **Evidence gaps and/or recommendations for future research:** The authors consider that this RCT provides good evidence for the catch up immunisation not working in the emergency

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
		Sample sizes: **Total** n= 1835 **Intervention** n= 610 (letter) n=611 (ED vaccination) **Control** n= 614 According to the decision rule 248 children in the vaccination group were under immunised 117 (47%) were offered immunisation and accepted The number of hospital staff involved is not specified. **Baseline comparisons:** Demographic characteristic, health insurance type, primary care sources, parental perception of immunisation and actual immunisation recorded. No differences were seen. **Study sufficiently powered?** Yes			department setting. They suggest future research should focus on primary care provision of immunisation. **Source of funding:** NR

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
(Skull et al. 1999) **Citation:** Evaluating the potential for opportunistic vaccination in a Northern Territory hospital **Aim of study:** To evaluate the potential for opportunistic vaccination aimed at improving vaccination coverage for children in hospital. **Study design:** Before and after study **Internal validity score:** **+** **Applicability:** C	**Source population/s:** Northern Territory (NT), Australia **Eligible population:** Healthcare professionals and administrative staff at a NT hospital. Children admitted to the paediatric ward or emergency department at a hospital in NT, Australia. **Selected population:** Healthcare professionals and administrative staff working in the paediatric ward or emergency department at a NT hospital. Children under 7 years of age who were discharged from paediatric wards (PW) and the emergency department (ED) at one NT hospital who records were available. **Excluded population/s:** Children under 7 years of age who were discharged from paediatric wards (PW) and the emergency department (ED) at one NT hospital whose	**Method of allocation:** NA **Intervention/s description:** The intervention comprised: 1. Five week training period during which doctors and nurses as to the importance of childhood vaccination & opportunistic vaccination 2. A practical backup system to ensure adequate vaccines in the hospital pharmacy and 3. A vaccination section was attached to the paediatric admission form. **Control/comparison/s description:** Before and after data **Sample sizes:** **Total** **Intervention n=** 443 (post intervention) **Control n=** 423 (pre intervention)	**Primary Outcomes:** Number of opportunistic vaccinations provided. **Secondary outcomes:** Different measures related to documentation of vaccinations **Follow-up periods:** 13 weeks **Method of analysis:** Data presented as proportions/percentages. p values and relative risk ratios were calculated for pre and post intervention.	**Primary outcomes:** Number of opportunistic vaccinations (administration of catch up vaccinations) In the paediatric ward there were 0% (0/11) opportunistic vaccinations provided pre intervention versus 62% (5/8) post intervention, p=0.005. Relative risk ratio for PW 2.67 (95% CI 1.09 to 6.52) In the ED there was 0% (0/8) opportunistic vaccinations provided pre intervention **v**ersus 6% (1/7) post intervention, p=0.68. Relative risk ratio for ED 1.06 (95% CI 0.94 to 1.20) **Secondary outcomes:** NR **Attrition details:** For 3/426 (pre) and 3/446 children (post) there were no medical records attainable.	**Limitations identified by author:** Sustainability of the intervention was not measured **Limitations identified by review team:** No details on this cohort of children other than age i.e. ethnicity, social background Therefore difficult to assess applicability of this cohort of children to the UK population in general. Precise details of the intervention are lacking, e.g. who delivered the education and when using what methods. **Evidence gaps and/or**

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
	records were not available. **Setting:** Public hospital in NT, Australia. (No further details) Northern territory has the youngest, most mobile population of any state or territory in Australia and in urban Darwin children under six have a lower age-appropriate vaccination rate (77%) than children from more remote regions (87%). **Vaccines:** Not specified.	The number of healthcare professionals and administrative staff is not reported. **Baseline comparisons:** NR **Study sufficiently powered?** NR			**recommendations for future research:** Further identification of barriers to delivery vaccination once a need for vaccination has been recognised e.g. lack of 24 hr access to immunisation records **Source of funding:** Commonwealth Department of Health and Family Services

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