**Supplementary: Cluster randomised controlled trials**

**Table 1. Cluster randomised controlled trials: review authors' judgements about risk of bias for each included study**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Selection Bias** | **Detection bias** | **Attrition Bias** | **Reporting Bias** |
| **Study** | **Random sequence generation** | **Allocation concealment** | **Blinding of participants, personnel** | **Blinding of data collection outcome assessment** | **Attrition** | **Selective outcome reporting** |
|  | judgement | evidence | judgement | evidence | judgement | evidence | judgement | evidence | judgement | evidence | judgement | evidence |
| Barcelo 20101 | Unclear | Method not described | Unclear | Method not described | High risk | No blinding of patients, practices or investigators | Low risk | No blinding but objective primary outcome (HbA1c)  | Low risk | All sites/ patients followed up. Minimal missing data, balanced across groups | Low risk | Primary and secondary measures defined and reported (but no protocol) |
| Dirks 20112 3  | Low risk | table of random numbers | Low risk | statistician not involved in trial and blind to sites | High risk | Intervention teams unblinded, patients likely unaware | Low risk | Outcome assessor blinded and objective outcome measure | Low risk | All sites followed up; Low patient attrition (3.9%), similar across groups | Low risk | As per protocol |
| Homer 20054 | Unclear | Method not described | Unclear | Method not described | Unclear | Patients blind, sites & study personnel unblinded | High risk | Patient reported outcomes but outcome assessor not reported as blind | High risk | High patient attrition (22%), similar across groups | Low risk | Primary and secondary measures defined and reported (but no protocol) |
| Horbar 20045 | Low risk | Secure computer program | High risk | Concealed except for investigator who notified hospitals | High risk | sites & study personnel unblinded | Unclear | Method not described | Low risk | All sites and patients recorded in electronic database followed up | Low risk | Primary and secondary measures defined and reported (but no protocol) |
| Kritchevsky20086 | Unclear | Method not described | Unclear | Method not described | High risk | sites & study personnel unblinded | Low risk | Outcome assessor not blinded but objective outcome (recorded antibiotic) | Low risk | All sites followed up and abstracted data | Low risk | Primary and secondary measures defined and reported (but no protocol) |
| Lee 20097 | Unclear | Method not described | Unclear | Method not described but stated concealed | unclear | sites & study personnel unblinded to assigned intervention but blinded to interventions of other group | High risk | Outcome assessors not reported as blinded | Low risk | Lost one site otherwise all other sites followed up and abstracted data | Low risk | Primary and secondary measures defined and reported (but no protocol) |
| Newhouse20138 | Low risk | Computer generated randomisation | Unclear | Method not described | High risk | sites & study personnel unblinded | High risk | Outcome assessor not blinded | High risk | 6/29 sites (21%) dropped out  | Low risk | Primary and secondary measures defined and reported (but no protocol) |
| Power 20149 | Low risk | Computer generated randomisation | Unclear | Method not described | High risk | sites & study personnel unblinded | Low risk | Outcome assessor not blinded but identical data extracted for separate National Audit | High risk | 6/24 sites (25%) dropped out. High patient attrition (11% intervention and 23% control group) | Low risk | Primary and secondary measures defined and reported (but no protocol) |
| Russell 201410 | Low risk | Random numbers assigned blindly to each pair | Unclear | Method not described | High risk | sites & study personnel unblinded | High risk | Outcome assessor not blinded | Low risk | Minimal attrition (2 sites acted as pilot), otherwise all followed up  | Low risk | measures defined and reported (but no protocol) |
| Shaw 201311 | Unclear | Method not described | Unclear | Method not described | High risk | Sites, patients & study personnel unblinded | Low risk | Outcome assessor not blinded but objective outcomes (test conducted or not) | Low risk | All sites followed up  | Low risk | measures defined and reported (but no protocol) |

**Figure 1. Cluster randomised controlled trials: Pictorial risk of bias summary generated by Revman 5.312 with authors' judgements about risk of bias for each included study**

NB; The category ‘Other bias’ noted whether intracluster correlations (ICC) were reported



*Circles: Green = done, yellow = unsure, Red = Not done*

**Figure 2. Pictorial Risk of bias graph generated by Revman 5.312: review of authors' judgements about risk of bias presented as percentages across all included studies.**

****

*Summary of risk of bias*

The included trials were set in Mexico,1 The Netherlands,2 13 Canada7 United Kingdom9 10 and USA.4-6 8 11 The QIC intervention was compared with usual care control sites in six trials. 2 4 8-11 One trial assigned one group to reduce bronchopulmonary dysplasia while the other group to reduce hospital associated infections; each providing a comparison to each other.7 Three trials had partial interventions occurring in control sites; two providing limited feedback reports to controls,5 6 and one trial, Barcelo et al., implemented a clinical information system for diabetes at all participating sites with all patients being offered blood testing at baseline and at the end of the project.1 The trial periods ranged from 12-24 months (median 20 months).

While all studies reported randomisation, five did not describe their methods of random sequence generation1 4 6 7 11 and eight did not describe allocation concealment methods.1 4 6-11 Given the nature of QICs, blinding of participant sites/teams was not possible. However, five studies either had blinded outcome assessment or the outcome was assessed as being sufficiently objective (for example, an automated laboratory test).1 2 6 9 11 Where outcome measures were obtained from chart extraction or collected by individuals, no study reported inter-rater reliability audits. While control sites did not receive the QIC intervention (or topic of interest), the possibility that they may be influenced could not be excluded since study sites were often in the same area or health service1 or health professionals knew they were controls.2 7 Furthermore, the recording of other environmental factors and policy changes that could have had an effect was reported in only one trial.6 All studies clearly defined their primary and secondary outcome measures, although only one study had an a priori published protocol.3 Eight of the ten trials had no or very low site/patient attrition.1 2 4-7 10 11 The remaining two studies had 75% and 79% follow-up respectively.8 9 Only three trials reported intracluster correlation coefficients (ICC) used in their analyses.4 5 9 In summary, the major risks of bias were uncertain allocation concealment and lacking of blinding (intervention and outcome assessment).

**SQUIRE v.1 standards14 abstracted**

**9. Planning the intervention**

a. Describes the intervention and its component parts in sufficient detail that others could reproduce it

b. Indicates main factors that contributed to choice of the specific intervention (for example, analysis of causes of dysfunction; matching relevant improvement experience of others with the local situation)

c. Outlines initial plans for how the intervention was to be implemented: e.g., what was to be done (initial steps; functions to be accomplished by those steps; how tests of change would be used to modify intervention), and by whom (intended roles, qualifications, and training of staff)

**10. Planning the study of the intervention**

a. Outlines plans for assessing how well the intervention was implemented (dose or intensity of exposure)

**Table 2. Reported QIC intervention, assessment of intervention, collaborative site engagement**

|  |  |  |  |
| --- | --- | --- | --- |
| **Study reference, country topic, QIC type\*** | **Description of the Intervention**  | **Assessment of intervention** | **Reported engagement with collaborative process** |
| Barcelo 20101 Mexico DiabetesBTS | Implementation of clinical information system (QUALIDIAB) and all patients offered HbA1c and lipid profile tests at baseline and at the end of the project. Teams of doctors, nurses and patients from each site were involved in three 3 group learning sessions that included training on improving diabetes care, structured patient education program, in-service diabetes management and QI methodology including PDSA cycles. Diabetes specialists plus unspecified national and international professionals provided advice throughout QIC. Site visits conducted by case management advisor. Described funding as limited to technical support and implementation. | **Rationale for choosing QIC intervention:** not clear**Topic** well described**Change package-** based on previous diabetes education model**Meetings-** three, length not reported (NR), curriculum (reported), who hosted (NR), who advised (reported), team composition (reported)**Coaching, support between meetings-**, advisor for case management visited, frequency (NR)**High level management involvement or support or resources** (not clear) | Attendance at learning sessions NR. All Intervention teams filled in Assessment of Chronic Illness Care (ACIC) questionnaire before and after intervention to help select priorities for improvement activities. Five out of six Chronic Care domains improved from 1st to 3rd learning session. |
| Dirks 20112 13Dirks 2012 NetherlandsThrombolysis acute strokemodified BTS | Set of implementation tools (presentations, checklists, papers and revised protocols) was developed aimed at expected barriers. Teams included stroke neurologist and stroke nurse who were asked to update their stroke guideline, identify local barriers, set goals and plan actions. Teams attended 5 half day sessions and one closing session. | **Rationale for choosing QIC intervention:** multidimensional barriers required a multifaceted intervention that addresses *“medical, intra- and inter- organisational as well as psychological and constraints”***Topic** well described**Change package-** not reported (NR) but described evidence and characterisation of barriers for implementation**Meetings-**5 half day sessions and one closing session. who hosted (NR), curriculum(not clear), who advised (NR), team composition (reported)**Coaching, support between meetings-**NR**High level management involvement or support or resources** NR | Attendance at meetings reported as “good”. One hospital team dropped out. Intervention adherence varied from very active to “doing as little as possible”. Investigated changes in intra- and extra-organisational protocols, education and infrastructure from baseline to end of study. Only intra-organisational protocols increased in intervention hospitals |
| Homer 20054USAChildhood AsthmaBTS | Three 1-day meetings for teams made up of doctor, nurse and front office staff person. First meeting included training on model for improvement, evidence-based asthma resources, tools to support implementation into practice (encounter forms and electronic patient registry). Curricula for 2nd and 3rd meeting NR. Coaching and support provided via biweekly conference calls, active email list, periodic performance feedback from expert review of monthly project team reports.  | **Rationale for choosing QIC intervention:** Continuous QI approach to close gaps in health care quality**Topic** well described**Change package-** NR although cites guidelines**Meetings-** Three 1-day meetings, who hosted (NR), curriculum(reported), who advised (NR), team composition (reported)**Coaching, support between meetings-**, biweekly conference calls, performance feedback, active email list**High level management involvement or support or resources** -NR | Attendance at the three learning sessions progressively declined from 1st to 3rd sessions; 41% attended all learning sessions. Overall 42% submitted performance data; 39% reported progress in any given month.  |
| Horbar 2004 USASurfactant for preterm infantsVON | One 3-day interactive training workshop, teams made up of doctors, nurses and respiratory therapists, site specific feedback and peer comparison given prior to meeting, Workshop curriculum included PDSA (plan, do, study, act) improvement model, developing aims and designing PDSA cycles, teams reviewing evidence from systematic reviews, reflecting on their own practices, applying systems thinking and look at underlying structures, patterns, and processes within their hospitals. Workshop exercises, discussion periods, the opening dinner, conference calls, and the email discussion list were designed to promote collaborative learning within and among teams. Teams received ongoing faculty support via quarterly conference calls and email discussion list.  | **Rationale for choosing QIC intervention:** states that an approach *“based on 4 key habits (change, evidence based practice, systems thinking and collaborative learning)modifies practice… improves outcomes and reduces costs”***Topic** well described**Change package-**NR but briefly describes systematic review evidence**Meetings-** One 3-day meeting, who hosted (NR), curriculum(reported), who advised (NR), team composition (reported)**Coaching, support between meetings-** site specific feedback and peer comparison given prior to meeting, email discussion list ,faculty support via quarterly conference calls **High level management involvement or support or resources** NR | 56/57 teams attended the one meeting held over three days |
| Kritchevsky6 2008USAAntibiotic prophylaxisQIC type NR | Hospitals received a comparative feedback report. Promotion of specific process changes, guidance from project staff, two in-person meetings led by clinical and improvement experts, monthly 90 minute conference calls; 10 minute team presentations to other sites at 2nd meeting. Team composition included staff from hospital epidemiology, infection control and pharmacy. Letter of agreement to participate signed by hospital leadership. | **Rationale for choosing QIC intervention:** not clear**Topic** well described**Change package-**briefly described promotion of specific changes**Meetings-** Two meetings, who hosted (NR), curriculum(few details), who advised (reported), team composition (reported)**Coaching, support between meetings-** monthly 90 minute conference calls**High level management involvement or support or resources –** Leadership agreement to participate | All 22 intervention sites attended 1st meeting, 20 attended 2nd and all sites participated in at least one of the 5 conference calls (average 15 hospitals/call (range 11-20). 40/44 sites submitted improvement activity logs for 18 months; median number of strategies 8 (IQR 5-12) intervention group and 8 (IQR 5-14) control |
| Lee7 2009CanadaBronchopulmonary dysplasia and Hospital associated infection | Site investigators attended a 3-day critical appraisal workshop conducted by the research methods committee. Topics included systematic reviews, qualitative methods, principles of continuous QI, neonatal infections, bronchopulmonary dysplasia and data interpretation. Site investigators from the 2 intervention groups separately defined questions for and topics for systematic review. Each site established a team (site investigator, neonatologist, nurse manager, nurse educator, QI officer, executive sponsor and an infection control or respiratory therapist as appropriate and attended a 2-day skills workshop on continuous QI including clinical value compass aims identification, satisfaction and behaviour, team building, clinical process analysis, flow charting, understanding variation, use of Pareto charts, histograms and control charts, benchmarking, use ofthe rapid cycle improvement models, communication strategies, and change management. At the end of phase 1, representatives from the infection and pulmonary groups met separately to share information and materials. Within each group, consensus was reached about potentially useful practices and priorities and potential strategies for implementing practice change. Communication strategies for practice change included information sessions, focus groups, order sheet prompts, posters, feedback boxes, computer-based learning resources and training sessions. Lessons learned and training resources were shared at regular group teleconferences. Selected outcome indicators and control chart feedback were available at 3-month intervals. Results were shared within each of the infection and pulmonary groups. Members of the research methods committee visited the hospital sites to trouble shoot and provide advice as needed.  | **Rationale for choosing QIC intervention:** not clear**Topic** well described**Change package-**briefly described consensus development through evidence review and discussions**Meetings-** Two meetings- 3 days and then 2 days, who hosted (reported), curriculum(reported), who advised (reported), team composition (reported)**Coaching, support between meetings-** multiple sharing and learning activities, site visits and conference calls**High level management involvement or support or resources –** executive sponsor included in each team | Attendance at meetings, or conference calls NR. |
| Newhouse8 2013USAHeart failureQIC type NR | Development of heart failure toolkit with resources for implementation (fact sheet, education modules, discharge checklist, patient education), 2-day in-person meeting for all, 1 in-person meeting for site coordinators at beginning (for training) and end of intervention phase (present results). Monthly conference calls with site coordinators and study team. Team composition: nurse and physician. Nurse executives committed to participation via phone call or in-person. | **Rationale for choosing QIC intervention: *“****a cost-effective approach to link remote settings, connecting professionals to focus on improvement efforts”***Topic** well described**Change package-**based on specific guidelines**Meetings-** Four meetings (2+2), who hosted (NR), curriculum(few details), who advised (NR), team composition (reported)**Coaching, support between meetings-** Monthly conference calls with site coordinators and study team.**High level management involvement or support or resources –** Leadership commitment to participate | Of the 29 randomised rural hospitals, 6 did not attend collaborative meeting. Attendance at monthly group conference calls NR |
| Power 20149UKStroke bundles of careBTS | Hospitals asked to appoint an executive lead, physician leader and project team comprising relevant leaders from clinical and ward areas.1x 2-day and 2x 1-day learning sessions, 90 days apart. Curriculum involved theory and practice of improvement,QI guidance, and shared results. Teams asked to implement bundles for stroke care; collect data on 20 patients per month; submit data online and produce monthly reports to reflect on performance. Support included direct access to project director, site visits; weekly online sharing by improvement advisor and team members via web-based portal. Two progress reviews by project director with hospital chief executive and team. | **Rationale for choosing QIC intervention:** not clear**Topic** well described**Change package-** specific bundles of care developed**Meetings-** 1x 2-day and 2x 1-day learning sessions, 90 days apart, who hosted (NR), curriculum(few details), who advised (NR), team composition (NR)**Coaching, support between meetings-** access to project director, executive mentoring site visits (frequency NR); weekly online sharing via web-based portal**High level management involvement or support or resources –** appointment executive lead, progress reviews with hospital chief executive | Attendance at meetings, weekly on-line sharing and use of web-based portal NR.  |
| Russell 201410UKLung cancer outcomesBTS + peer review | Teleconferences and two face to face workshops for intervention teams. Support: multidisciplinary team meetings, facilitated reciprocal site visits by teams with discussion sessions between host and visiting site teams, follow-up visits by quality improvement facilitator; QI facilitator supported teams via email, telephone and follow-up visits; multidisciplinary team co-ordinator and lung nurse specialist were involved with intervention | **Rationale for choosing QIC intervention:** not clear**Topic** well described**Change package-** not specified but based around National Lung Cancer Audit**Meetings-** Two meetings, who hosted (NR), curriculum(NR), who advised (few details), team composition (NR)**Coaching, support between meetings-** facilitated reciprocal site visits by teams, follow-up visits by quality improvement facilitator; QI facilitator support via email, telephone and follow-up visits (frequency NR) **High level management involvement or support or resources –**NR | Attendance at workshop NR but assumed all as all sites participated in review visits. 29/31 teams submitted a total of 67 quality improvement plans with 18 teams collecting local data to measure impact |
| Shaw 201311USAColorectal cancer screeningQIC type NR | Intervention included facilitators guiding teams in change, decision making and QI work, Teams had two cycles of 4-6 meetings within each practice and 2 day-long learning collaborative meetings to foster cross practice learning. Two members of each practice attended (at least one physician) Curriculum included presentations from experts on cancer screening (modalities, prevention cancer, barriers), survivorship and organizational change followed by reflective discussions. Facilitators also conducted qualitative evaluation of team processes. | **Rationale for choosing QIC intervention:** not clear but states as a method “*for translating evidence-based guidelines into practice”***Topic** Described QI processes but not colorectal cancer and screening **Change package-** NR**Meetings-** Two meetings, who hosted (NR), curriculum(reported), who advised (NR), team composition (reported)**Coaching, support between meetings-** Teams had 2 cycles of 4-6 facilitated meetings within each practice. 6 and 12-month follow-up visits **High level management involvement or support or resources –** facilitators guided each team | Of the 12 intervention practices, 7 fully engaged in the intervention, 2 practices failed to participate, and 3 practices never fully engaged in developing collaborative processes |

\*QIC type: BTS Breakthrough Series, VON Vermont Oxford Network, NR Not Reported;

\*NR= not reported

**References**

1. Barcelo A, Cafiero E, de Boer M, et al. Using collaborative learning to improve diabetes care and outcomes: the VIDA project. Primary care diabetes 2010;**4**(3):145-53.

2. Dirks M, Niessen LW, van Wijngaarden JDH, et al. Promoting thrombolysis in acute ischemic stroke. Stroke 2011;**42**(5):1325-30.

3. Dirks M, Niessen LW, Huijsman R, et al. Promoting Acute Thrombolysis for Ischaemic Stroke (PRACTISE): Clinical trial protocol. International Journal of Stroke 2007;**2**(2):151-9.

4. Homer CJ, Forbes P, Horvitz L, et al. Impact of a quality improvement program on care and outcomes for children with asthma. Archives of Pediatrics & Adolescent Medicine 2005;**159**(5):464-9.

5. Horbar JD, Carpenter JH, Buzas J, et al. Collaborative quality improvement to promote evidence based surfactant for preterm infants: a cluster randomised trial. BMJ 2004;**329**(7473):1004.

6. Kritchevsky SB, Braun BI, Bush AJ, et al. The effect of a quality improvement collaborative to improve antimicrobial prophylaxis in surgical patients: a randomized trial. Annals of Internal Medicine 2008;**149**(7):472-80.

7. Lee SK, Aziz K, Singhal N, et al. Improving the quality of care for infants: a cluster randomized controlled trial. CMAJ Canadian Medical Association Journal 2009;**181**(8):469-76.

8. Newhouse RP, Dennison Himmelfarb C, Morlock L, et al. A phased cluster-randomized trial of rural hospitals testing a quality collaborative to improve heart failure care: organizational context matters. Medical Care 2013;**51**(5):396-403.

9. Power M, Tyrrell PJ, Rudd AG, et al. Did a quality improvement collaborative make stroke care better? A cluster randomized trial. Implementation Science 2014;**9**(1):40.

10. Russell GK, Jimenez S, Martin L, et al. A multicentre randomised controlled trial of reciprocal lung cancer peer review and supported quality improvement: results from the improving lung cancer outcomes project. British Journal of Cancer 2014;**110**(8):1936-42.

11. Shaw EK, Ohman-Strickland PA, Piasecki A, et al. Effects of facilitated team meetings and learning collaboratives on colorectal cancer screening rates in primary care practices: a cluster randomized trial. Annals of Family Medicine 2013;**11**(3):220-8, S1-8.

12. Review Manager (RevMan) [Computer program] Version 5.3. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration 2014.

13. Dirks M, Baeten SA, Dippel DW, et al. Real-life costs and effects of an implementation program to increase thrombolysis in stroke. Neurology 2012;**79**(6):508-14.

14. Davidoff F, Batalden P, Stevens D, et al. Publication guidelines for improvement studies in health care: evolution of the SQUIRE Project.[Reprint of Qual Saf Health Care. 2008 Oct;17 Suppl 1:i3-9; PMID: 18836063]. Annals of Internal Medicine 2008;**149**(9):670-6.