

Abstract

Background

The ARena study (Sustainable Reduction of Antimicrobial Resistance in German Ambulatory Care) is a nested, three-armed, cluster randomized trial and is one of few attempts to evaluate a multifaceted implementation program under the specific conditions of the German setting. Accompanied by a prospective, observational process evaluation, this study aims to measure fidelity to the ARena program and to further assess the relationship between engagement in implementation program components and the primary study outcome.

Methods

This observational study is based on survey data targeting participating physicians of the ARena program as well as attendance data collected by the research group. Attendance in quality circle formats and utilization of additional reimbursement schemes (P4P) representing key elements of ARena were the measures of primary intent. In a binary logistic regression approach, moderating fidelity domains affecting P4P engagement were identified. A multiple linear regression model was applied to identify moderating fidelity domains affecting engagement with quality circle themes. The hierarchical data structure was considered in an additional multilevel model approach. A contextualization of primary study outcomes with regards to the fidelity analysis was applied by descriptive analyses.

Results

96.4% of planned quality circles were exposed to study participants and 89.3% of entitled physicians received one additional reimbursement. 88.4% of physicians engaged in the P4P scheme and 56.1% of physicians engaged in all four offered quality circle themes. On average participants achieved 51.8% of the possible monetary bonus sizes. Moderating domains of participant responsiveness (OR = 2.298) and Context (OR = 2.146) significantly affected P4P engagement. Moderating domains of participant responsiveness (B = 0.718), context (B = 0.323) and culture of shared decision-making (B = -0.334) significantly affected quality circle engagement. In a pre/post manner, antibiotic prescription rates of participating practices significantly decreased ($p < 0.00$).

Conclusion

This analysis assigns a robust feasibility to analysed interventions and indicates that study outcomes are attributable to the implementation program. Intervention engagement was facilitated by positive attributions towards primary care network memberships and responsiveness to interventions. In quality circles, efforts of shared decision-making antagonized intervention engagement. These insights support further tailoring of complex interventions to the context of rational antibiotic use in German ambulatory care.

Trial registration: ISRCTN, ISRCTN58150046

Keywords: complex intervention, fidelity analysis, pragmatic trial, rational antibiotics use, pay for performance, quality circles