Let’s Talk About Antibiotics: a randomised trial of two interventions to reduce antibiotic misuse

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ABSTRACT

Background Children with acute respiratory tract infections (ARTIs) receive ≈11.4 million unnecessary antibiotic prescriptions annually. A noted contributor is inadequate parent–clinician communication, however, efforts to reduce overprescribing have only indirectly targeted communication or been impractical.

Objectives Compare two feasible (higher vs lower intensity) interventions for enhancing parent–clinician communication on the rate of inappropriate antibiotic prescribing.


Setting Academic and private practice outpatient clinics.

Participants Clinicians (n=41, 85% of eligible approached) and 1599 parent–child dyads (ages 1–5 years with ARTI symptoms, 71% of eligible approached).

Interventions All clinicians received 20 min ARTI diagnosis and treatment education. Higher intensity clinicians received an additional 50 min communication training. All parents viewed a 90 sec antibiotic education video.

Main outcome(s) and measure(s) Inappropriate antibiotic treatment was assessed via blinded medical record review by study clinicians and a priori defined as prescriptions for the wrong diagnosis or use of the wrong agent. Secondary outcomes were revisits, adverse drug reactions (both assessed 2 weeks after the visit) and parent ratings of provider communication, shared decision-making and visit satisfaction (assessed at end of the visit on Likert-type scales).

Results Most clinicians completed the study (n=38, 93%), were doctors (n=25, 66%), female (n=30, 78%) and averaged 8 years in practice. All parent–child dyad provided data for the main outcome (n=855 (54%) male, n=1043 (53%) ≤2 years). Inappropriate antibiotic prescribing was similar among patients who consulted with a higher intensity (54/696, 7.8%) versus a lower intensity (85/904, 9.4%) clinician. A generalised linear mixed effect regression model (adjusted for the two-stage nested design, clinician type, clinic setting and clinician experience) revealed that the odds of receiving inappropriate antibiotic treatment did not significantly vary by group (AOR 0.99, 95% CI: 0.52 to 1.89, p=0.98). Secondary outcomes of revisits and adverse reactions did not vary between arms, and parent ratings of satisfaction with quality of parent–provider communication (5/5), shared decision making (9/10) and visit satisfaction (5/5) were similarly high in both arms.

Conclusions and relevance Rate of inappropriate prescribing may need to be re-examined or may not have as much of an impact in practices where prescribing has improved in recent years.

Trial registration number NCT03037112.

In the USA, most antibiotic prescribing occurs in the outpatient setting where children with acute respiratory tract infections (ARTIs) receive ≈34 million antibiotic prescriptions annually. Estimates indicate that at least 29% of these prescriptions are unnecessary.

Antibiotic prescribing behaviour is a complex and multifaceted process, but the communication between parents or legal guardians (hereafter referred to as parents) and clinicians is central. Clinicians cite strong parent demand as a major cause of inappropriate prescribing. Clinicians often capitulate to this perceived pressure because they do not want parents/patients to leave ‘empty-handed’ and/or
view explaining why antibiotics are not necessary as time-consuming and unrewarding.8,9

Efforts to reduce inappropriate antibiotic prescribing in the paediatric setting have typically taken the form of educational interventions to increase antibiotic knowledge among clinicians and/or parents, electronic decision support systems and/or behavioural interventions informed by behavioural economics and psychological science.12–15 Many have been successful, with those that target parent–clinician communication and simultaneously intervene on parents and clinicians evidencing the strongest results.13 Of the communication interventions tested, only one has directly targeted clinicians’ perceptions of parental expectations for antibiotics alongside antibiotic education and shared decision-making.16 This UK-based study provided intensive communication training for clinicians and a multipage patient–clinician interactive educational booklet to enhance shared decision making. Clinicians in the intervention arm demonstrated statistically and clinically significant reductions in antibiotic prescribing as compared with control clinicians. While impactful, the intervention was viewed impractical for most real-world settings.17

Effective interventions that are efficacious and feasible in routine outpatient paediatric care in the USA are lacking. Using the Francis et al16 intervention as our model, we sought to: (1) develop a version of this efficacious intervention that would enhance parent–clinician communication while being feasible in ambulatory paediatric care and (2) compare it to a feasible educational intervention on the rate of inappropriate antibiotic prescribing.

METHODS

Study overview

This was a multisite, parallel group, cluster randomised comparative effectiveness trial conducted in two paediatric outpatient clinics, with clinicians randomised (1:1) to a higher intensity intervention (prescribing education and communication skills training) or a lower intensity intervention (prescribing education only). Parent–child dyads enrolled in the study were exposed to either intervention according to the clinician who conducting their clinic visit. We hypothesised that compared with parent–child dyads managed by clinicians randomised to the lower intensity intervention, parent–child dyads managed by clinicians randomised to the higher intensity intervention would evidence lower rates of inappropriate antibiotic prescriptions (see protocol paper for additional details).18

Patient and public involvement

In the early planning stages for this study, we conducted focus groups and individual interviews with clinical, parent, payer and community stakeholders to assess the viability and inform the design of the study. We then recruited a parent research associate who became a core member of our research team, attended all study meetings and co-led our community advisory board (CAB). Our CAB was composed of 15 parent, provider and community stakeholders and was diverse (ie, 3 males, 7 Latinx (3 exclusively Spanish speaking) and 3 African American members). CAB meetings occurred regularly throughout the study. All aspect of the study design, settings, participant burden, materials, procedures, interpretation of data and dissemination of study findings were informed by the CAB and community research associate. Study results were disseminated to all clinic providers. A parent summary of findings will be provided to study sites to share with parents after this paper is published.

Study setting

The study was conducted at an academic medical facility (CMH Primary Care Clinics) in Kansas City, Missouri, USA and both locations of a private practice (Heartland Primary Care) in Kansas City and Lenexa, Kansas, USA.

Participants

Clinicians

All clinicians at both clinics were screened for eligibility. Inclusion criteria were being a paediatrician (medical doctor (MD) or doctor of osteopathic medicine (DO)) or nurse practitioner (certified paediatric nurse practitioner (CPNP) or advanced practice registered nurse (APRN)) and actively and independently conducting consultations with our target population. Eligible clinicians were recruited during study orientation sessions, where interested clinicians completed informed consent and were given a sealed envelope prepared by the study statistician that contained their group assignment. Clinicians were stratified by patient volume and clinic.

Parent–child dyads

Parent–child dyads were recruited from March 2017 to March 2019. Study staff prescreened all potentially eligible parent–child dyads and provided a study flyer during check-in. Interested dyads were given information about the study and offered eligibility screening. If more than one caregiver was present, they were asked to designate one person who would independently complete the written informed consent and all assessments. Clinicians had no role in identifying potentially eligible dyads, screening, consenting or data collection. Clinic staff who scheduled patients’ appointments were blinded to clinician randomisation. Dyads were eligible if the patient was between ages 1 and 5 years, had ARTI symptoms and his/her parent was fluent in English or Spanish.18 Children were not eligible if they had received an antibiotic in the last 30 days, had a concurrent probable bacterial non-respiratory infection, known immunocompromising conditions, complex chronic care condition,19 required hospitalisation during the visit or had previously participated in the study.
**Table 1** Diagnostic criteria for bacterial acute respiratory tract infections (ARTIs) and appropriate antibiotic selection

<table>
<thead>
<tr>
<th>Bacterial ARTI</th>
<th>Diagnostic criteria</th>
<th>Primary antibiotic</th>
<th>Secondary antibiotics for penicillin allergy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Otitis Media (either criteria)</td>
<td>1. Fever ≥38.3°C with either A or B: A. Moderate to severe bulging of tympanic membrane on exam, or B. Mild bulging of TM and recent (&lt;48 hours) onset of ear pain 2. New onset of otorrhea not due to acute otitis externa</td>
<td>Amoxicillin</td>
<td>Cefdinir, cefpodoxime, ceftriaxone, cefuroxime, clindamycin</td>
</tr>
<tr>
<td>Sinusitis (any of the three criteria)</td>
<td>1. Daytime cough or nasal discharge for greater than 10 days 2. High fever (&gt;39°C) with purulent nasal discharge or facial pain lasting three consecutive days at the beginning of the illness 3. Worsening signs or symptoms characterised by the new onset of fever, headache, or increase in nasal discharge following a typical viral URI</td>
<td>Amoxicillin</td>
<td>Cefdinir, cefpodoxime, cefuroxime, clindamycin</td>
</tr>
<tr>
<td>Community acquired Pneumonia (either criteria)</td>
<td>1. Fever, tachypnoea and focal findings on pulmonary exam 2. (A) Fever, (B) Tachypnoea, cough or retractions and (C) chest radiograph consistent with a focal consolidation</td>
<td>Amoxicillin, Cefpodoxime, Cefprozil, Cefuroxime, Clindamycin</td>
<td></td>
</tr>
<tr>
<td>Streptococcal pharyngitis (both criteria)</td>
<td>1. Fever, pharyngitis and positive rapid streptococcal antigen test or culture 2. Lack of viral signs and symptoms</td>
<td>Amoxicillin, Cephalexin (preferred unless previous type I hypersensitivity reaction to penicillin) Clindamycin, Azithromycin</td>
<td></td>
</tr>
</tbody>
</table>

TM, tympanic membrane; URI, upper respiratory infection.

**Intervention components and description of arms**

**Parent video**

The 90 s video used gain-framed messages20 21 to explain when antibiotics are and are not indicated while emphasising the risk of side effects and resistant organisms. Research has shown that people react to the same trade-off in different ways depending on whether the possible outcomes are presented as losses or gains.20 We tailored all parent materials to highlight the gains of not using antibiotics (eg, staying safe from side effects) that might increase parents’ comfort with not getting an antibiotic prescription for their child. The video also highlighted information that clinicians should provide (eg, estimate of illness duration, recommendations for system relief) during a visit. The video was successful in reducing parents’ interest in obtaining an antibiotic for their child, especially among those with higher baseline interest.22

**Parent educational trifold brochure**

The inside of the brochure provided ‘gain-framed’ information about when antibiotics are and are not necessary and the risks involved in taking antibiotics. The outside of the brochure included a place to write the child’s first name and parent tips for communicating with clinicians. It also included check boxes for the clinician to indicate the diagnosis, if antibiotics were needed, recommended home care treatments and expected recovery time.

**Clinician general antibiotic education**

Using didactic and interactive learning strategies, study physicians (AM and JGN) provided a 20 min, in-person general antibiotic education training on diagnosis and treatment of ARTI. The training covered pros and cons of antibiotics, impact of inappropriate use, Centers for Disease Control and Prevention antibiotic prescribing guidelines, common reasons for antibiotic misuse and viewing/discussing the 90 s parent video. Refresher trainings for all study clinicians were provided twice during the study.

**Clinician communication skills training**

The in-person, 50 min communication skills training provided by the study’s behavioural psychologist (KG) used didactic and interactive learning strategies, including viewing/discussing motivational role model videos. The goal was to enhance clinicians’ skills and confidence in the use of proven parent-centred communication strategies and the parent educational trifold brochure (see protocol paper for additional details).18 Clinicians were also trained to consider parents’ ratings of their interest in obtaining antibiotics after viewed the video.

**Lower intensity intervention**

This intervention was modelled on proven parent-focused and clinician-focused educational interventions.13 23 Clinicians completed the general antibiotic education described above.

In exam rooms prior to the consultation, parents who saw a clinician trained in the Lower Intensity intervention completed the baseline survey, saw the video and the inside of the parent brochure, and rated their desire for antibiotics all via a tablet computer. They did not receive a hard copy of the study brochure and their interest in an antibiotic rating was not shared with their clinician.

**Higher intensity intervention**

The higher intensity, Let’s Talk About Antibiotics, intervention was informed by a series of evidence-based interventions conducted in the UK and Europe.16 24–29 Clinicians randomised to this arm completed the general antibiotic education and communication skills training described above. Before meeting with dyads, clinicians in this arm were provided with parents’ ratings of their interest in obtaining antibiotics after watching the parent
video via a sticky note on the exam room door. To assess fidelity to the communication skills and check for contamination between arms, a subsample of all visits (10%) were audio recorded and objectively coded by blinded raters using established methods.30 31

In exam rooms prior to the consultation, parents who saw a clinician trained in the higher intensity intervention completed the baseline survey, saw the video and the inside of the parent brochure, rated their desire for antibiotics via a tablet computer and received a personalized (child’s name written in) hard copy of the study brochure.

**Figure 1** Parent–child dyads enrolment.

**Strategies to reduce the risk of contamination**

We employed several strategies to reduce the likelihood of contamination between study arms. Specifically, we (1) designed intervention components to not be easily transferred between clinicians (eg, the brochure was distributed by study staff to ensure that only parents who were consulted by clinicians in the Higher Intensity arm receive them), (2) ensured that all communication (written or in person) with clinicians in the lower intensity arm did not reveal any of the strategies from the higher intensity arm, (3) reviewed the importance of keeping intervention arms distinct during clinician training and asked higher intensity clinicians to pledge not to share any details or materials with their colleagues randomised to the lower intensity arm and (4) trained higher intensity arm clinicians in communication strategies for dealing with lower intensity arm colleagues who ask for more information.

**Primary outcome**

The primary outcome was rate of inappropriate antibiotic prescribing (ie, number of patients receiving an inappropriate prescription/number of patients in arm). Inappropriate prescribing was assessed by blinded study physicians (AM and JGN) who reviewed the medical record documentation for each patient. Prescriptions were considered inappropriate if they were, prescribed: (1) for a viral ARTI, (2) for a presumed bacterial ARTI that does not meet table 1 criteria, (3) broad-spectrum antibiotic for a bacterial ARTI in a child without a penicillin allergy or...
appropriateness of the patient’s diagnosis. Ten per cent of all chart reviews were verified by the other study physician blinded to the initial coding, inconsistencies were reconciled.

**Secondary outcomes**

Data on revisits and adverse drug reactions were collected via follow-up phone calls with parents 2 weeks after the visit. Revisits were assessed by asking parents if they sought any additional treatment for their child for the same symptoms or complications from any treatment provided in the initial visit. Side effects and adverse drug reactions were assessed if antibiotics were prescribed.

Shared decision-making was assessed immediately following the visit using an adapted version of the three-item CollaboRATE questionnaire. Parents rated How much effort was made to: (1) help you understand your child’s health issue; (2) listen to the things that matter most to you about your child’s health issues; and (3) include what matters most to you in choosing what to do next? on a 10-point response scale ranging from ‘no effort was made’ to ‘every effort was made.’ The scale’s psychometric properties have been established.

Quality of parent–clinician communication was assessed immediately following the visit with the question, ‘How satisfied were you with the communication between you and your child’s healthcare clinician?’ Overall visit satisfaction was assessed with the question, ‘Overall, how satisfied were you with the visit?’ Both items were scored on a five-point scale ranging from ‘very dissatisfied’ to ‘very satisfied’.

**Analyses**

All analyses were conducted using an intention-to-treat strategy. We constructed a two-stage nested design, with parents nested within clinicians (level-1 units) and study site (level-2 units) generalised linear mixed-effect regression models (GLMM) to assess the impact of intervention type on our primary outcome of inappropriate antibiotic prescribing using Stata. Alternative covariance structures were investigated, but as hypothesised, the exchangeable structure was sufficient. We employed robust standard errors to help minimise misspecification and examine time as a potential random effect. We examined the effects of the potential prespecified covariates on the outcomes with the goal of identifying the most parsimonious final models and we explored the heterogeneity of treatment effect. Variables considered included: clinic, clinician type, years of experience, patient age and sex, parent education level, race/ethnicity, preferred language, relationship to patient and insurance type. We created a binary indicator for each variable and included each as an interaction term in a separate regression model. We examined these interaction terms across intervention arms and explored within-arm differential trends in our primary and secondary outcomes over time.

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**Table 2** Parent and patient demographics (N=1599)

<table>
<thead>
<tr>
<th>Gender of parent</th>
<th>Higher intensity</th>
<th>Lower intensity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>584 (83.9%)</td>
<td>764 (84.6%)</td>
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<table>
<thead>
<tr>
<th>Ethnicity of parent</th>
<th>Higher intensity</th>
<th>Lower intensity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hispanic</td>
<td>129 (18.5%)</td>
<td>171 (18.9%)</td>
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<table>
<thead>
<tr>
<th>Race of parent</th>
<th>Higher intensity</th>
<th>Lower intensity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asian</td>
<td>13 (1.9%)</td>
<td>10 (1.1%)</td>
</tr>
<tr>
<td>Black</td>
<td>90 (12.9%)</td>
<td>104 (11.5%)</td>
</tr>
<tr>
<td>White</td>
<td>537 (77.2%)</td>
<td>721 (79.8%)</td>
</tr>
<tr>
<td>Multiracial</td>
<td>15 (2.2%)</td>
<td>24 (2.7%)</td>
</tr>
<tr>
<td>Other</td>
<td>10 (1.4%)</td>
<td>13 (1.4%)</td>
</tr>
<tr>
<td>Chose not to answer</td>
<td>31 (4.5%)</td>
<td>31 (3.4%)</td>
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</table>

<table>
<thead>
<tr>
<th>Preferred language</th>
<th>Higher intensity</th>
<th>Lower intensity</th>
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<tbody>
<tr>
<td>Spanish</td>
<td>41 (5.9%)</td>
<td>60 (6.6%)</td>
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<table>
<thead>
<tr>
<th>Education</th>
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<tr>
<td>Less than high school</td>
<td>38 (5.5%)</td>
<td>49 (5.4%)</td>
</tr>
<tr>
<td>High school degree or GED</td>
<td>151 (21.7%)</td>
<td>183 (20.3%)</td>
</tr>
<tr>
<td>Some college</td>
<td>228 (32.8%)</td>
<td>335 (37.1%)</td>
</tr>
<tr>
<td>Secondary degree</td>
<td>196 (28.2%)</td>
<td>240 (26.6%)</td>
</tr>
<tr>
<td>Postsecondary degree</td>
<td>79 (11.4%)</td>
<td>94 (10.4%)</td>
</tr>
<tr>
<td>Other/unknown</td>
<td>4 (0.6%)</td>
<td>2 (0.2%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient age</th>
<th>Higher intensity</th>
<th>Lower intensity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>249 (35.8%)</td>
<td>307 (34.0%)</td>
</tr>
<tr>
<td>2</td>
<td>126 (18.1%)</td>
<td>172 (19.0%)</td>
</tr>
<tr>
<td>3</td>
<td>104 (14.9%)</td>
<td>145 (16.1%)</td>
</tr>
<tr>
<td>4</td>
<td>96 (13.8%)</td>
<td>136 (15.1%)</td>
</tr>
<tr>
<td>5</td>
<td>121 (17.4%)</td>
<td>143 (15.8%)</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Patient sex</th>
<th>Higher intensity</th>
<th>Lower intensity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>327 (47.1%)</td>
<td>414 (45.9%)</td>
</tr>
<tr>
<td>Male</td>
<td>367 (52.9%)</td>
<td>488 (54.1%)</td>
</tr>
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<table>
<thead>
<tr>
<th>Patient diagnosis</th>
<th>Higher intensity</th>
<th>Lower intensity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viral URI/pharyngitis/OME</td>
<td>352 (50.6%)</td>
<td>440 (48.7%)</td>
</tr>
<tr>
<td>Strep throat</td>
<td>20 (2.9%)</td>
<td>16 (1.8%)</td>
</tr>
<tr>
<td>AOM</td>
<td>126 (18.1%)</td>
<td>162 (17.9%)</td>
</tr>
<tr>
<td>Sinusitis</td>
<td>2 (0.3%)</td>
<td>4 (0.4%)</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>6 (0.9%)</td>
<td>13 (1.4%)</td>
</tr>
<tr>
<td>Multiple or other diagnosis</td>
<td>190 (27.3%)</td>
<td>268 (29.7%)</td>
</tr>
</tbody>
</table>

(4) non-recommended alternative antibiotic for a bacterial ARTI (see table 1) in a child with a penicillin allergy.

To guard against the potential for clinicians to use diagnostic codes to support their antibiotic prescribing, study physicians reviewed detailed symptoms, physical examination findings and diagnostic tests to assess the

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Sample size calculation and power

Prior research examining our primary outcome showed 30% of the antibiotics prescribed in the outpatient ARTI visits were inappropriate.3 33 Prior intervention studies produced 20%–81% reductions in inappropriate prescribing.30 37 Based on the intraclass correlation coefficient (ICC) observed in the Meeker et al study,37 we assume an ICC of 0.04. With 40 clinicians, α of 0.05 and 80% power, we estimated that a sample size of 760 per arm would be needed to detect a 9% difference between arms. Allowing for an attrition rate of 5%, we aimed to recruit 1600 participants to ensure adequate power.

RESULTS

Clinicians

All clinicians at both sites (N=51) were voluntarily screened for eligibility; five were ineligible, four failed to respond after multiple contacts and one declined to enrol in the study. All 41 clinicians enrolled (22 (54%) randomised to the higher intensity arm; 19 (46%) randomised to lower intensity arm) conducted clinic visits with enrolled participants. Three clinicians (all in the higher intensity arm) left their practices during the study, leaving 38 clinicians who all completed the follow-up survey and interview. Most clinicians were female (n=30, 78%) and MD/DO physicians (n=25, 66%) with 8 median years in practice (IQR 4–14; range 1–40). Clinician demographics were similar across arms and between those who did and did not participate in the study.

Parent–child dyads

Figure 1 illustrates the flow of parent–child dyads from prescreening through the 2-week follow-up visit. Table 2 displays demographics for the 1599 dyads included in the primary analysis. Demographic characteristics of parents and children were similar among those exposed to the higher or lower intensity intervention. Spanish-speaking parents and those who had more education were more likely to complete the 2-week assessment, no other differences were observed. Missing survey responses were rare overall (<1% for all variables) and did not exhibit any systematic patterns so we did not impute values.

Fidelity assessment

Analysis of 141 visit audio recordings confirmed a similar mean duration of visits (higher=11.7 vs lower=10.2 min) and no evidence of contamination between arms. Compared with lower intensity clinicians, higher intensity clinicians consistently delivered more of the communication content they were taught in training and no higher intensity materials were used in sessions conducted by lower intensity clinicians.

Primary outcome: inappropriate antibiotic prescribing

A total of 429 (26.8%) patients received an antibiotic prescription with 139 (32.4%) meeting criteria for being inappropriate (table 3). The most common reasons for an antibiotic to be considered inappropriate were being prescribed for a presumed bacterial ARTI that did not meet diagnostic criteria (n=109; 78.4%) and prescribing a broad-spectrum antibiotic for a child without a penicillin allergy (n=24; 17.3%). The rate of inappropriate prescriptions among all enrolled patients in each arm was similar among higher intensity (54 of 696; 7.8%) and lower intensity (85 of 903; 9.4%) clinicians. Inappropriate antibiotic prescribing also did not vary significantly based on study site or clinician type. In the unadjusted GLMM, we found that the odds of receiving inappropriate antibiotic treatment for the higher intensity arm did not vary significantly when compared with the lower intensity arm (OR 1.09; 95% CI 0.56 to 2.10; ICC=0.11; table 4).

Heterogeneity of treatment effect

After adjusting for clinician type, clinic setting and clinician experience, there was still no significant intervention effect (Adjusted Odds Ratio (AOR) 0.99; 95% CI 0.52 to 1.89). However, the interaction of the treatment arm and clinician type was significant in the adjusted GLMM model (AOR 0.12; 95% CI 0.04 to 0.37; see online supplemental table)

<table>
<thead>
<tr>
<th>Table 3</th>
<th>$\chi^2$ comparison of overall and inappropriate antibiotic prescribing (N=1599)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Any antibiotic prescribed</td>
</tr>
<tr>
<td></td>
<td>n</td>
</tr>
<tr>
<td>Study arm</td>
<td></td>
</tr>
<tr>
<td>Higher</td>
<td>696</td>
</tr>
<tr>
<td>Lower</td>
<td>903</td>
</tr>
<tr>
<td>Site</td>
<td></td>
</tr>
<tr>
<td>Private practice</td>
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</tr>
<tr>
<td>Academic</td>
<td>307</td>
</tr>
<tr>
<td>Clinician type</td>
<td></td>
</tr>
<tr>
<td>MD/DO</td>
<td>907</td>
</tr>
<tr>
<td>CPNP/APRN</td>
<td>692</td>
</tr>
</tbody>
</table>

APRN, advanced practice registered nurse; CPNP, certified paediatric nurse practitioner; MD/DO, medical doctor/doctor of osteopathic.
Specifically, the MD/DO clinicians in the higher intensity intervention were less likely to prescribe an inappropriate antibiotic than MD/DO clinicians in the lower intensity intervention arm. The reverse was true for the CPNP/APRN clinicians. No interaction between intervention and gender or location was observed. No interaction between treatment and any of the parent–patient dyad variables (ie, patient age or sex, parent education level, race/ethnicity, preferred language, relationship to patient or insurance type) was observed.

Secondary outcomes
Revisits and adverse drug reactions: Approximately 12% of patients had a return visit within 2 weeks of their index visit. The rate of revisits did not vary between patients seen by higher or lower intensity clinicians (12.2% vs 11.9%, p=0.879). Adverse reactions to the prescribed antibiotic were similar across arms (16.5% vs 12.8%, p=0.27). (Antibiotic prescription rates for different ARTI diagnoses are presented by arm in online supplemental table 2).

Shared decision-making: Parents’ CollaboRATE ratings were extremely high overall (likely evidencing a ceiling effect) and similar across higher and lower intensity arms (median 9.0 (IQR: 8.7–9.0) vs 9.0 (IQR: 8.3–9.0), p=0.85).

Quality of parent–clinician communication and visit satisfaction: Parent rated satisfaction with their clinician’s communication during the visit (median 5 (IQR: 5–5) vs 5 (IQR: 5–5), p=0.20) and their overall visit satisfaction (median 5 (IQR: 5–5) vs 5 (IQR: 5–5), p=0.38) were also very high overall and similar between arms.

Clinician satisfaction and feasibility
Most clinicians (84%) reported being ‘very satisfied’ with the programme, thought it would be ‘very’ (71%) effective in reducing inappropriate prescribing and all would recommend it to other clinicians.

Parent satisfaction
The majority of parents who completed the 2-week follow-up survey (n=1337) reported being ‘very’ (92%) satisfied with the programme and 93% reported that they would recommend it to others.

DISCUSSION
This randomised comparative effectiveness trial comparing two feasible interventions for enhancing parent–clinician communication found no evidence of a difference in inappropriate antibiotic prescriptions. Inappropriate antibiotic prescribing was lower than recently published estimates of inappropriate prescribing in the US Midwest (14.3%), which have been on the decline, especially among paediatricians. Nevertheless, it was still higher than findings from other successful intervention studies (rates from 1.5% to 3.9%). In the main outcome analysis, the odds of receiving an inappropriate antibiotic did not vary significantly between the higher and lower intensity arms, even after adjusting for clinician type, clinic setting and clinician experience.

Secondary outcomes of revisits and adverse reactions did not vary between patients seen by higher or lower intensity clinicians. These findings indicate that there is no evidence that one of the interventions presented a greater risk to patients than the other. Parent ratings of shared decision making, satisfaction with quality of parent–clinician communication and visit satisfaction were all very high and similar between arms. Ceiling effects on the measures were apparent and likely reduced our ability to observe any true differences between arms. Nevertheless, these findings indicate that both interventions were highly satisfactory to parents.

In this study, higher intensity MD/DO clinicians were significantly less likely to prescribe inappropriate antibiotics than their MD/DO counterparts in the lower intensity arm. The reverse was true for the CPNP/APRN clinicians. The reasons for this difference among MD/DO clinicians are unclear and we likely have too few CPNP/APRN clinicians to draw any

Table 4 ORs of receiving inappropriate antibiotic (N=1599)

<table>
<thead>
<tr>
<th></th>
<th>Unadjusted</th>
<th>Adjusted*</th>
</tr>
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<tr>
<td></td>
<td>OR 95% CI</td>
<td>OR 95% CI</td>
</tr>
<tr>
<td></td>
<td>Lower  Upper</td>
<td>Lower  Upper</td>
</tr>
<tr>
<td>Intervention arm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Higher intensity (vs lower)</td>
<td>1.09 0.56 2.10</td>
<td>0.99 0.52 1.89</td>
</tr>
<tr>
<td>Clinician type</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CPNP/APRN (vs MD/DO)</td>
<td>1.24 0.63 2.44</td>
<td>1.29 0.67 2.46</td>
</tr>
<tr>
<td>Practice type</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Academic (vs private)</td>
<td>1.21 0.63 2.30</td>
<td>1.13 0.60 2.16</td>
</tr>
<tr>
<td>Clinician years of experience</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10+ years (vs &lt;10years)</td>
<td>1.40 0.73 2.66</td>
<td>1.42 0.73 2.77</td>
</tr>
</tbody>
</table>

*Adjusting for intervention arm, clinician type, practice type and clinician years of experience.

APRN, advanced practice registered nurse; CPNP, certified paediatric nurse practitioner; MD/OD, medical doctor/doctor of osteopathic.
definitive conclusions about this subgroup, but there are data to support the notion that CPNP/APRN are simply more likely to adhere to guidelines\textsuperscript{41} so the educational training provided in both arms was likely sufficient to ensure similar low rates of inappropriate prescribing among CPNP/APRNs. Future studies should continue to explore differences in response to intervention between different types of clinicians.

The lack of a statistically significant or clinically meaningful main effect may indicate that shared decision-making and the other communication factors targeted by the higher intensity intervention were not as strongly related to inappropriate prescribing as had been expected. This may indicate a cultural shift in parental expectations and/or clinician comfort in withholding unnecessary antibiotics, challenging the relevance of early literature to the social and communication dynamics at play today. It may be that the antibiotic education training for clinicians in both arms and study video that significantly reduced parents’ desires for an antibiotic\textsuperscript{29} might have been enough to make a meaningful impact on prescribing. Other recent studies have found success focusing on clinician education about appropriate antibiotic prescribing and the effects of peer comparison.\textsuperscript{37,40} Clinician education interventions may be sufficient to yield long-term benefits, as parental expectations for antibiotics continue to decrease from an overall cultural shift or from exposure to a high-quality parent education video like the one used in this study.

Limitations

The overall low rate of inappropriate antibiotic prescribing across interventions and sites is encouraging, but our design did not allow us to draw conclusions about the role of either intervention in these lower rates compared with usual care. Future studies should target settings with high rates of inappropriate prescribing. Higher intensity intervention clinicians may not have been given a sufficient ‘dose’ of the training. Lack of a control group or baseline antibiotic prescribing information limits our ability to understand how the rates of inappropriate prescribing we observed in the two intervention arms differs from usual practice at the study sites.

CONCLUSION

Implementing evidence-based clinician and parent interventions to improve antibiotic prescribing can be acceptable to clinicians and parents and feasible in both academic and private pediatric outpatient settings. Clinician education coupled with high-quality parent education delivered via video may be sufficient to yield low inappropriate antibiotic prescribing rates.

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Contributors KG conceptualised, designed and oversaw the study, designed and implemented the parent education and clinician communication training, designed and directed all study procedures and materials, directed the data analysis and interpretation of results, drafted the initial manuscript, and revised the manuscript. EAH contributed to the design of the study, facilitated recruitment, intervention delivery and data collection, contributed to data analysis and interpretation of results, led qualitative data analysis and interpretation of results, drafted sections of the initial manuscript, and critically reviewed the manuscript for important intellectual content. BRL contributed to the design of the study, conducted the data analysis, contributed to the interpretation of results, drafted sections of the initial manuscript, and critically reviewed the manuscript for important intellectual content. AB-E and CB contributed to the design of all aspects of the study, co-led the engagement with the Community Advisory Board and critically reviewed the manuscript for important intellectual content. KP and EEdM contributed to the design study procedures, conducted recruitment and data collection, conducted the analysis and interpretation of qualitative results, drafted sections of the initial manuscript, and critically reviewed the manuscript for important intellectual content. DY, KW, SL and CCB contributed to the design of the study and critically reviewed the manuscript for important intellectual content. JGN and ALM designed the study, designed and implemented the ARTI diagnosis and treatment training, conducted the blind review of the EMR and critically reviewed the manuscript for important intellectual content. KG is responsible for the content as guarantor of the manuscript accepting full responsibility for the work and/or the conduct of the study. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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Competing interests

None declared.

Patient and public involvement

Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication

Not applicable.

Ethics approval

This study involves human participants and was approved by Children’s Mercy Hospital Pediatric Institutional Review Board (#1600466). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review

Not commissioned; externally peer reviewed.

Data availability statement

Data are available on reasonable request. Deidentified data limited to visit-based inappropriate prescribing rates, patient characteristics and dummy variables for clinic site will be shared. No protected health information will be shared. Data will be provided as a comma-separated values file with a data dictionary defining all variables included in the file and will be transferred via a secure file transfer protocol after establishing a data use agreement. No additional data or codes will be made available. The data will be made available after publication of the primary studies to researchers who provide
a detailed methodologically sound proposal. Proposals should be submitted to KG (koggin@cmh.edu).

**Supplemental material**

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