Supplementary materials for

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Supplemental Appendix

ADDITIONAL METHODS DETAIL

Recruitment

General practices were recruited using a variety of methods, including approaches of practices in the Gold Coast region listed on the local Primary Health Network website. As recruitment was slower than anticipated, a trial invitation was posted on a closed Facebook page of Australian GPs (GPs DownUnder) by one of the authors (a member) and interested GPs asked to contact the trial's research assistant. Practices were approached by a research assistant, in person for local practices (with a lunch provided where a lunchtime meeting was possible) and via telephone for interstate practices, to discuss the trial. Participating practices were provided with a $AUD1000 payment (to be spent at the practice's discretion).

Randomisation blocking

The blocking factor was number of participating GPs, classified as either (1, 2 or 3) or (4 or more). The blocks were size 4 and 6, with blocks chosen at random for each of the strata.

Intervention details

Details of the intervention, its development, and piloting are provided in supplemental Table 1.

Supplemental Table 1. Details of the intervention and its development

Template for Intervention Description and Replication (TIDieR)[1] item	**Description**
Brief name	Patient decision aids for ARIs and brief video-based training for GPs
Rationale	To present the information needed, including the evidence-based benefits and harms, of using and not using antibiotics for common ARIs. The intent was for GPs and patients to have an informed discussion about the options and reach a collaborative decision about the management of the acute illness.
What: Materials	Patient decision aids: 3 aids, one each for AOM, acute sore throat (pharyngitis), and acute bronchitis. Each aid is a two-page (double-sided) document and presents the options of managing the condition with and without antibiotics, and the evidence-based benefits and harms of each option. They are available (under the 'shared decision making' dropdown menu) at: https://iebh.bond.edu.au/education-services/research-tools The aids were provided in three ways to enable flexibility in their use: 1) printed, tear-off pads that enable the aid to be discussed with and then provided to patients as a hand-out; 2) laminated documents that can be shown to and discussed with patients; and 3) PDFs that could be displayed electronically. The printed decision aids were provided in a professional presentation plastic folder, with the spine and cover prominently labelled to enable easy access. The folder also contained 1) a list of frequently asked questions that GPs might have; this was informed by questions asked by GPs during piloting of the aids; and 2) a USB stick which contained two brief training videos. Training videos: One video ($7^1/_2$ mins) explained shared decision making, its role in ARI consultations, and the purpose of patient decision aids. Another video ($7^1/_2$ mins) was of a consultation between a GP and a standardised patient demonstrating how the decision aid could be incorporated into a consultation. The videos are available: https://iebh.bond.edu.au/education-services/research-tools
What: Procedures	The intervention materials were provided to GPs in the intervention arm and use of the materials was at their discretion. They were given details of the study team to contact if they had any questions or needed more materials. The research assistant checked with each practice by

	email or telephone at about one month after randomisation, to check if any of participating GPs had questions.
Who provided	Within a few weeks of randomisation, a research assistant delivered the intervention packages to local practices or mailed them to interstate practices.
How	All intervention details were provided within the intervention package.
Where	The aids were designed to be used within GP consultations.
When and how much	The intervention package was provided once and contained 150 patient decision aids (50 of each aid) and GPs could contact the study team if more were required.
Tailoring	No aspect of the intervention was tailored, other than the choice of which format of aid to use (as described above)
Modifications	In the trial protocol, it was stated that a brief visit would occur at 6 months to answer any queries or provide further materials. Due to the difficulty in scheduling a time for visits that were convenient to the GPs and the recruitment of interstate practices, participants and practice managers, were instead emailed and advised to contact the study team at any time if they had queries or required more materials.
How well	At the 12-month follow-up interview, GPs in the intervention group were asked about their use of the aids and videos. Adherence to the intervention is described in the Results section.
Development and piloting of the intervention*	The content of each decision aid was informed by (i) findings from our earlier research[2-4](ii) other research [e.g.[5]], (iii) the relevant Cochrane systematic reviews (acute otitis media[6], acute bronchitis[7], sore throat[8], and a meta-analysis of antibiotic harms[9] for quantification of antibiotic benefits and harms; (iv) risk communication research about optimal methods for numerical, graphical and narrative presentation of benefit and harm data [e.g. Carling 2009[10]]. Their development followed the recommended process for decision aid development[11] and the International Patient Decision Aids Standard criteria.[12] The decision aids were evaluated for face and content validity with an advisory group of clinicians and researchers with clinical and research expertise in general practice, ARIs, infectious diseases, evidence-based practice and shared decision making. The aids were developed iteratively and reviewed and revised during pilot testing with a sample of members of the public (n = 12) and GPs (n = 6). GPs were also shown the videos and asked to provide feedback. The aids were evaluated in a randomised trial involving a hypothetical scenario, in which significantly more participants in the decision aid group made an informed choice about antibiotic use for a future ARI compared to control group participants.[13]

* not a TIDieR item

Monitoring for adverse events

We monitored for adverse events by providing GPs with a log form and asking them to keep a de-identified log of any adverse events (defined as patient-initiated re-consultation for the same illness episode, chest x-ray referrals, hospital or emergency room admissions) that occurred for patients with ARIs that they saw. GPs were asked to provide the log form to the research assistant at the follow-up interview.

Sample size

We aimed to detect a relative rate reduction in dispensing of 20%, as a minimum clinically important difference. This was plausible for our less intensive intervention, given our Cochrane review of shared decision making for ARIs,[14] found an average absolute reduction in prescribing rate of 18%, from 47 per 100 consultations for ARIs in the control group to 29 per 100 in the intervention group; a relative rate reduction of approximately 40%. For the primary outcome of antibiotic dispensing, power calculations suggested a required sample size of 18 practices (9 intervention, 9 control; a total of about 90 GPs). This was calculated as follows: approximately 15% of GP consultations are for an ARI,[15] representing an average of 750 of 5,000 consultations per year. Of these, approximately 410 receive an antibiotic.[15] This means that with an average of 5 GPs per practice, there will be an average of 2,040 antibiotic prescriptions from 25,000 consultations (8.2%). With 80% power, a significance level of 5%, and an intra-class correlation coefficient for the effect of clustering of 0.15, we calculated that we would require 18 practices to detect a relative 20% reduction in dispensing rate, to 6.6% in the intervention group. The intra-class correlation coefficient has been taken from the Cochrane review,[14] being the average of studies. No adjustment was made for loss to follow-up, as all primary outcome data were collected from the PBS.

Analysis

Primary outcome: Generalised estimating equations negative binomial regression was used to compare mean dispensing rates between intervention and control groups, adjusting for clustering by GP practice and baseline (pre-randomisation) dispensing rate. All practices were included on an intention-to-treat basis. Data from the 12 months prior to randomisation were used to estimate baseline dispensing rate, and data for the 12 months post-randomisation were used to estimate follow-up dispensing rate. The model fitted included categorical explanatory variables for time (pre-intervention period and post-intervention period), treatment group, and the interaction between time and treatment group. For one GP, we only had 6 months of MBS data at baseline and no follow-up data, hence this GP was dropped from the primary analysis.

Sensitivity analyses: For one GP, we only had 6 months of MBS data at baseline and no follow-up data, hence this GP was dropped from the primary analysis. In a sensitivity analysis, we included this GP and estimated their yearly number of consultations by doubling the data on their number of consultations in 6 months. In a second sensitivity analysis, we used a 12-month data period delayed by two weeks after the date of randomisation to allow

for the possibility it took GPs in the intervention group up to 2 weeks to familiarise themselves with and begin using the decision aids.

Secondary outcomes: For the secondary outcome of GP knowledge, we compared the summed number of correct questions by group using generalized estimating equations analysis of covariance to adjust for baseline summed number of correct responses and clustering by GP practice. Further, we compared the individual knowledge questions using clustered log binomial regression to estimate the relative proportion correct in the treatment group compared to the control group. However, for 3 questions there were either zero correct responses or zero incorrect responses for one of the groups. To allow us to fit the log binomial model and obtain treatment effect estimates for these 3 questions we added 1 additional correct and 1 additional incorrect response to each treatment group. Responses to quantitative estimate questions were considered correct if a participant's answer was within ±1 day of the answer for questions about duration and ±5 of the answer for questions about the number of people out of 100. For Likert-response questions about influences on antibiotic prescribing, we used generalised estimating equations analysis of covariance to compare groups after adjusting for baseline values. Responses to the interview questions were summarised, with descriptive statistics calculated where possible, and responses to open-ended questions grouped according to frequency of response.

Differences between trial registry entry and trial report

In the trial registry entry, the 9 questions about 'influences on prescribing' were inadvertently grouped with the outcome of knowledge questions as all were contained in the same questionnaire. These 9 questions should have been listed separately as a secondary outcome. They have been analysed and are reported separately in the paper.

RESULTS

Sensitivity analyses

Results of the first sensitivity analysis for the GP with missing follow-up data (see Methods) are shown in supplemental Table 2, with minimal difference to the formal analysis results. Results of the second sensitivity analysis (delay of 2 weeks in the follow-up data commencement) are not presented as the results are unchanged.

Supplemental Table 2. Rate of antibiotic dispensing for intervention and control groups - sensitivity analysis (primary outcome analysis presented for comparison)

Group	Mean baseline rate (95% CI)	Mean follow up rate (95% CI)	Rate ratio (95% CI)	P-value
Primary outcome: rate of antibiotic dispensing for target antibiotic classes				
Intervention	3.5% (2.9-4.3%)	2.9% (2.4-3.5%)	1.01 (0.89-1.15)	0.84
Control	3.2% (2.7-3.8%)	2.6% (2.2-3.1%)		
Sensitivity analysis for the primary outcome (including data from 1 GP with estimated consultation rate based on 6 months of data)				

Intervention	3.5% (2.9-4.3%)	2.9% (2.4-3.5%)	1.07 (0.93-1.23)	0.33
Control	3.8% (2.8-5.1%)	2.9% (2.3-3.7%)		

GP knowledge

We compared the individual knowledge questions using clustered log binomial regression to estimate the relative proportion correct in the treatment group compared to the control group – see supplementary Table 3.

Adverse effects

No adverse event log forms were returned by any GP at the follow-up interview.

Perceived usefulness of the patient decision aids

Responses to the open-ended interview questions from the intervention group GPs about their experiences of using the patient decision aids and influencing factors are summarised in supplemental Table 4.

Supplementary Table 3. Individual knowledge question results compared between groups using clustered log-binomial regression

		% correct at baseline		% correct at follow-up			
Q		**Control group**	**Intervention group**	**Control group**	**Intervention group**	**Relative proportion (95% CI)**	**P-value**
Natural history and antibiotic benefits and harms for these infections							
F2a	How many days do you think AOM usually lasts for, without antibiotic treatment?	20/48 (42%)	20/72 (28%)	17/42 (40%)	37/64 (58%)	1.4 (0.90 – 2.1)	0.14
F2b	How many days do you think bronchitis usually lasts for, without antibiotic treatment?	14/48 (29%)	25/73 (34%)	16/42 (38%)	26/64 (41%)	1.1 (0.68 – 1.7)	0.78
F2c	How many days do you think sore throat usually lasts for, without antibiotic treatment?	17/48 (35%)	29/72 (40%)	19/42 (45%)	37/64 (58%)	1.2 (0.8 – 1.9)	0.34
F4a	Of 100 people with AOM, who **do not take** antibiotics, about how many will be better (no pain) after about 3 days?	8/48 (17%)	16/73 (22%)	13/43 (30%)	28/64 (44%)	1.4 (0.91 – 2.2)	0.13
F4b	Of 100 people with sore throat, who **do not take** antibiotics, about how many will be better (no sore throat) after about 3 days?	5/31 (16%)	9/41 (22%)	6/43 (14%)	26/65 (40%)	3.5 (1.6 – 7.5)	0.002
F4c	Of 100 people with bronchitis, who **do not take** antibiotics, about how many will be better (no cough) after about 1-2 weeks?	2/48 (4%)	4/74 (5%)	0/43 (0%)	19/65 (29%)	12 (2.0 – 80)	0.008
F7a	Of 100 people with AOM who **do not take** antibiotics, about how many will have symptoms such as diarrhoea, vomiting, or a rash anyway?	5/47 (11%)	12/74 (16%)	7/43 (16%)	25/65 (38%)	2.2 (1.2 – 4.3)	0.017

F7 b	Of 100 people with sore throat who **do not take** antibiotics, about how many will have symptoms such as diarrhoea, vomiting, or a rash anyway?	2/47 (4%)	9/74 (12%)	4/43 (9%)	24/65 (37%)	3.8 (1.7 – 8.9)	0.002
F7 c	Of 100 people with bronchitis who **do not take** antibiotics, about how many will have symptoms such as diarrhoea, vomiting, or a rash anyway?	3/47 (6%)	13/74 (18%)	5/43 (12%)	26/65 (40%)	3.4 (1.3 – 8.7)	0.011
F3 a	How many days do you think AOM usually lasts for, **with** antibiotic treatment?	29/48 (60%)	36/73 (49%)	24/43 (56%)	47/65 (72%)	1.3 (0.93 – 1.8)	0.13
F3 b	How many days do you think bronchitis usually lasts for, **with** antibiotic treatment?	16/48 (33%)	23/72 (32%)	14/43 (33%)	27/64 (42%)	1.4 (0.92 – 2.1)	0.12
F3 c	How many days do you think sore throat usually lasts for, **with** antibiotic treatment?	16/48 (33%)	29/72 (40%)	15/42 (36%)	38/65 (58%)	1.6 (1.0 – 2.5)	0.05
F5 a	Of 100 people with AOM, who **do take** antibiotics, about how many will be better (no pain) after about 3 days?	13/48 (27%)	25/73 (34%)	16/43 (37%)	34/64 (53%)	1.5 (0.90 – 2.5)	0.11
F5 b	Of 100 people with sore throat, who **do take** antibiotics, about how many will be better (no sore throat) after about 3 days?	3/31 (10%)	5/40 (13%)	1/43 (2%)	31/65 (48%)	13 (2.1 – 80)	0.005
F5 c	Of 100 people with bronchitis, who **do take** antibiotics, about how many will be better (no cough) after about 1-2 weeks?	3/48 (6%)	1/73 (1%)	0/43 (0%)	20/65 (31%)	11 (1.8 – 70)	0.01
F6 a	Of 100 people with AOM who **do take** antibiotics, about how many will have side effects (such as diarrhoea, vomiting, or a rash)?	6/47 (13%)	8/74 (11%)	6/43 (14%)	24/65 (37%)	2.8 (1.3 – 5.8)	0.007

F6b	Of 100 people with sore throat who **do take** antibiotics, about how many will have side effects (such as diarrhoea, vomiting, or a rash)?	7/47 (15%)	15/74 (20%)	11/43 (26%)	27/65 (42%)	1.6 (0.88 – 3.0)	0.12
F6c	Of 100 people with bronchitis who **do take** antibiotics, about how many will have side effects (such as diarrhoea, vomiting, or a rash)?	5/47 (11%)	8/74 (11%)	7/43 (16%)	25/65 (38%)	2.5 (1.3 – 4.8)	0.005
General questions about antibiotics							
F1	Can you predict if a patient will benefit from taking antibiotics for any of these infections?	28/48 (58%)	44/74 (59%)	20/43 (47%)	26/66 (39%)	0.85 (0.50 – 1.4)	0.55
F17	The vast majority of acute respiratory infections resolve without antibiotic use	48/48 (100%)	71/74 (96%)	41/43 (95%)	66/67 (99%)	1.0 (0.94 – 1.1)	0.52
F18	Unnecessary antibiotic use drives antimicrobial resistance	47/48 (98%)	74/74 (100%)	42/43 (98%)	67/67 (100%)	1.0 (0.96 – 1.1)	0.38
F19	Acute otitis media is best treated with first line/ narrow spectrum antibiotics when needed	48/48 (100%)	74/74 (100%)	29/43 (67%)	57/67 (85%)	1.2 (0.95 – 1.6)	0.11
Questions about influences on prescribing (1= always; 2 = most times; 3 = often; 4 = sometimes; 5= never)*							
	Question	**mean (SD, range)**	**mean (SD, range)**	**mean (SD, range)**	**mean (SD, range)**	**Estimate (95% CI)**	**P-value**
8	to avoid secondary bacterial infection	N=48 4.2 (0.7, 2-5)	n=74 4.2 (0.8, 1-5)	N=43 4.4 (0.7, 2-5)	N=66 4.2 (0.8, 2-5)	0.19 (-0.02 – 0.39)	0.071
9	because you are not certain if the infection is of viral or bacterial origin	N=48 3.8 (0.7, 2-5)	N=74 3.7 (0.7, 2-5)	N=43 3.9 (0.6, 2-5)	N=66 3.9 (0.5, 2-5)	-0.04 (-0.21 – 0.13)	0.61
10	because the patient is feverish for >5 days	N=48 3.0 (1.0, 1-5)	N=74 2.9 (1.0, 1-5)	N=43 3.3 (0.9, 1-5)	N=67 3.1 (1.0, 1-5)	0.15 (-0.09 – 0.39)	0.23

11	because of a past history of bacterial infection	N=48 4.0 (0.8,1-5)	N=74 3.8 (0.9, 1-5)	N=43 4.2 (0.8, 1-5)	N=67 3.8 (0.9, 2-5)	0.29 (0.00 – 0.57)	0.05
12	because the child has a yellowish /greenish nasal discharge	N=48 4.5 (0.6, 3-5)	N=74 4.6 (0.6, 3-5)	N=43 4.7 (0.5, 3-5)	N=67 4.6 (0.6, 3-5)	0.10 (-0.04 – 0.25)	0.15
13	because the patient/parents are very anxious	N=48 4.1 (0.7, 2-5)	N=74 4.2 (0.5, 3-5)	N=43 4.3 (0.6, 3-5)	N=66 4.2 (0.7, 2-5)	0.11 (-0.10 – 0.32)	0.31
14	because the patient looks unwell despite having typical signs of upper respiratory tract infection	N=48 3.6 (1.0, 2-5)	N=74 3.4 (0.8, 1-5)	N=43 3.8 (0.8, 2-5)	N=67 3.7 (0.8, 2-5)	-0.02 (-0.32 – 0.28)	0.89
15	because the patient/parent expects antibiotics	N=48 4.3 (0.5, 3-5)	N=74 4.4 (0.5,3-5)	N=43 4.4 (0.5, 3-5)	N=66 4.4 (0.6, 3-5)	0.04 (-0.08 – 0.16)	0.52
16	because the patient/parent requests antibiotics	N=48 4.2 (0.6, 3-5)	N=74 4.2 (0.5, 2-5)	N=43 4.3 (0.5, 3-5)	N=66 4.2 (0.5, 3-5)	0.09 (-0.08 – 0.25)	0.31

*ANCOVA for clustered data

Supplemental Table 4. Intervention group GPs (n=57) responses to follow-up interview questions about use of decision aids and training video

GPs' experiences of using the decision aids	n
Positive experiences	
- Generally useful and helpful	23
- Helped to structure or illustrate discussions	5
Negative experiences	
- Too time consuming	9
- Too complicated visually and too much information	7
- Inconvenient to access hard copy when in different room	2
- Not suitable for patients from non-English speaking background	2
- Did not suit personal style of practice	1
GPs' reports of patients' reactions to use of the aids	
Positive reactions	
- Well received	21
- Appreciated the explanation and/or a copy of the aid	8
Negative reactions	
- Some parts of the aid difficult to understand	11
- Difficult when young children were the patients	4
Factors influencing GPs' use of the aids	
Patient factors	
- Patient expectation of antibiotics	16
- Perceived receptiveness	9
- Patient health literacy and language	5
Practice factors	
- Time constraints	23
- Inconsistent access to paper-based aids when consulting in another room	4
- Remembering to use them	1
Most useful aspects of decision aids reported by GPs	
Design and content aspects	
- Visual aids / graphics	21
- Easy to understand and concise	13
- Handout for patient to take away	2
Process benefits	
- Structure to guide the consultation conversation	9
- "Authenticated" GPs' advice for no antibiotics	8
- Education of patients; medical students and registrars	5

* responses exceed number of GPs responding to this question as more than 1 reason could be given

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