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ORIGINAL RESEARCH ARTICLE

Preparing Parents to Make An Informed Choice About Antibiotic Use for Common Acute Respiratory Infections in Children: A Randomised Trial of Brief Decision Aids in a Hypothetical Scenario

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Abstract

Background Childhood acute respiratory infections (ARIs) are one of the most common reasons for primary care consultations and for receiving an antibiotic. Public awareness of antibiotic benefit and harms for these conditions is low. To facilitate informed decision making, ideally in collaboration with their doctor, parents need clear communication about benefits and harms. Decision aids may be able to facilitate this process.

Objective The aim of this study was to evaluate the effectiveness of three decision aids about antibiotic use for common ARIs in children.

Methods Adult parents of children aged 1–16 years ($n = 120$) were recruited from community settings and then randomised using a computer-generated randomisation sequence to receive a decision aid ($n = 60$) or fact sheet ($n = 60$). Allocation was concealed and used sealed and opaque sequentially numbered envelopes. Participants self-completed questionnaires at baseline and immediately post-intervention. The primary outcome was informed choice (conceptual and numerical knowledge; attitudes towards, and intention to use, antibiotics for a future ARI). Secondary outcomes were decisional conflict, decisional self-efficacy, and material acceptability.

Results After reading the information, significantly more intervention group participants made an informed choice [57%] compared with control group participants [29%] [difference 28, 95% confidence interval (CI) 11–45%, $p < 0.01$], and had higher total knowledge [mean difference (MD) 2.8, 95% CI 2.2–3.5, $p < 0.01$], conceptual knowledge (MD 0.7, 95% CI 0.4–1.1, $p < 0.01$) and numerical knowledge (MD 2.1, 95% CI 1.6–2.5, $p < 0.01$). Between-group differences in attitudes or intention to use antibiotics were not significant. Most intervention group participants found the information understandable and liked the aids' format and features.

Conclusion The decision aids prepared parents to make an informed choice about antibiotic use more than fact sheets, in a hypothetical situation. Their effect within a consultation needs to be evaluated.

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Key Points for Decision Makers

There is a trade-off between antibiotic benefits and harms for acute respiratory infections (ARIs) in children. To make informed decisions, parents need to understand these trade-offs.

Decision aids can be used to help communicate evidence about antibiotic benefits and harms.

In this randomised trial, decision aids improved parents' knowledge and informed choice about antibiotic use for ARIs in a hypothetical situation. Effects of the decision aids in a consultation should be evaluated next.

1 Introduction

Acute respiratory infections (ARIs) in children are one of the most common reasons for primary care consultations [1–5]. Antibiotic prescribing rates for common childhood ARIs remain excessive [2, 3, 5, 6], even after the dissemination of evidence that antibiotics typically have minimal benefit in reducing symptoms or complications [7–9], and that small benefits may be outweighed by harms. These include common and relatively minor harms, such as diarrhoea [10], but also the risk of contributing to antibiotic resistance [11]. Antibiotic resistance, now a global public health crisis, is directly caused by antibiotic use [12]. Reducing antibiotic use for ARIs in primary care is a priority because this use is the most common and least necessary of uses of antibiotics [12, 13].

Several factors influence whether antibiotics are prescribed in this setting. Children are perceived by doctors and parents to be more vulnerable than adults to the risk of harm from ARIs [14]. Diagnostic uncertainty is coupled with concern that the disease might progress, and many doctors perceive that patients/parents expect an antibiotic [15]. Patients generally overestimate the benefits of treatments and underestimate their harms [16]. This also applies to beliefs about antibiotics, with many parents overestimating antibiotic benefits and underestimating their harms [17, 18]. This can be a contributor to some patients believing that antibiotics are a necessary treatment for ARIs and explicitly requesting them [19]. Antibiotic prescribing reinforces expectations of antibiotics for future ARIs [20, 21].

The counterpoise between antibiotic benefits and harms suggests a need for preference-sensitive care. Shared decision making is a way to provide this [22], with its focus on communication and evidence-based practice skills, and steps that include eliciting patients' expectations and preferences, clarifying misperceptions, and discussing evidence for the benefits and harms of each option [23]. Patient decision aids are one of several types of tools that can be used to support shared decision making. They can improve patients' knowledge about treatment options, accuracy of perceptions about the benefits and harms of each option, active participation in decision making, and clinician–patient communication [24].

In a Cochrane review [25], we recently showed that interventions that aimed to facilitate shared decision making significantly reduced antibiotic prescribing for ARIs in primary care in the short-term, without an increase in reconsultations for the same illness episode or a decrease in patient satisfaction; however, the scope, extensive training requirements, and accessibility of most of these interventions are prohibitive to widespread and sustainable implementation. Some studies used written patient materials as a component of multifaceted interventions, but only two studies (one pilot [26], one main trial [27]) incorporated the use of a decision aid. The decision aid combined all ARIs into a single aid, was predominately aimed at clinicians (as it included diagnostic probabilities to assist with managing clinical uncertainty), and its acceptability to patients has not been evaluated. Further analysis of the main trial found no significant intervention effect on patients' intention to engage in shared decision making for antibiotic use in future occurrences of ARIs, and concluded that patient-targeted interventions may be necessary to achieve this aim [28].

Despite the prevalence of antibiotic prescribing for common childhood ARIs in primary care, as well as the need for parents to be adequately informed prior to making preference-sensitive decisions in collaboration with their doctor about antibiotic use, there is a lack of existing brief decision support tools whose acceptability has been evaluated with parents. With the eventual goal of facilitating shared decision making about antibiotic use in ARI consultations, we developed three brief decision aids for parents relating to acute otitis media, acute pharyngitis (sore throat), and acute bronchitis in children. This study is one stage of a multi-stage evaluation, as is recommended in the development of decision aids [29]. The aim of the present study was to evaluate the ability of the decision aids to help parents make an informed choice in a hypothetical scenario, and parents' perceptions of the usefulness and acceptability of the decision aids.

2 Methods

2.1 Study Design

This was a two-arm, parallel group, randomised trial.

2.2 Participants

A convenience sample of eligible parents was recruited between September and December 2015 from several community locations, such as playgroups in South-East Queensland, Australia. Adult (≥18 years) parents or primary caregivers of children aged 1–16 years (inclusive) were invited to participate. Children were not required to be experiencing an ARI at that time for parents to be eligible to participate. Eligible parents who were interested in participating were provided with a participant information sheet prior to being invited to provide voluntary written consent. The trial was approved by the Bond University Human Research Ethics Committee and was registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12615000843550).

2.3 Randomisation and Blinding

Eligible participants were randomly assigned to one of two information formats: one of the new decision aids (intervention) or a fact sheet (control), for one of three common childhood ARIs (acute otitis media, sore throat, and acute bronchitis). The randomisation sequence was computer-generated (www.randomization.com) by a researcher independent of the project team, who placed and sealed the allocated information format and corresponding pre- and post-questionnaire into sequentially numbered opaque envelopes. Group allocation was concealed to both participants and interviewers until written consent had been obtained.

2.4 Procedure

The consenting parent and study researcher signed and dated a consent form attached to the envelope. The researcher opened the envelope and asked the participant to self-complete the pretest questionnaire to assess baseline knowledge and attitudes about antibiotic use for the ARI covered in the information allocated to them, and the intention of using antibiotics when their child had a similar future illness. The researcher returned the completed questionnaire to the envelope, and then provided the participant with either the intervention or control information (for one of the three infections) that they had been randomised to. Participants could read the information at their own pace. The researcher unobtrusively recorded the time this took. After returning the intervention or control information to the envelope, the participant immediately completed the post-test questionnaire. This contained antibiotic knowledge, attitude, and intention questions identical to those in the baseline

questionnaire, as well as questions about confidence in making a decision and any discomfort with the decision reached. A copy of the pre- and post-questions for acute otitis media are provided as an example in Online Resource 1. The interaction between the researcher and participant was standardised, and the written materials were provided to both groups in a neutral manner and with minimal interaction beyond conveying procedural instructions. Researchers did not provide participants with any additional information, or counsel them about ARIs or antibiotic use.

2.5 Intervention

The patient decision aids were systematically developed in accord with the updated review of the International Patient Decision Aids Standards (IPDAS) international quality criteria and development processes [29]. The content of each decision aid was informed by (i) findings from systematic reviews [15, 30] and observational studies [14, 17, 18, 31–33] exploring patients' and parents' beliefs about, and expectations of, antibiotics for ARIs; (ii) the relevant Cochrane systematic reviews (acute otitis media [7], acute bronchitis [8], sore throat [9]), and a meta-analysis of antibiotic harms [10] for quantification of antibiotic benefits and harms; and (iii) risk communication research about optimal methods for numerical, graphical and narrative presentation of benefit and harm data [34, 35].
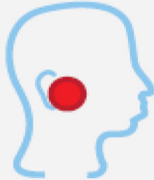
The decision aids were evaluated for face and content validity with an advisory group of clinicians and researchers with clinical and research expertise in general practice, ARIs, infectious diseases, evidence-based practice and shared decision making. The decision aids were developed iteratively, and were reviewed and revised during pilot testing with a purposeful sample of eligible parents ($n = 12$) and general practitioners ($n = 6$). Figure 1 shows the front page of the two-page A4 decision aid for acute otitis media.

2.6 Control

The fact sheets provided to the control group contained information currently available, for each ARI, to the Australian public from *NPS MedicineWise,* an independent, not-for-profit organisation who, as part of their activities, provide health information resources. Their website contained a downloadable fact sheet for acute otitis media and antibiotics in children [36]. For sore throat [37] and acute bronchitis [38], the consumer information on the website was not formatted for easy download or printing, therefore we converted it into a format that matched the acute otitis media fact sheet.

Middle ear infection: should my child take antibiotics?

- This decision aid is to help you decide whether to use antibiotics when **your child** has a middle ear infection.
- This can help you to talk and make a **shared decision** with your doctor about what is best for your child.

What causes middle ear infection?

- It can be caused by a viral or bacterial infection. It is hard for your doctor to tell which it is.
- It is also called 'acute otitis media'. Acute means it is a short-term infection.

How long does the earache last?

- Symptoms (such as earache) usually get better in 2 to 7 days, without antibiotics.

What are the treatment **options**?

There are 2 options that you can discuss with your doctor:
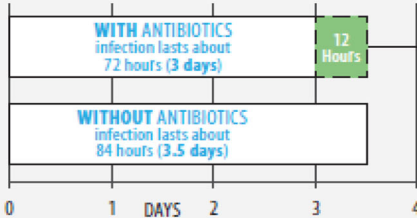
1. Not taking antibiotics
This means letting the infection get better by itself.

2. Taking antibiotics

Symptoms, such as pain and fever, can be treated with over-the-counter medicines.
They can be used with either option.

What are the likely **benefits and harms** of each option?

☐ Average length of middle ear infection

▨ Average reduction in length of infection

WITH ANTIBIOTICS
infection lasts about
72 hours **(3 days)**

12 Hours

WITHOUT ANTIBIOTICS
infection lasts about
84 hours **(3.5 days)**

0   1   DAYS   2   3   4

Children who take antibiotics have the earache for only about **12 hours less** than children who do not.

These figures show what happens to children with middle ear infection who **do not** take antibiotics and those who **do**. Each circle is one child. We can't predict whether your child will be one of the children who is helped or harmed.

- ○ gets better by 2-3 days
- ● gets better by 2-3 days due to antibiotics
- ● not better by 2-3 days

- ○ has problems
- ● has problems due to antibiotics
- ● no problems

100 children who **don't** take antibiotics

100 children who **do** take antibiotics

84   89

Will be **better**
(no pain) at 2-3 days

16 Not better 11

With antibiotics, **5 more children** will be better after 2-3 days.

After about **4 days** most children will be better anyway – without antibiotics.

100 children who **don't** take antibiotics

100 children who **do** take antibiotics

20   27

Will have **problems**, such as vomiting, diarrhoea or rash

80 No problems 73

With antibiotics, **7 more children** will have problems like vomiting and diarrhoea. Other antibiotic harms are:

- the **cost** of buying them
- **remembering** to take them
- the risk of **antibiotic resistance** (see next page)

Fig. 1 Front page of the A4-page decision aid for acute otitis media

2.7 Outcomes

Our primary outcome was a composite measure of informed choice. This is based on the multidimensional model of informed choice [39], which has been previously used in trials of decision aids [40, 41], and contains constructs of decision quality that are often used when evaluating decision aids [42]. It consists of three constructs: knowledge, attitudes, and intentions. A participant's choice was considered to be informed if his/her level of knowledge was adequate, and their attitudes and intention consistent [40] (i.e. positive attitude to antibiotic use and high intention to use; or negative attitude to antibiotic use and low intention to use). There were ten knowledge questions (see Table 2)—five assessing conceptual knowledge questions about antibiotic use for the relevant ARI (true/false), and five assessing numerical knowledge about the quantitative benefits and harms of antibiotic use (open-ended responses). A score of ≥50% (with at least two correct numerical items) was set as the threshold for adequate knowledge [43]. Attitude to antibiotic use was measured using a validated 6-item scale [40, 41, 44], with five response options ('strongly disagree' to 'strongly agree'), forming a scale from 6 to 30. The threshold for a positive attitude (to antibiotic use) was set at 24, based on previous work [40]. A single question with five response options ('definitely will not' to 'definitely will') was used to assess the intention to use an antibiotic for a child's ARI in the future. Secondary outcomes were decisional conflict (10-item low-literacy decisional conflict scale) [45]; self-efficacy in decision making (four items from the decision self-efficacy scale) [46]; and usability and acceptability of the decision aids [40].

2.8 Sample Size Calculation

Using an alpha of 0.05 and 90% power to detect a difference of 30% (based on data from previous studies [47, 48]) in the proportion of people who made an informed choice, we estimated a minimum of 104 people would be required. This was rounded to 108 to enable equal group sizes.

2.9 Statistical Analysis

Quantitative data were entered into Stata version 13 (StataCorp LP, College Station, TX, USA). Responses to numerical knowledge questions were considered correct if a participant's answer was within ±10 of the actual estimate. For example, in the acute otitis media question about the number of children out of 100 who will get better without antibiotics, in which the answer was 84, any response in the range of 74–94 was marked as correct. When analysing responses to the intention question, the 'likely to' and 'definitely will' response categories were collapsed to indicate a positive intention, and 'definitely will not' and 'not likely to' were collapsed to indicate a negative intention.

The primary analysis was a comparison of the proportion of participants in the intervention and control groups who were making an informed choice. Continuous outcomes were analysed using independent sample t tests, and categorical and binary outcomes were analysed using Chi square tests. Adjustment for differences between the groups in the baseline intention-to-use measure was performed using ordinal logistic regression for the between-group analysis for post-intervention responses to this question. Data from open-ended questions about the acceptability of the aids were categorised independently by two authors for thematic analysis.
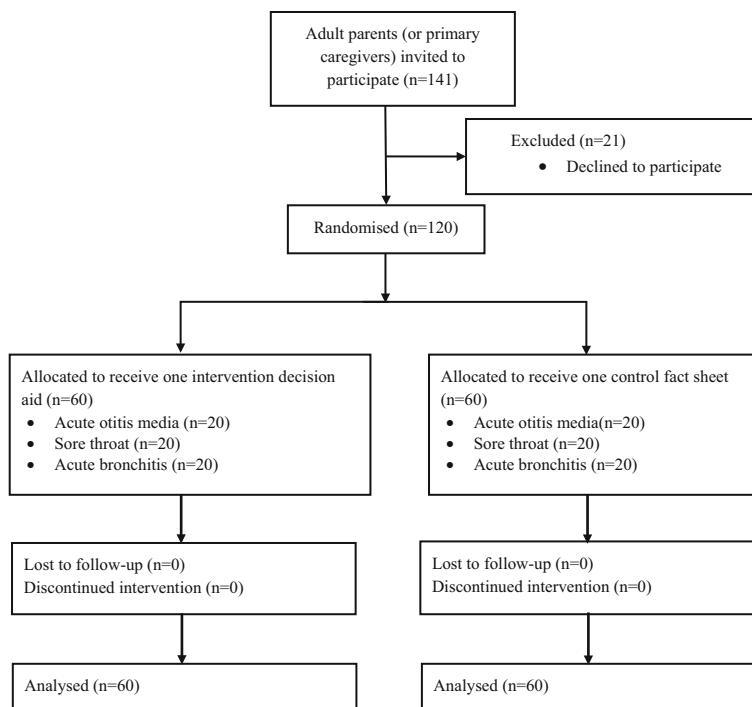
3 Results

During the recruitment phase (September–December 2015), 141 eligible participants were invited to participate, 120 were recruited and none were lost to follow-up (Fig. 2). Most participants were Australian-born, female, between 36 and 45 years of age, married or living with a partner, had completed tertiary education, and were employed full-time. Baseline characteristics for the two groups were similar for all characteristics except education, in which a higher proportion of participants in the intervention group had a higher level of educational attainment (Table 1). Although the groups did not differ on baseline knowledge scores (conceptual, numerical or combined) (Table 2), we conducted a post hoc analysis using logistic regression to adjust for level of educational attainment, and found it was not statistically significant and did not lead to any substantial change in the primary outcome.

Baseline knowledge level was moderate in both groups (Table 2). The intervention group's mean conceptual knowledge score (maximum possible score of 5) was 3.0, while the control group's score was 3.1. Numerical knowledge scores (out of 5) were lower, with a mean of 1.5 in both groups. Baseline attitude towards antibiotic use was positive in 18% of participants in the intervention group and 19% of participants in the control group, while a greater proportion of intervention group participants (42%) had a positive intention to future antibiotic use than in the control group (32%). At baseline, the proportion of participants who made an informed choice about antibiotic use was low and similar between the intervention (15%) and control (18%) groups.

After the materials had been read, more participants in the intervention group [28% more, 95% confidence interval (CI) 11–45%, $p < 0.01$] than in the control group made an

Fig. 2 Flow of participants through the trial

informed choice about antibiotic use for a child's future ARI. Individual constructs of this composite outcome also reflect this (Table 2). Intervention group participants also had higher scores for total knowledge [mean difference (MD) 2.8, 95% CI 2.2–3.5, $p < 0.01$], conceptual knowledge (MD 0.7, 95% CI 0.4–1.1, $p < 0.01$) and numerical knowledge (MD 2.1, 95% CI 1.6–2.5, $p < 0.01$). More participants in the intervention group had adequate knowledge than in the control group (48% more, 95% CI 33–63%; $p < 0.01$).

At post-intervention, there were no significant differences between the number of participants in each group who had a positive attitude towards antibiotic use. After adjustment for the baseline difference between groups in the proportion of participants with a positive intention to antibiotic use, the intervention group participants were more likely to have a positive intention than those in the control group, but the difference was not statistically significant (odds ratio 0.43, 95% CI 0.18–1.09, $p = 0.08$). Decisional conflict scores were low, and self-efficacy for making the decision was high, in both groups, with no significant between-group differences (Table 2).

Table 3 summarises participants' views about the intervention and control materials. The majority of participants thought the length of materials was just right, although significantly more in the intervention group (90%) compared with the control group (60%) [95% CI 15–45%, $p < 0.01$]. The time in minutes taken to read the information was similar in both groups, with a mean (SD) of 4.3 (1.4) in the intervention group and 4.7 (2.2) in

the control group. There were no significant differences between the groups in the proportion of participants who thought the information was new, clear and easy to understand, and helpful in deciding about antibiotic use for a child's illness. Significantly more participants who received a decision aid (95%) than control information (76%) agreed or strongly agreed they would recommend the information to other parents deciding about antibiotic use for a child with an ARI (19% difference, 95% CI 7–31%, $p < 0.01$).

More participants who received decision aids provided a response to the open question "What did you like about the information sheet?". Frequent responses included the format, structure and content; that the information was concise, clear, and easy to read and/or understand; and the graphical representation of benefits and harms numerical information. A few participants ($n = 5$) also indicated that they liked the neutral presentation of information. In response to the question "How could the decision aids be improved?" a few suggestions included adding information on viral versus bacterial aetiology ($n = 1$), the role of antibiotics in preventing complications ($n = 1$), types of antibiotics ($n = 1$), and other treatment options ($n = 2$).

4 Discussion

We developed and evaluated the effect of decision aids on parents' ability to construct informed preferences and make informed choices about antibiotic use in three common

Table 1 Baseline characteristics of participants ($n = 120$)

	Intervention group ($n = 60$)	Control group ($n = 60$)
Gender		
Female	43 (73)	45 (78)
Age, years		
18–25	0 (0)	1 (2)
26–35	18 (31)	20 (35)
36–45	32 (54)	30 (52)
46–55	9 (15)	4 (7)
≥56	0 (0)	3 (5)
Country of birth		
Australia	45 (76)	45 (78)
Other	14 (24)	13 (22)
Main language spoken at home		
English	57 (97)	56 (97)
Other	2 (3)	2 (3)
Marital status		
Married or living with a partner	54 (90)	58 (98)
Single adult with primary caregiving responsibility	5 (8)	1 (2)
Other	1 (2)	0 (0)
Highest level of education		
Junior high school	1 (2)	1 (2)
Senior high school	0 (0)	7 (12)
Trade certificate or apprenticeship	0 (0)	2 (3)
Graduate diploma or certificate	16 (27)	11 (19)
Undergraduate degree	25 (42)	22 (37)
Postgraduate student	18 (30)	16 (27)
Employment		
Full-time (≥30 h per week)	34 (57)	31 (53)
Part-time (<30 h per week)	12 (20)	16 (27)
Casually employed	6 (10)	2 (3)
Not currently in paid employment	8 (13)	10 (17)

Data are expressed as n (%). Responses to some questions had missing data for one to three participants

childhood ARIs in the context of a hypothetical decision, as a precursor to evaluating their effect on facilitating shared decision making during a clinical consultation. This trial found that the decision aids enabled more parents to make an informed choice about antibiotic use in this type of hypothetical situation and improved parents' knowledge, but did not alter their attitudes towards antibiotic use or their intention to use antibiotics when their child has an ARI in the future.

The findings that the decision aids substantially improved conceptual and numerical knowledge are consistent with systematic review findings on the effects of decision aids on knowledge and risk perception accuracy for other treatment decisions [24]. The substantial improvement in numerical knowledge in the intervention group is not surprising as the information was only provided in the decision aids. The importance of improving this type of knowledge comes from studies showing that patients typically overestimate the benefits and underestimate the harms of treatments [16], including for antibiotics in ARIs [17, 18]. These overly optimistic expectations contribute to unnecessary treatment [16]. Shared decision making provides the opportunity to redress this [23], with clinicians and patients able to discuss the likelihood of benefit and harm, and the trade-off between the two. It is unclear to what extent individuals, when deciding about antibiotic use, weigh more proximal individual perceptions about antibiotic benefit and harm, against the more distal individual or community consequences of antibiotic resistance (the 'tragedy of the commons' [49]). Measurement of parents' risk perceptions about the benefits and harms of antibiotics is another contribution of this study to the literature. As far as we are aware [16], no other studies have quantified people's expectations about antibiotic benefits and harms, and for their use in any condition. Our baseline knowledge scores provide this information and reveal that parents generally have inaccurate risk perceptions about antibiotic benefits and harms. Inaccurately high expectations of antibiotic benefits in ARIs have been reported in primary care paediatricians and have been identified as a driver of inappropriately high prescribing rates [50]; understanding the contribution that patients/parents also bring to the consultation is important when exploring the issues surrounding antibiotic decision making.

After reading the materials, there was reduction in the proportion of parents who had a positive attitude to antibiotic use in both groups, although the difference between the groups was not significant. The intervention and control materials took different approaches to trying to influence parents' attitudes about antibiotics; the fact sheets explicitly stated that antibiotics were unnecessary and the decision aids presented the benefits and harms in a balanced manner (which is a criterion for the presentation of information in a decision aid [51]). The proportion of parents who intended to use antibiotics in the future also decreased in both groups but did not differ between the groups. As decisions about antibiotic use typically occur in the context of a consultation with a doctor, it is not possible to know from this study, which used a hypothetical situation, what effect the decision aids may have on parents' attitudes and actual antibiotic use when their child is ill. It may be that both authoritatively presented information, which directs parents not to take antibiotics, and information that presents the benefits and harms, and encourages

Table 2 Baseline and post-intervention outcomes for the intervention and control groups

	Baseline		Post-intervention		Difference (95% CI)	p value
	Intervention group	Control group	Intervention group	Control group		
Informed choice[a] [n (%)]						
Would make an informed choice	9 (15)	11 (18)	34 (57)	17 (29)	28 (11–45)	<0.01
Conceptual knowledge [n (%) correct]						
Antibiotics are needed for viral infection	46 (77)	50 (83)	55 (92)	54 (92)	0.2 (−10 to 10)	0.97
Antibiotics reduce symptom duration	40 (68)	45 (75)	48 (81)	53 (91)	−10 (−22 to 2)	0.12
People do not usually need to take antibiotics	35 (60)	36 (60)	57 (95)	55 (93)	2 (−7 to 10)	0.67
If a person takes an antibiotic, the antibiotic might not work for a serious infection another time	35 (58)	27 (45)	58 (97)	37 (63)	34 (21–47)	<0.01
Doctors can predict if your child will benefit from taking antibiotics	26 (43)	27 (45)	48 (81)	20 (34)	48 (32–63)	<0.01
Total conceptual knowledge score [mean (SD)]	3.0 (1.3)	3.1 (1.1)	4.4 (0.8)	3.7 (1.1)	0.7 (0.4–1.1)	<0.01
Numerical knowledge [n (%) correct]						
Average duration of illness	48 (81)	46 (79)	55 (92)	53 (90)	2 (−9 to 12)	0.72
Number out of 100 better without an antibiotic	5 (9)	7 (13)	45 (76)	7 (14)	63 (46–77)	<0.01
Number out of 100 better with an antibiotic	11 (20)	10 (18)	44 (75)	10 (19)	55 (40–71)	<0.01
Number out of 100 with side effects from an antibiotic	8 (15)	11 (19)	42 (71)	16 (30)	42 (25–58)	<0.01
Number out of 100 with side effects without an antibiotic	16 (30)	13 (23)	39 (67)	13 (24)	44 (27–60)	<0.01
Total numerical knowledge score [mean (SD)]	1.5 (0.8)	1.5 (0.9)	3.8 (1.5)	1.7 (1.0)	2.1 (1.6–2.5)	<0.01
Total knowledge score [mean (SD)][b]	4.5 (1.5)	4.5 (1.4)	8.2 (1.7)	5.4 (1.3)	2.8 (2.2–3.4)	<0.01
'Adequate' knowledge [n (%)][c]	19 (32)	18 (30)	52 (87)	23 (39)	48 (33–63)	<0.01
Positive attitude to antibiotic use (score ≥24)[d] [n (%)]	11 (18)	11 (19)	7 (12)	2 (3)	8 (−1 to 18)	0.09
Decisional conflict score[e] [mean (SD)]	–	–	8.0 (14.5)	11.0 (16.6)	−3.0 (−8.7 to 2.7)	0.29
Decision self-efficacy score[f] [mean (SD)]	–	–	86.4 (16.1)	84.1 (17.3)	2.2 (−3.8 to 8.3)	0.47

SD Standard deviation, *CI* confidence interval

[a] Informed choice was defined as an adequate level of knowledge, and consistent attitudes and intention (i.e. positive attitude to antibiotic use and intention to use; or negative attitude to antibiotic use and no intention to use)

[b] Knowledge scale of 0–10 contained conceptual and numerical items

[c] Adequate knowledge defined as five or more correct items, including two or more numerical items

[d] Attitude items were rated on a scale from strongly disagree (1) to strongly agree (5), and items included 'Taking antibiotics is beneficial', 'Taking antibiotics is harmful' (reverse scored), 'Taking antibiotics is a good thing', 'Taking antibiotics is a bad thing' (reverse scored), 'Taking antibiotics is important', and 'Taking antibiotics is worthwhile'. Total scores could range from 6 to 30, with higher scores indicating a more positive attitude to antibiotic use

[e] Decisional conflict scores can range from 0 (no decisional conflict) to 100 (extremely high decisional conflict)

[f] Decision self-efficacy scores can range from 0 (extremely low self-efficacy) to 100 (extremely high self-efficacy)

parents to be involved in making the decision, may alter attitudes and behaviour. However, when it comes to health decisions, the majority of participants prefer to be involved in decision making [52–54]. For decisions about antibiotics for children, most parents (75%) prefer to participate in making this decision with their doctor [18].

The findings that decisional conflict was low in both groups and below the threshold (of 25) associated with an ability to implement decisions [45], and that decisional self-efficacy was high in both groups, also need to be interpreted cautiously. These scores might not reflect the actual decisional self-efficacy and decisional conflict that occurs when parents have a child ill with an ARI and have consulted a doctor about their child's care. However, low decisional conflict may also reflect that ARIs are familiar to parents, occur frequently, are not perceived as serious, and hence the decision making associated with them is not likely to produce high levels of decisional conflict. In a review of decisional conflict in shared decision-making situations in Canadian primary care (including decision

Table 3 Participants' responses about the suitability of the information materials

	Intervention group n(%)	Control group n(%)	Difference (95% CI)	*p*-value
Length of information sheet				
Too long	6 (10)	19 (33)	−23 (−37 to −0.1)	<0.01
Just right	53 (90)	35 (60)	30 (15–45)	<0.01
Too short	0 (0)	4 (7)	−7 (−14 to −0.0)	0.04
Information was new				
None	0 (0.0)	2 (3)	−3.4 (−8 to 1)	0.15
Some of it	43 (73)	46 (79)	−6.4 (−22 to 9)	0.42
Most of it	14 (24)	7 (12)	12 (−2 to 25)	0.10
All of it	2 (3)	3 (5)	−2 (−9 to 6)	0.63
Information was clear and easy to understand				
Strongly disagree or disagree	2 (3)	3 (5)	−2 (−9 to 5)	0.58
Neither agree nor disagree	3 (5)	4 (7)	−2 (−11 to 7)	0.65
Agree or strongly agree	54 (92)	51 (88)	4 (−7 to 15)	0.47
Information was helpful in making a decision about antibiotic use for a child				
Strongly disagree or disagree	2 (3)	6 (10)	−7 (−16 to 2)	0.12
Neither agree nor disagree	10 (17)	10 (17)	0 (−14 to 14)	1.00
Agree or strongly agree	47 (80)	42 (72)	8 (−7 to 23)	0.47
Would recommend this information to other parents				
Strongly disagree or disagree	1 (2)	6 (10)	−8 (−17 to 1)	0.07
Neither agree or disagree	2 (3)	8 (14)	−11 (−21 to 1)	0.03
Agree or strongly agree	56 (95)	44 (76)	19 (7–31)	<0.01

Data are expressed as *n* (%). Responses to some questions had missing data for one to three participants

CI confidence interval

making about antibiotics for ARIs), a 'clinically significant' level of decisional conflict was found in a low proportion (10–31%) of encounters [55].

Development of the decision aids followed the recommended phased approach [29], and during development they were iteratively tested with patients and general practitioners, with feedback about the layout and wording incorporated into the version tested in the current study. Acceptability and usefulness of the decision aids was confirmed in this study, with most intervention group participants reporting them to be easy to read and understand, useful, and liking the length and visual presentation of probability data. Evaluation of the decision aids when they are used in a consultation with general practitioners and their effect on antibiotic use, as well as the quality of the decision making during consultations, will be the next phase. Whether using decision aids will alter antibiotic prescribing rates is unclear.

Strengths of our trial include the systematic development of the decision aids, randomised design, and no loss to follow-up. We prespecified a conservative threshold for the type of knowledge required to make an informed choice, using conceptual and numerical measurement, underpinned by a theoretical framework [43]. We also directly compared decision aids with consumer information

of high standard (considerably greater than is routinely provided in primary care in Australia), which may have underestimated the effectiveness of the decision aids when used within a clinical context.

Limitations in the generalisability of results stem from asking parents about a hypothetical illness situation. Although this is somewhat mitigated by the high prevalence of ARIs during childhood [56] (ARIs are the most frequent reason for children to be seen by a primary care doctor), so few parents in this study will have not experienced their child having had at least one of these illnesses at least once. Nevertheless, the hypothetical scenario may have influenced measurement of some constructs of the composite informed choice endpoint, although this outcome has been used in other trials of decision aids in which participants were not necessarily needing to make a decision at the time of receiving a decision aid but perhaps at some point in the future (such as cancer screening decisions) [40, 57, 58]. Knowledge and risk perception is unlikely to be affected by the hypothetical scenario, whereas parents' attitudes toward antibiotic use, intent to use an antibiotic, and level of decisional conflict might differ when their child is sick and there is a need to make and act on a decision. These constructs might also be influenced by the interaction with a doctor in a consultation

(where the decision aids are ultimately intended for use). Parents' judgement of the usability and acceptability of the materials is unlikely to be affected by the hypothetical setting. The high educational attainment of the participants in both study groups may limit generalisability. A further limitation is that recall accuracy (particularly of risk probability questions) may have been aided by administration of the post-test questionnaire immediately after reading the allocated information, although this would not be particularly different from how the aids would be used during primary care consultations, and is a common approach in trials of decision aids [24].

5 Conclusions

Brief decision aids about antibiotic use for common ARIs in children enabled more parents to make an informed choice about this decision in a hypothetical situation. However, substantial improvements in knowledge about the benefits and harms of antibiotics may not be sufficient to change parents' attitudes about antibiotics or their intention to use them for a child with an ARI. Parents liked the format and structure of the decision aids, balanced content, and visual presentation of benefit and harm data. Evaluation of the effectiveness of the decision aids on antibiotic prescribing in primary care is required. Decision aids are intended for use as a tool to facilitate shared decision making between the doctor and patient during a clinical encounter, and their effectiveness in this clinical context needs to be established next.

Compliance with Ethical Standards

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