Intervention planning for Antibiotic Review Kit (ARK): a digital and behavioural intervention to safely review and reduce antibiotic prescriptions in acute and general medicine

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Background: Hospital antimicrobial stewardship strategies, such as ‘Start Smart, Then Focus’ in the UK, balance the need for prompt, effective antibiotic treatment with the need to limit antibiotic overuse using ‘review and revise’. However, only a minority of review decisions are to stop antibiotics. Research suggests that this is due to both behavioural and organizational factors.

Objectives: To develop and optimize the Antibiotic Review Kit (ARK) intervention. ARK is a complex digital, organizational and behavioural intervention that supports implementation of ‘review and revise’ to help healthcare professionals safely stop unnecessary antibiotics.

Methods: A theory-, evidence- and person-based approach was used to develop and optimize ARK and its implementation. This was done through iterative stakeholder consultation and in-depth qualitative research with doctors, nurses and pharmacists in UK hospitals. Barriers to and facilitators of the intervention and its implementation, and ways to address them, were identified and then used to inform the intervention’s development.

Results: A key barrier to stopping antibiotics was reportedly a lack of information about the original prescriber’s rationale for and their degree of certainty about the need for antibiotics. An integral component of ARK was the development and optimization of a Decision Aid and its implementation to increase transparency around initial prescribing decisions.

Conclusions: The key output of this research is a digital and behavioural intervention targeting important barriers to stopping antibiotics at review (see http://bsac-vle.com/ark-the-antibiotic-review-kit/ and http://antibioticreviewkit.org.uk/). ARK will be evaluated in a feasibility study and, if successful, a stepped-wedge cluster-randomized controlled trial at acute hospitals across the NHS.

Introduction

Antimicrobial resistance is an important public health risk, resulting in increased healthcare costs, treatment failure and mortality. Antibiotic exposure increases the risk of antibiotic resistance, so it is vital to reduce antibiotic over-use. Two successful strategies in primary care are avoiding and delaying prescribing antibiotics. However, these approaches are not appropriate in hospitals, as patients may have a life-threatening bacterial infection for which delaying antibiotics increases mortality. Hospitals therefore need to balance early and effective antibiotic treatment with reducing unnecessary antibiotic use.

‘Start Smart, Then Focus’ is an antimicrobial stewardship initiative developed by the UK Department of Health. It promotes early initiation of antibiotics followed by active review and revision of
antibiotic prescriptions within 48–72 h, with five actions: stop, continue, change (narrow/broaden), move from intravenous to oral formulations, or move to outpatient parenteral antimicrobial therapy (OPAT). Although often started appropriately, in practice few antibiotic prescriptions get modified following initial prescription.¹⁰ There is currently a lack of evidence regarding how best to implement ‘review and revise’ in clinical practice.¹¹ Several behavioural and organizational factors can impede ‘review and revise’, including a reluctance on the part of healthcare professionals (HCPs) to revise antibiotic prescriptions made by others, even when a patients’ clinical status has evolved.¹²

The aim of the current research was to develop the Antibiotic Review Kit (ARK) intervention. ARK aims to safely reduce antibiotic use through increasing effective implementation of ‘review and revise’, focusing on facilitating stopping antibiotics when they are no longer needed. The target population is HCPs involved in administering or prescribing antibiotics in acute and general medicine, and associated medical specialities. This paper comprehensively describes the planning, development and optimization of ARK.

Methods and results

ARK is a complex digital, behavioural and organizational intervention that was developed using an integrated approach to intervention development, combining theory-, evidence- and person-based approaches.¹³–¹⁵ This approach has been used successfully to develop digital and behavioural interventions in a variety of contexts, including reducing antibiotic usage in primary care.¹⁶,¹⁷ ARK was developed and optimized using a novel application of the person-based approach that used iterative stakeholder consultation with HCPs. Stakeholder consultation has long been advocated as a method for maximizing the acceptability and feasibility of interventions and their implementation.¹⁸ However, it has been little used in this field,¹⁹ and there are few explicit descriptions of how it can be used in practice.²⁰ The intervention was developed in three iterative stages: (1) initial intervention planning and development; (2) optimization of the digital intervention (an online educational, motivational and decision support tool); and (3) optimization of the implementation. Evidence of potential barriers and facilitators to stopping antibiotics at ‘review and revise’ and effective implementation was collated at each stage using stakeholder consultation (Table 1). All workshops was recorded and detailed notes were taken by at least two minute-takers at each workshop, with audio recordings used as a cross-reference.

Where appropriate, additional qualitative research was used to gain a more in-depth understanding of the intervention’s target users’ needs, issues, context and challenges. This evidence informed the planning, development and optimization of the intervention and its implementation at each stage of development.

The methods and key results for each stage are presented below.

Table 1. Summary of aims and outcomes of the stakeholder workshops

| Workshop workshop          | Aims                                                                 | Participants                                                                 | Feedback from workshop                                                                 | Outcomes of workshop                                      |
|----------------------------|----------------------------------------------------------------------|------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|------------------------------------------------------------|
| Workshop 1, March 2016 (Stage 1) | To explore views on the initial proposed design and elements of the intervention and identify key acceptability and feasibility issues. | 18 healthcare professionals working in infectious disease, microbiology, paediatrics, geriatrics, public health, general medicine and/or acute medicine. This included 8 consultant-grade doctors, 8 training-grade doctors, a pharmacist and a nurse. | Information about the context of ‘review and revise’ and stopping antibiotics in hospitals, key clinical issues, and experiences of existing antimicrobial stewardship initiatives. Feedback on the main tasks and timeline of the implementation phases. Feedback on the initial plan for the audit tool. | Identification of barriers and facilitators to stopping antibiotics at ‘review and revise’ to inform intervention planning. Development of initial intervention components and materials. Refinement of the number and content of the implementation phases. Development and refinement of the implementation documents. |
| Workshop 2, December 2016 (Stage 3) | To elicit feedback on the proposed implementation plan and documents (implementation phases, audit and feedback, checklist and audit tool). | 12 healthcare professionals working in infectious diseases, microbiology, general medicine and/or acute medicine. This included 9 consultant-grade doctors, 1 training-grade doctor and 2 pharmacists. | Feedback on how teams could implement the Decision Aid categories and audit tool in their hospital. Clarifications about the required steps of the implementation phases. | Refinement of the implementation phases and documents. Refinement of the digital materials. |
| Workshop 3, February 2017 (Stage 3) | To elicit views on the complete ARK intervention from teams who were planning to implement it shortly. | 21 healthcare professionals working in infectious disease, microbiology, general medicine and/or acute medicine from 4 hospitals who were candidates for taking part in the feasibility and pilot studies. This included 12 consultant-grade doctors, 4 training-grade doctors and 5 pharmacists. | Feedback on how teams could implement the Decision Aid categories and audit tool in their hospital. Clarifications about the required steps of the implementation phases. | Refinement of the implementation phases and documents. Refinement of the digital materials. |

Each workshop lasted around 3 h.
Stage 1: initial intervention planning and development

Stage 1 involved the initial planning and development of the intervention. This process was informed predominantly by the results of Stakeholder Workshop 1 (Table 1), which provided the basis for two key outputs: (i) ‘guiding principles’ to orientate the intervention’s key components/techniques and outcomes (Figure 1). A description of the intervention following TIDieR guidance was also complete, and the elements of the intervention were mapped onto a generic theoretical framework and taxonomy (Supplementary data).

Stakeholder Workshop 1

The first stakeholder workshop presented the aims of ARK and potential intervention components (Table 1). Previous research into methods to reduce antibiotic usage in hospitals was limited, and therefore the initial plan was informed by previous interventions targeting antibiotic reduction in primary care. Six intervention components were initially proposed:

- A 30 min personalized digital education module for self-completion.
- The introduction of antibiotic prescribing ‘moments’ (initial prescription, ‘review and revise’), analogous to WHO hand-hygiene ‘moments’.
- A standardized ‘review and revise’ pro forma and algorithm for describing clinical presentation and deciding what diagnostic tests would be needed to inform and optimize ‘review and revise’ decisions.
- Regular antibiotic stewardship ward rounds and/or regular ward pharmacist review.
- Regular 45–60 min peer-led seminars for discussing experiences of ‘review and revise’.
- A patient leaflet.

Participants were asked for their feedback on the proposed intervention components, their ideas and experiences, and examples of ‘review and revise’ in their hospitals.

Stakeholder feedback

Participants were sceptical about the acceptability of the digital education module due to high workload and the large amount of existing e-learning modules, which many found boring and pointless. Although discussions about ‘review and revise’ were seen as helpful, participants stated that it can be difficult to get people to attend seminars. Alternative suggestions were to link in with ward ‘huddles’ and handover meetings.
One of the biggest problems stakeholders reported was that initial prescription and ‘review and revise’ were undertaken by different HCPs. The reason for initial prescription and degree of certainty regarding the initial need for antibiotics was often unclear, meaning that the reviewer was reluctant to revise the initial prescription in case they had missed something important about the initial presentation. In the absence of accurate information about the status of the patient at the initial prescription, stopping was seen as riskier than continuing antibiotics. It was suggested that acknowledging the degree of uncertainty in initial prescriptions would be helpful. Participants felt that senior staff needed to input into ‘review and revise’ decisions but had limited time. Whilst junior doctors, pharmacists and nurses might have important roles in supporting ‘review and revise’, they might lack confidence in doing so. It was felt that HCPs would benefit from understanding the consequences of stopping antibiotics, why it was safe, and how restarting antibiotics (if needed) was acceptable. Analogies were made to discharging patients, accepting that while a small minority might need to be re-admitted, most did well.

Overall, participants disliked the idea of having a standardized pro forma and algorithm, partly because of substantial challenges in introducing it into diverse hospital contexts, with different, competing policies and practices. Some hospitals had paper-based prescribing, others e-prescribing. It was suggested that ARK would need to integrate into existing routines and practices, and should provide a selection of tools to facilitate implementation, such as a system for flagging up prescriptions needing review, e.g. by using pop-ups, stickers or highlighters on the drug chart.

**Consultation outcomes**

Stakeholder Workshop 1 highlighted a few key issues regarding the intervention’s design and adjustments that needed to be made to the initial plan and its components. Key guiding principles for the intervention’s design are shown in Table 2.

### Table 2. The guiding principles for the development of the ARK intervention

| Intervention design objectives | Key features |
|-------------------------------|--------------|
| To increase HCPs’ (a) motivation and (b) confidence to stop antibiotics | • (a) Provide scientific evidence and case studies to convince HCPs that:  
  o Stopping antibiotics is safe.  
  o Continuing antibiotics puts patients at increased risk from antibiotic resistance.  
  • (b) Provide tools to support the ‘review and revise’ process and stopping antibiotics, including:  
  o The Decision Aid categories as a solution to the problem of not understanding how the original prescriber viewed the patient’s presenting condition.  
  o The patient leaflet to support communicating ‘review and revise’ and the risks of antibiotics to patients and to provide safety-netting advice. |
| To provide easily accessible tools that are suitable for a range of staff groups and grades (prescribers and non-prescribers) | • Make tools easily accessible as web-based and phone app.  
  • Make the online tool very short, simple and engaging, suitable for busy doctors, pharmacists and nurses. |
| To empower and support acceptable and feasible implementation of effective ‘review and revise’ across a range of hospital contexts | • Offer a variety of implementation resources that can be adapted to a variety of clinical contexts.  
  • Promote the HCPs’ ownership of the implementation, giving them the opportunity to work out how the resources could best be implemented within their context. |

HCPs, healthcare professionals.

Several changes were made to the intervention plan. Firstly, the standardized pro forma and algorithm was replaced with a flexible Decision Aid for communicating the degree of certainty surrounding the initial decision to prescribe antibiotics (Figure 2). Initial antibiotic prescriptions are categorized as either ‘possible’ risk of infection (infection is less likely but antibiotics are being prescribed as a precaution) or ‘probable’ risk of infection (infection is likely but more information is required before finalizing the diagnosis/treatment). At review, prescriptions are either stopped (no evidence of a continued need for antibiotics) or finalized (decision made about final agent, route and duration).

Secondly, the 30 min personalized digital education module was changed to a brief online tool (7–10 min) to take into account the demands on HCPs’ time and negative perceptions regarding...
length of other e-learning modules. Thirdly, peer-led seminars were replaced with brief, regular, supportive discussions embedded within routine clinical team meetings. Finally, it was decided that the implementation team, including an ARK Champion (site lead) and a small number of other HCPs representing key disciplines and staff grades, needed a selection of resources and guidance to help them implement ARK flexibly depending on local needs. The development and optimization of these resources is discussed more fully below in the section describing Stage 3. The final intervention logic model is shown in Figure 1 and a complete description of the intervention can be found in the Supplementary data.

Stage 2: optimization of the digital intervention

Ethics
Ethical approval for the qualitative research was obtained from the London–Westminster Research Ethics Committee (REC: 16/LO/0789). All participants provided written informed consent.

Design and procedure
In Stage 2, the key HCP intervention materials (online tool and Decision Aid) were optimized through in-depth qualitative research using think-aloud interviews with a broader range of HCPs who were involved with antibiotic prescribing. The development and optimization of the patient leaflet will be reported separately (F. Mowbray, K. Siyver, M. Santillo, N. Jones, T. E. A. Peto, A. S. Walker, M. J. Llewelyn, L. Yardley, unpublished data).

Participants were recruited through the stakeholder network, with stakeholders approaching colleagues at different hospitals to ask them to promote the study to their colleagues. Interested individuals then directly contacted the research team to arrange an interview. Face-to-face think-aloud interviews were carried out with 20 HCPs (6 consultant-grade doctors, 6 training-grade doctors, 6 pharmacists, 2 nurses) from six hospitals to elicit detailed feedback on the online tool. Participants were asked to read each page of the website (or the mobile-friendly version) and say aloud what they were thinking while reading the pages. Interviews lasted 40–60 min and were recorded and fully transcribed. Data collection was an iterative process, with initial interviews leading to modifications, followed by further interviews to assess these modifications. Interview feedback and resulting modifications to the online tool can be found below.

Feedback was collated into a table of positive and negative comments for each page of the online tool (totalling 70 pages). Potential changes identified from these comments were discussed with the core research team throughout intervention development in order to agree modifications to the online tool.

Interview feedback
The think-aloud interviews elicited mainly positive views of the online tool, but, crucially, the implication that some clinicians were unconvinced by earlier versions that antibiotics could be stopped safely. Participants wanted more information about the evidence regarding the risks and benefits of shorter versus longer courses of antibiotics. They also suggested providing information about current guidelines for antibiotic durations in different countries and guidelines relating to ‘surviving sepsis’, as they considered these important to informing ‘review and revise’. They requested more explanation of the intervention and how the Decision Aid could help to safely reduce antibiotic prescribing.

Intervention outcomes
The content of the online tool was refined. More information was added about different clinical guidelines and the evidence for shorter versus longer courses of antibiotics. A page was added to clarify the roles of non-prescribers in supporting ‘review and revise’ to make the intervention more inclusive. The roles of senior members of staff and specialists were made more explicit. Additional information was provided about how the Decision Aid would help to safely reduce antibiotics. The Decision Aid categories were refined to make them easier to understand for different professional groups and to make them more clinically accurate.

Stage 3: optimization of the implementation

Stage 3 developed and optimized the implementation guidance and resources. These materials were informed by previous research supporting the positive effects of audit and feedback on antibiotic prescribing, and research that used the Theoretical Domains Framework Implementation (TDFI) approach, to provide guidance and tools to support team-based implementation. Refinements were informed by Stakeholder Workshops 2 and 3 (Table 1).

Stakeholder Workshop 2
This workshop presented an overview of the initial implementation guidance and resources to participants from Workshop 1 (Table 1). The following resources were presented:

• Phases of implementation and implementation checklist.
• Kick-off meeting slides for introducing ARK to clinical teams.
• Data collection tool.

Participants were asked to give feedback on the phases of implementation and other resources, and to identify potential barriers to implementation.

Stakeholder Workshop 3
This workshop presented the revised implementation guidance and resources, including a spreadsheet version of the data collection tool that was aligned with the Commission for Quality and Innovation (CQUIN) in place at the time. This workshop included HCPs from hospitals that were candidates for the feasibility and pilot studies, and therefore had a specific interest in understanding how to implement ARK in their hospitals.

Stakeholder feedback
Participants in Stakeholder Workshop 2 expressed concerns about how the implementation team would be trained and updated about new developments in the long term. They also reported concerns about incorporating the Decision Aid categories into practice, including how long it would take to change the drug chart and how to do so in e-prescribing systems. They suggested that it
might be difficult communicating with different clinical teams about ARK and that there might be poor completion of the online tool before kick-off. Participants were unsure how data collection would work, although it was felt it would be important to show local rates for ‘review and revise’ and stopping antibiotics.

Similar issues arose in Stakeholder Workshop 3. Participants responded positively to the kick-off slides and rationale for ARK, particularly the ‘Elevator pitch’, which provided a quick but direct summary of the rationale for ARK. However, participants were still unsure how best to implement the Decision Aid categories in practice, and wanted further clarification on how best to do data collection. Whilst the new data collection tool was seen as useful, it was suggested that it needed simplifying. Participants also requested that it provide other useful data (e.g. information about decisions taken at review). Participants reported concerns around how to facilitate understanding of the Decision Aid categories and suggested that it would be helpful to have clinical scenarios in online tool to practise applying the Decision Aid categories. Participants were also concerned about the potential impact of staff turnover.

**Intervention outcomes**

The phases of implementation were adjusted to introduce piloting the Decision Aid categories and the data collection tool to ensure that hospitals had tested and were familiar with these processes before implementing them. A new phase was added, which focused on publicizing ARK to the clinical teams and encouraging completion of the online tool to increase its uptake (Figure 3).

Several new resources were created. A spreadsheet data collection tool was developed following Workshop 2 in response to concerns about data collection, and refined following feedback at Stakeholder Workshop 3 (e.g. simplifying the layout, clarifying definitions and instructions, providing additional graphs). To support ongoing training and facilitate sharing resources between hospitals, an ARK Network was developed for the implementation team (e-mail list and teleconferences). The online resources were also extended so that example materials from different hospitals could be uploaded.

Finally, a short quiz was added to the online tool for participants to practise and get feedback on applying the Decision Aid categories to clinical examples. The ‘Elevator pitch’ was also added to the online tool to enhance the persuasiveness of the message about the rationale for ARK.

The final phases of implementation and full behavioural analysis can be found in the Supplementary data.

**Discussion**

This paper describes the development of the ARK intervention, which aims to safely reduce antibiotic use in hospitals through stopping unnecessary antibiotics at ‘review and revise’. Intervention development used a novel adaptation of the ‘person-based’ approach to intervention development, which used stakeholder consultation with HCPs involved in antibiotic prescribing to explore experiences of ‘review and revise’ and stopping, and to elicit feedback on the proposed intervention and its implementation.

This provided a better understanding of HCPs’ previous experiences of initiatives around prescribing, the current context of antibiotic prescribing in hospitals, and potential barriers and facilitators to ‘review and revise’ and the implementation of ARK. In-depth think-aloud interviews added more detailed information about reactions to the online tool from a broader sample of HCPs. These methods underpinned the planning, development and optimization of ARK and its implementation to increase its acceptability, feasibility, and, ultimately, its effectiveness. Crucially, ARK provides potential suggestions for addressing barriers. This is likely to be helpful for other initiatives incorporating similar activities.

Research suggests that clinicians can be reluctant to revise others’ prescriptions due to a culture of ‘non-interference’, with senior clinicians having a strong influence on this process. The current research extends this, highlighting the role of poor communication about the reason for and degree of uncertainty about the need to initially prescribe antibiotics. This was reportedly a key barrier, and resulted in the development of one of the core elements of the intervention: the ARK Decision Aid. Prior research
has identified that stopping antibiotics ‘early’ is perceived as risky, and that junior doctors in particular may lack confidence in this.²¹ Some clinicians report scepticism regarding guidelines for stopping antibiotics.²² This was also found here, further highlighting that beliefs about the need to ‘continue the (antibiotic) course’ are a barrier to ‘review and revise’.³³ This informed the development of another core element of the intervention: the online tool, which provided a rationale for ‘review and revise’ and evidence for shorter versus longer courses of antibiotics.

Stakeholder consultation highlighted that the intervention needed to consider the wide range of hospital contexts that ARK could be implemented in and the different HCP groups that it could affect. This led to the development of multi-faceted tools to support flexible implementation depending on local needs, which targeted all members of the clinical team (doctors, nurses and pharmacists). Previous studies have identified a lack of clear/agreed roles for pharmacists/nurses in ‘review and revise’, and a perception that ‘review and revise’ was the responsibility of prescribers.³⁴,³⁵ Although these findings emerged in Australia, where pharmacists and nurses cannot prescribe, and may apply less to the UK, a key benefit of ARK is its inclusive nature, with both prescribers and non-prescribers supporting ‘review and revise’ as a team.

Research into barriers and facilitators to implementing antimicrobial stewardship initiatives has focused on existing programmes that have usually been running for >1 year,³⁶–³⁸ so little is known about barriers to implementing new initiatives. However, both organizational culture and availability of resources have been identified as important for implementation.³⁶,³⁸ There has been little research into the acceptability and feasibility of particular intervention components and how best to implement them.³⁷ Particular implementation barriers for ARK included: lack of uptake of the online tool due to negative perceptions of e-learning; poor attendance at seminars, suggesting the need to integrate with existing meetings; and uncertainty about how to integrate the Decision Aid categories into practice. All of these barriers informed the development of the intervention and its implementation. For example, the online tool was designed to be brief (7–10 min) and engaging, and a range of suggestions for different ways to implement ARK were provided.

A major strength of this research was the use of stakeholder consultation throughout planning, development and optimization of ARK and its implementation, which previously has been lacking in the field.¹⁹ This agile new method allowed the research team to rapidly understand and respond to target users’ needs and views.²⁰ This permitted dialogue between researchers and key stakeholders and facilitated the co-creation of intervention materials. It was an efficient method for developing and testing initial ideas for the intervention and its implementation. It was nevertheless vital to complement stakeholder consultation with in-depth qualitative research with a more representative and diverse sample from the target user population. Stakeholder workshop attendees were enthusiastic, exceptionally well-informed volunteers, most of whom had an interest in antimicrobial stewardship. A large proportion were clinicians. Pharmacists were under-represented at earlier stages of development, and nurses throughout. They therefore did not fully represent the target population. Moreover, stakeholder workshops cannot provide the detailed, individual feedback that was obtained by using qualitative research methods. The think-aloud interviews collected structured, in-depth data on participants’ personal reactions to every element of intervention content, and were undertaken with a range of staff groups and grades who were involved in antibiotic prescription and administration but not necessarily antimicrobial stewardship. These interviews revealed crucially different views that the intervention needed to address.

One programme is unlikely to fit all needs; however, a good solution might be to provide a toolkit and advice based on potential barriers to allow implementation based on local needs.³⁷ ARK fits well with this approach, being explicitly designed to address barriers and facilitators to stopping antibiotics at ‘review and revise’ and implementation. A key issue in translating interventions into practice is finding the balance between intervention fidelity and the need for adaptation.⁴⁹ Adaptation is integral to ARK, designed to support its translation into practice. This need was highlighted by stakeholders as a key design feature to support implementation across diverse hospital contexts. Identifying implementation barriers and facilitators and defining and developing antimicrobial stewardship initiatives have both been identified as research priorities.⁶⁰ Nonetheless, further research is needed to assess how well this works in practice. ARK’s acceptability, feasibility and effectiveness also needs to be established. A feasibility trial in one hospital has already been undertaken; initial results suggest that ARK is acceptable and feasible to both HCPs and patients. ARK is now being tested in a stepped-wedge randomized controlled trial at acute NHS hospitals, which will include a full process evaluation. The ARK online tool has now been made freely available at http://bsac-vle.com/ark-the-antibiotic-review-kit/, and the implementation resources are freely available at http://antibioticreviewkit.org.uk/.

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Disclaimer
The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

Supplementary data
A description of ARK (Supplement 1), behavioural analysis of ARK (Supplement 2) and an overview of the phases of implementation (Supplement 3) are available at JAC Online.

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