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A Wicked Problem and the SIMPlE Solution

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Introduction

Antibiotics can be both a necessary and a lifesaving treatment option. However, after years of over and mis use of this once miracle drug, we are entering a new era where antibiotics will no longer work to cure infections. There is currently no new antibiotics under development. Antibiotic Resistance (ABR), the term used to describe when an antibiotic has lost the ability to kill a bacteria effectively, is a major threat to public health. The consequences of ABR are far reaching and include for example increased cost of illness through treatment failure and prolonged illnesses. Antibiotics make the treatment of infection possible and as ABR reaches critical levels action is urgently required to address this public health risk.

Situation Analysis

ABR is a wicked problem and although ABR is having a major impact on our health, causes are far reaching and span beyond our health system to sectors such as agriculture, veterinary, food production and public policy. There is little consensus between the major stakeholders from these sectors on how best to tackle the problem. For example ABR can spread through our consumption of antibiotics, be passed from person to person as we share bacteria and be directly and indirectly passed through our water system. As such ABR contributes to a collective action problem whereby the more we use antibiotics the greater the consequences (Anomaly 2013); a holistic collaborative approach is required to begin the change process (Edgar, Boyd et al. 2009, Duane, Domegan et al. 2015). Scientific discovery and changes in behaviour at both individual, community and population levels must play a role in the solution (Amyes 2000).

This case study focuses on addressing ABR in our health system, and more specifically antibiotic prescribing by general practitioners (GPs) in the community.

Segmentation: ABR and General Practice

GPs have been recognised as one contributor to the problem of ABR due to the over prescription and inappropriate prescription of antibiotics (Wise, Hart et al. 1998, Cunney 2001, Lipsitch and Samore 2002, Vellinga, Cormican et al. 2011). Examining the issue at a local level, Ireland is one of only three countries in Europe where outpatient antibiotic

prescribing is increasing (Vellinga, Murphy et al. 2010, Vellinga A 2010). Here, 80% of antibiotic prescribing takes place in the community by GPs (Murphy M, Byrne S et al. 2011). Therefore improving the quality and quantity of antibiotic prescribing at this level will have a positive impact on the overall ABR issue. A major challenge however, is that many GPs and patients do not see ABR as a reason to stop using antibiotics (Costelloe, Metcalfe et al. 2010). GPs can also feel pressurised by patients to prescribe an antibiotic (Public Health England 2010). We also know from previous research that although antibiotic prescribing guidelines are available in Ireland, in the case of urinary tract infections (UTI), less than 40% of antibiotic prescriptions for UTIs were according to those recommended (Vellinga, Tansey et al. 2012). UTIs are the second most common infection presented in primary care and ABR is impacting on their treatment. UTIs are often treated empirically. This means that GPs make the decision to treat a UTI based on their clinical experience and the interaction with the patient i.e. the symptoms the patient describes as opposed to waiting on the results of a microbiological analysis that confirms the infection which can take a few days to receive.

Although the researchers were aware that GPs were inappropriately prescribing antibiotics, we needed to understand why and in what circumstances GPs were deciding to prescribe inappropriately.

Formative Research

Rigorous formative research was instrumental in designing this social marketing complex intervention as well as its recruitment and retention strategies. The formative research explored the culture of antibiotic prescribing and consumption in the community for UTI from the perspective of both the GPs (n=15) and community members (n=6 community focus groups with 42 participants). It identified key barriers and facilitators to change. The topic guides were developed in consultation with a multidisciplinary team of experts and a review of literature. Two decision making theories also guided the development of the topic guide and the analysis process. The Trans theoretical Model (TTM) (Prochaska and Velicer 1997) and the Buyer Behaviour and Decision Making Model (Howard and Sheth 1969) were adopted to understand the interrelating contextual factors and processes which contributed to the decision to prescribe or consume an antibiotic. Table 1 summaries the key questions discussed.

Table 1: Summary of key questions discussed within this research

GP Interview Questions	Focus Group Questions
Section 1: Usual practice for treating a UTI	Section 1: General Health and GP Consultations
Can you talk me through how you would normally diagnose someone with a UTI? What treatment do you recommend, how do you make this choice? Please describe the role of the patient in the diagnosis?	Activity to establish participants health seeking behaviours and current relationship with GPs
Section 2: Antibiotics	Section 2: Awareness of Antibiotics
Overall, what are your views on prescribing antibiotics? Positive/negative aspects? Do these views change for a UTI patient? Have you ever received any guidelines on prescribing antibiotics? Can you remember what the guidelines are? Do they include UTI? How did you feel about using this guidelines in practice?	Can you explain to me what an antibiotic is? Have you been prescribed any kind of antibiotic in the past year? Did you ask your GP/doctor any questions relating to the prescription? Can you describe the benefits and consequences of taking an antibiotic?
Section 3: Antimicrobial resistance	Section 3: Urinary Tract Infections Experiences and Associations
Are there any adverse side effects to prescribing antibiotics? Do you know what the antimicrobial resistance patterns are in your area?	Scenario based exercise describing symptoms experienced by a typical UTI patient. Discussions of personal experiences of having a UTI and the actions taken throughout the illness. Has anyone here ever experienced a Urinary Tract Infection (UTI) or known someone that has had one – what words or phrases would you associate with it? Please describe the steps that you go through when deciding to go to see your GP doctor key priorities. Scenario based exercise to discuss association between UTI illness and antibiotic.
Section 4: Intervention Design	Section 4: Antibiotic Resistance
Discussion of possible strategies to facilitate changing their attitudes and behaviours towards prescribing antibiotics for UTI.	Have you ever heard of the term antimicrobial resistance? What does it mean to you? In what context did you hear it?
	Section 5: Intervention Design
	Discussion of possible strategies to facilitate changing their attitudes and behaviours towards consuming antibiotics for UTI.

(Duane, Domegan et al. 2016)

The results of the formative research and its influence on the design on the intervention are summarised in Table 2. Although the UTI consultation itself was quite routine the decision to prescribe or consume an antibiotic for a UTI is a set of complex interacting processes. The interaction between the GP and patient both at the time of consultation and from previous experiences was instrumental in determining its outcome – whether the patient received an antibiotic or not. Additionally, not every GP or patient were at the same stage of change. For example, some GPs were confident in prescribing an antibiotic for every suspected UTI they saw (habitual prescriber- pre-contemplator). Other GPs tried to avoid immediate antibiotic treatment by suggesting delayed treatment, whereby the patient waits and sees if their symptoms improve for a few days before considering antibiotic treatment (questioning prescriber – contemplation/ action).

Three profiles of patients emerged from the research; the young professional (quick fixers- pre-contemplation), the young mothers (advice seekers- contemplation/action) and the mature patient (experienced consulters- precontemplators). Each type of patient could be satisfied differently by the GP from a ‘simple’ UTI consultation. The ‘quick fixers’, adopt a low involvement approach and are satisfied to receive their antibiotic prescription. The ‘advice seekers’ adopt a higher involvement perspective, discussing treatment options for their illness, an antibiotic is not a satisfactory outcome in all instances. Finally, the experienced consulters, have experienced a UTI and antibiotic treatment in the past reinforcing the norm and expectations of treatment. In all cases, the GPs decision making power hinges directly on the type of patient consulting for a UTI and vice versa. The findings indicated the interaction within the consultation and dialogue between the GP and patient which activate the outcome (Duane, Domegan et al. 2016). Similarly to other research, the GPs interviewed favoured an intervention that would support their skills (Velasco, Ziegelmann et al. 2012) and would not have a major impact on the duration of the consultation as time was also an important factor. GPs would not participate in an intervention if it unnecessarily elongated the consultation – which was usually short and straightforward. Focus group participants wanted a conversation with the GP about their illness and the treatment options available (Duane, Callan et al. 2013, Duane, Domegan et al. 2016).

SIMPlE Intervention

Combining what we knew from the situational analysis with what we found in the formative research the ‘Supporting the improvement and management of prescribing for urinary tract infections’ (SIMPlE) study was designed by a team of multidisciplinary researchers. Our team combined knowledge and expertise from social marketing, health economics, microbiology, general practice and epidemiology to design this successful intervention. GPs were prioritised as the target of the SIMPlE intervention as they were the gatekeepers who gave patients access to antibiotics through prescribing. SIMPlE focused on the interaction between the GP and patient within the UTI consultation.

Objectives

SIMPlE’s overall aim was to design, implement and evaluate the effectiveness of a complex intervention on GP antibiotic prescribing and adult (18 years of age and over) patients’ antibiotic consumption when presenting with a suspected UTI. More specifically we sought to increase the number of first-line antibiotic (nitrofurantoin) prescriptions, as recommended in the Guidelines for Antimicrobial Prescribing in Primary Care in Ireland (2011), for suspected UTIs in primary care by 10% in adult patients (Duane, Callan et al. 2013).

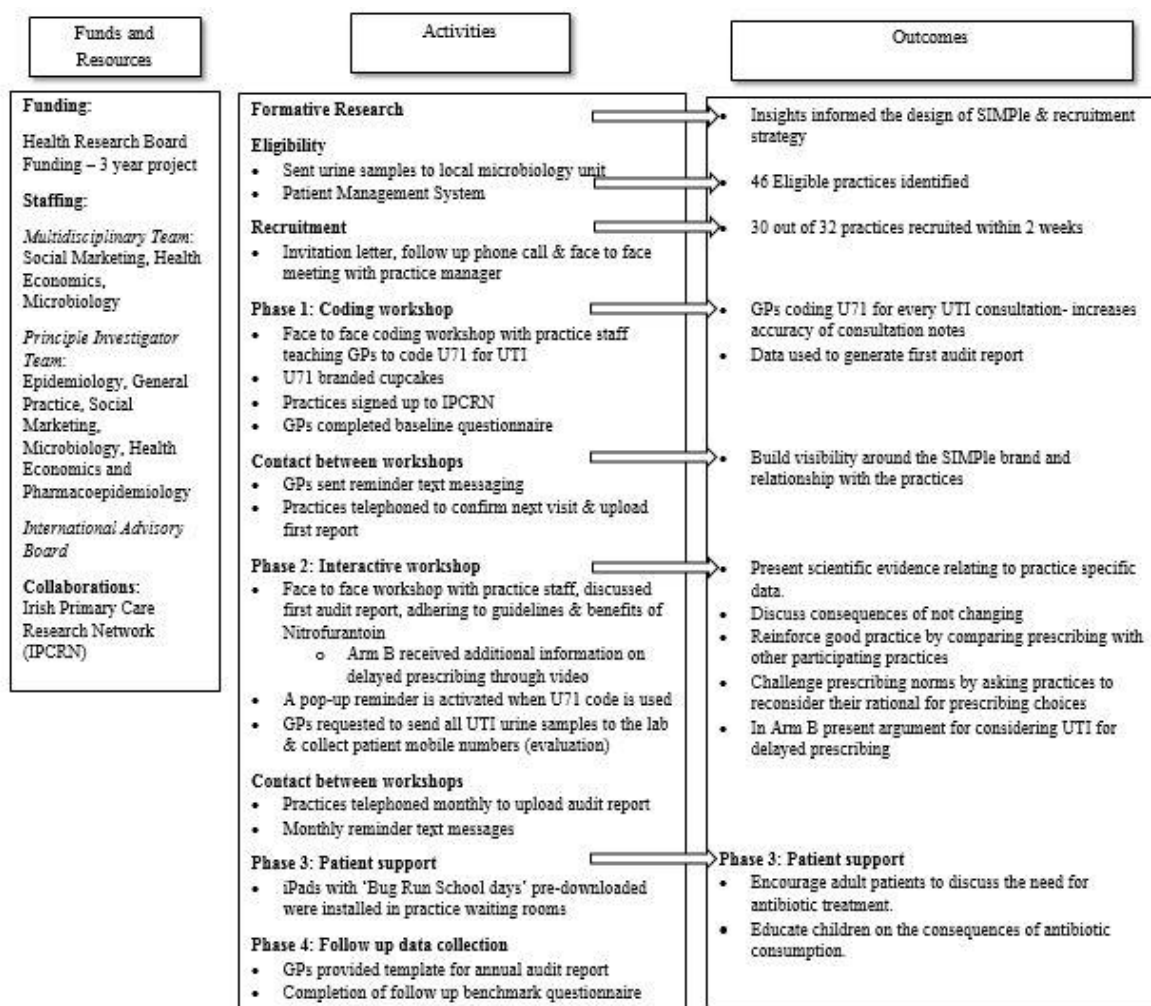
Table 2: Summary of results from formative research

Theme	Community Member	GP	Influence on intervention design options
Knowledge of Antibiotic resistance (ABR)	<ul style="list-style-type: none"> • Knew what ABR was but found it difficult to define or explain • Discussed becoming immune to antibiotics • Women were interpreted to be more knowledge than men • Believed antibiotics would always be available 	<ul style="list-style-type: none"> • Knowledgeable about what it is and what contributes to it • Focus on long term consequences • Overprescribing contributes to ABR • Other sectors had a role to play 	<ul style="list-style-type: none"> • Simplify key messages and information • Reinforce short term consequences for patients
Treatment of UTI	<ul style="list-style-type: none"> • Severity of symptoms, previous experiences and personal circumstances • Antibiotic was not a satisfactory outcome in all cases, patients also needed reassurance 	<ul style="list-style-type: none"> • Common, easy to treat infection • Prescribed the same antibiotic routinely- could not recall why • Received no guidance on the impact it has on ABR • Dipstick impacted on the GP's decision to prescribe 	<ul style="list-style-type: none"> • Different types of patient emerged, therefore it is not possible to satisfy everything each needing a different conversation • Keep the simplicity of the consultation • Review antibiotics prescribed • Provide evidence for change • Communication and interaction could impact on treatment
The Consultation	<ul style="list-style-type: none"> • Medical card status influenced when the patient decided to consult • Past experiences developed expectations • Patients interpretation of a satisfactory outcome depended on past experience and knowledge • Satisfaction associated with consultation length, the duration, closeness of relationship and communication • Wanted a conversation with their GP in relation to treatment 	<ul style="list-style-type: none"> • Quick, easy in uncomplicated consultation • Unpredictable nature • Wanted patients to be satisfied with outcome 	<ul style="list-style-type: none"> • Integration into routine care • Focus on the interaction within the consultation • Facilitate a conversation
Time	<ul style="list-style-type: none"> • Different profiles of patient had different interpretations of time. Needed to get back to health quickly vs wanted reassurance on the duration of symptoms 	<ul style="list-style-type: none"> • Many determinants of time impacted on consultation, past experience with patient, busy waiting rooms, interpretation that UTI were easily treated 	<ul style="list-style-type: none"> • Integration into routine care • Could not elongate the consultation
Intervention Components	<ul style="list-style-type: none"> • Wanted material to be easy to understand • Make sure it was relevant to them 	<ul style="list-style-type: none"> • Wanted patients to be satisfied with outcome • Valued feedback on prescribing behaviours from experts 	<ul style="list-style-type: none"> • Provide GP with evidence • Focus on interaction between GP and patient

Intervention Design

The SIMPle intervention was a three arm cluster randomised control trial (RCT). Behavioural change was analysed at a general practice level therefore, involving all GPs within each of the 30 practices recruited was important. The thirty recruited general practices were randomised to one of the three intervention arms. Arm A (n= 10 practices) assessed improved antibiotic prescribing according to national guidelines; Arm B (n= 10 practices) improved antibiotic prescribing with the suggestion to delayed antibiotic treatment where appropriate; the control arm (n= 10) usual care. SIMPle incorporated 4 phases; Coding Workshop, Interactive Workshop, Patient support and follow up. Figure 1 illustrates a logic model of the SIMPle intervention.

Figure 1 SIMPle Logic Model



(Duane, Domegan et al. 2017)

Marketing Mix

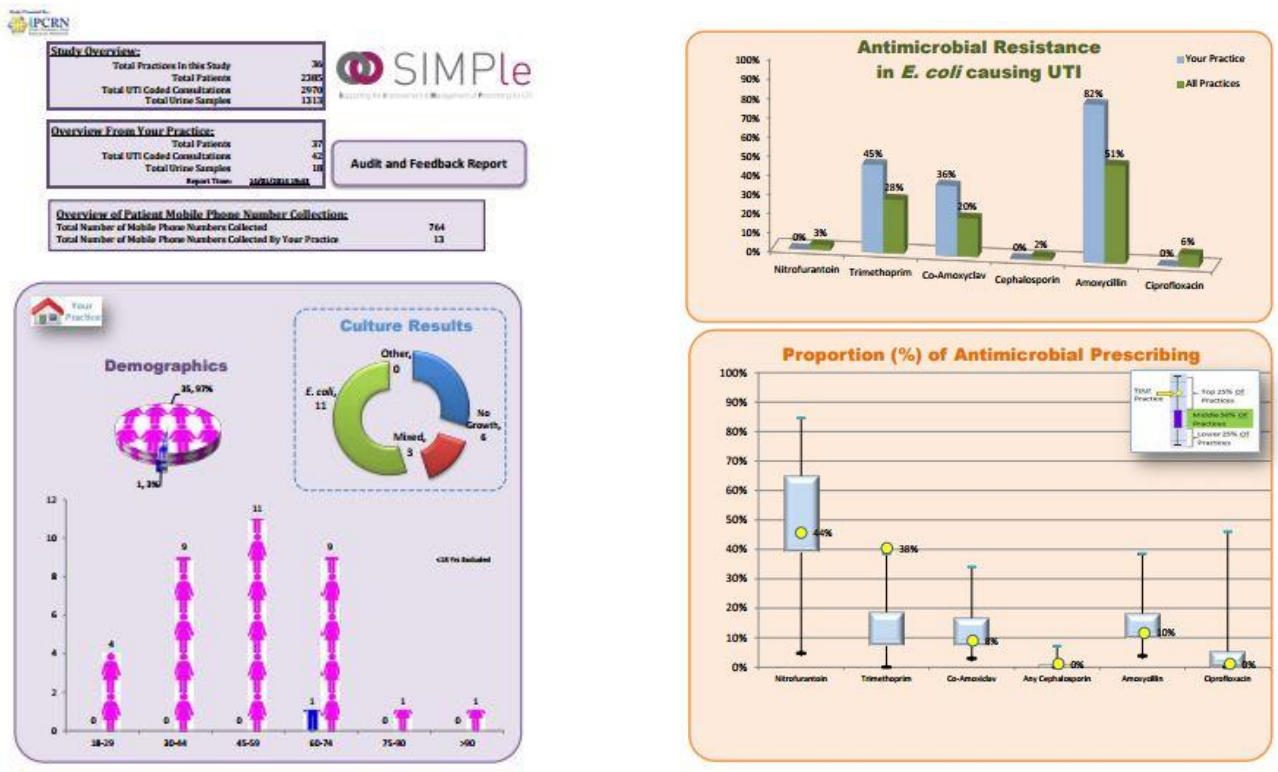
Product

In phase 1, the coding workshop, all GPs within participating practices were taught to code UTI patients (U71) within their patient management software. GPs would have been familiar with the concept of coding consultations for chronic illnesses, however, not all GPs coded every consultation. They were less likely to code acute illnesses such as UTI. Demonstrating to the GP how to code UTI patients (U71) ensured they became familiar with the process and could ask the researcher any questions relating to coding. UTI consultation coding was important for a number of reasons. Firstly, it ensured accurate practice audit and feedback reports were generated, it also helped to maintain accurate patient records. Consultation coding allowed the researchers to electronically extract consultation data to evaluate changes in antibiotic prescribing within participating practices.

Phase 2 began with an interactive workshop. Formative research uncovered issues which impacted on what antibiotic the GP chose to prescribe, the duration of the antibiotic and habit – they prescribed the same antibiotic each time. Practices in intervention arm A and B received information on the national antimicrobial prescribing guidelines and a factsheet outlining the importance of prescribing Nitrofurantoin- the only first line antibiotic the researchers were recommending. This factsheet emphasised the correct dosage, duration of the antibiotic prescription and current levels of community resistance. Practices were also given their first audit and feedback report. This report was very concise (two pages) but contained the evidence the GPs said they required to persuade them to change their antibiotic prescribing behaviours. The audit and feedback report illustrated what the practice was currently prescribing compared with other participating practices and the levels of ABR in their area. Presenting the GPs with an audit and feedback report at this stage allowed the GPs the opportunity to examine what they were prescribing. Practices were encouraged to discuss the prescribing decisions they were making. They could also benchmark themselves against other practices in their area (Figure 2). Therefore the GPs became aware of where changes could be made. By providing the practices with these reports we saved the GPs a lot of time as they could be used to fulfil the GPs professional competency requirements. GPs also received CPD (Continuing Professional Development) points for participating in the workshops.

The intervention practices received a monthly audit of their antibiotic prescribing for UTI by email. To standardise the intervention, control practices received a workshop which focused on their coding routine.

Figure 2 Examples of intervention Material
Product - Audit and feedback report



Treatment of UTI in Primary Care

- ✓ **Nitrofurantoin** is recommended as a first line antibiotic for the treatment of UTI in adult patients (www.antibioticprescribing.ie)¹.
- ✓ Currently only 4% of *E. coli* causing UTI in the west of Ireland are resistant to **nitrofurantoin**. This is in contrast to 30.5% for co-amoxyclav, 30.5% for trimethoprim and 8.3% for ciprofloxacin².
- ✓ Resistance to **nitrofurantoin** is difficult for bacteria to maintain and does not spread within bacterial communities as readily as resistance to other antibiotics^{2, 3}.
- ✓ Research has demonstrated that the uniform use of **nitrofurantoin** for treating UTI can be as effective as other antibiotics but dramatically reduces drug costs².

Product- Nitrofurantoin factsheet

During the interactive workshop practices in intervention arm B also received additional evidence to support delayed prescription of antibiotics for suspected UTI. The GPs were also shown a video demonstrating how to have a conversation with patients about delayed prescribing (<https://www.youtube.com/watch?v=4gFUNTP4DsM>).



All GPs who coded UTI consultations U71 within their patient management software system received a reminder (electronic prompt) outlining the national antibiotic prescribing guidelines (including the web link www.antibioticprescribing.ie). For practices in arm B the reminder also urged the GP to consider delayed prescribing.

Phase 3 (Patient Support) introduced our award winning multimedia application which included a game for children and an infomercial for adults addressing antibiotic awareness (Bug Run School Days). (<https://www.youtube.com/watch?v=wecthQ7Md-Q>). Bug Run school days was designed to support prescribers and patients to begin the conversation in relation to the issue of ABR. Bug Run School Days was installed in the waiting room on an iPad which was supplied to participating general practices. Phase 3 was not introduced in the control practices.

Figure 3 Screen from Bug Run School days



After the six month intervention period (phase 2 and 3), control practices were offered a workshop in which all the supporting materials to create an audit report were presented. At the end of the intervention, control practices received all the intervention material as well as their audit report.

Phase 4, the follow-up period, started at the end of the intervention and included a 5 month period of passive data collection to evaluate sustainability (Vellinga, Galvin et al. 2015).

Place

The SIMPLE intervention was designed to be implemented within general practice in Ireland. SIMPLE was conducted within 20 General Practices, an additional ten general practices were recruited as control practices. Recruited General Practices were required to use the same patient management software. This allowed the researchers to develop electronic prompts (reminders of recommended guidelines) within their patient management system which was activated when the GP coded the UTI patient U71. It also allowed for the electronic extraction of patient information.

SIMPLE was designed so that it could be implemented into routine care and sustainability was emphasised. All intervention components were implemented within each general practice at a time that was convenient. The researchers made appointments before each point of contact. Change was measured at practice level therefore it was important that all GPs within participating general practices engaged with the researcher's.

Price

The formative research highlighted that time was a big pressure for the GP both in their general working environment and within individual consultations. Therefore we used this as leverage for exchange. By coding their UTI patients U71 we were able to remotely extract UTI patient data – this saved the GPs time inputting data. It also allowed us to generate their practice specific audit and feedback reports. The more the GPs coded the more comprehensive their reports were.

Promotion

The researchers developed the SIMPlE logo which emphasised to the GPs that only a simple transition was needed to improve their treatment of UTIs. The researchers ensured that the branding for the study was consistent at any point of contact with the GPs from the audit and feedback reports to sending the practices Christmas cards. We even brought cupcakes with us to the initial workshops to reinforce the study's messages – code UTI patients U71. GPs were also sent text messages on a monthly basis to remind them of the study and what they had been asked to do.

Figure 4 Promotional Material



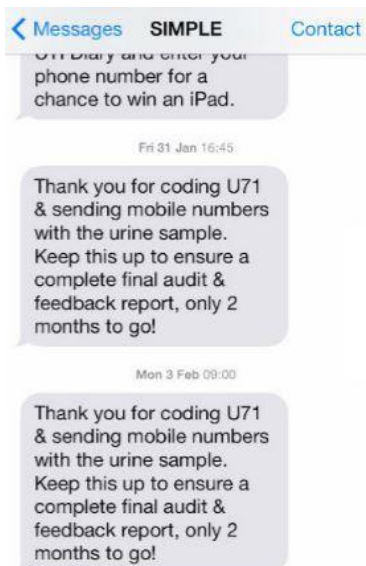


Table 3 Summary of the SIMPlE Marketing Mix

	Marketing Mix			
	Product	Place	Price	Promotion
Phase 1: Coding Workshop	<ul style="list-style-type: none"> Demonstration of how to code UTI patients (U71) within the GP patient management software 	<ul style="list-style-type: none"> In practice. Appointments were scheduled at the convenience of practice staff 	<ul style="list-style-type: none"> Time – to participate in the workshop and to code thereafter Rewarded at the end with accurate feedback reports GP received CPD recognition 	<ul style="list-style-type: none"> Highlighting to the GPs that they needed to code to receive accurate audit and feedback reports Factsheet on how to code within their patient management system Cupcakes with U71 included on them Access to coding demonstration video Monthly text messages to the GPs to remind them to code U71 Posters for waiting room informing the patients that an intervention was taking place
Phase 2: Interactive Workshop	<ul style="list-style-type: none"> An interactive workshop consisted of: 	<ul style="list-style-type: none"> In practice. Appointments were scheduled 	<ul style="list-style-type: none"> Time – to participate in the workshop and 	<ul style="list-style-type: none"> Monthly text messages to the GPs to remind

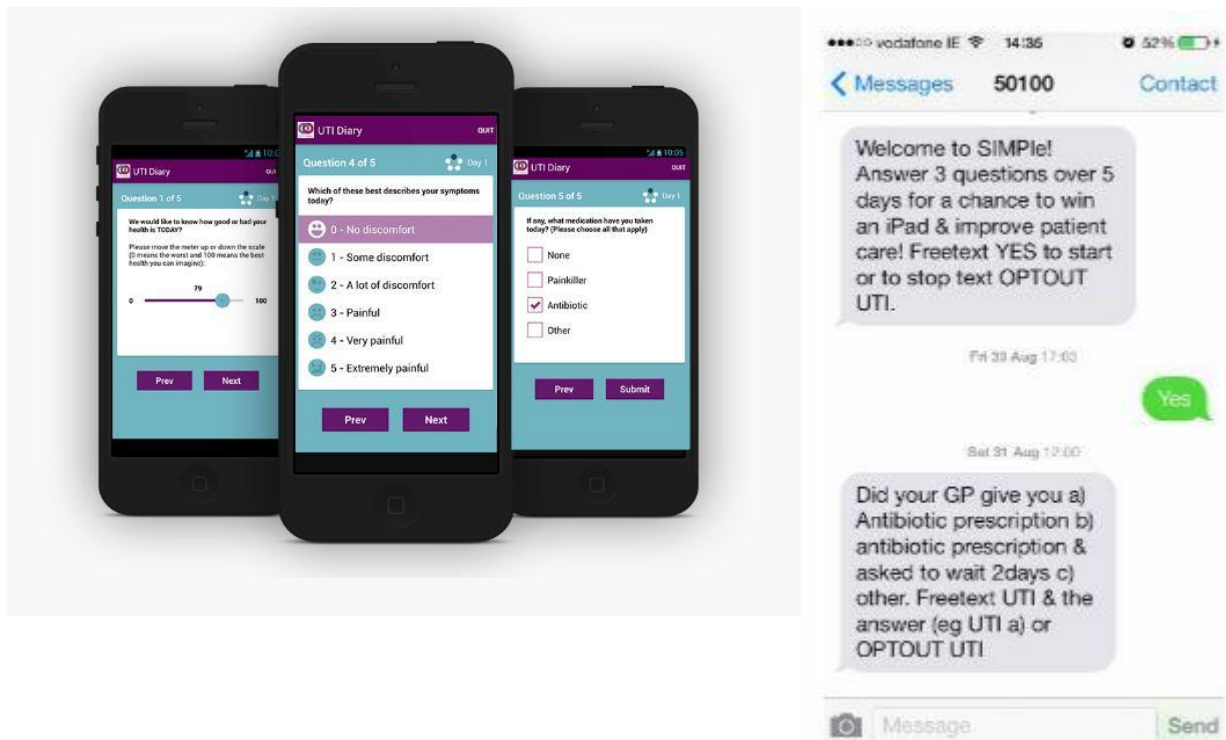
	<ul style="list-style-type: none"> • Presentation of what SIMPlE was about • First audit and feedback report. • GPs were encouraged to openly discuss their prescribing choices across phase 1 period – why they prescribed specific antibiotics • Nitrofurantoin myth buster fact sheet <p>In addition GPs in arm B received:</p> <ul style="list-style-type: none"> • A video demonstrating how to begin a conversation with patients on delayed prescribing. 	at the convenience of practice staff	<p>prescribe antibiotic at every point</p> <ul style="list-style-type: none"> • To reconsider their prescribing choices • GP received CPD recognition 	<p>them to code U71</p> <ul style="list-style-type: none"> • Popup enabled reminding the GP of what to prescribe once they coded UTI patient u71 • Monthly audit and feedback report which included SIMPlE branding • Sent a Christmas card from SIMPlE team • Monthly telephone call from SIMPlE team to receptionist to download study data • Patient information leaflet • CPD sign up information
Phase 3: Patient Support	<ul style="list-style-type: none"> • iPad with Bugrun Schooldays and infomercial uploaded was installed in waiting rooms 	<ul style="list-style-type: none"> • Practice waiting rooms 	<ul style="list-style-type: none"> • Free of charge 	<ul style="list-style-type: none"> • Bugrun Schooldays and infomercial branded and continuous played • Practice visit to ensure no issues were arising • Monthly telephone call from SIMPlE team to receptionist to download study data
Phase 4: Follow Up	<ul style="list-style-type: none"> • Practices asked to continue coding U71 		<ul style="list-style-type: none"> • Continue coding 	<ul style="list-style-type: none"> • Practices received audit and feedback report made available • Monthly telephone call from SIMPlE team to receptionist to download study data

Evaluation

The medical research council in the United Kingdom describes complex interventions as “*interventions that contain several interacting components*” (Medical Research Council 2006 p.7) and by their very nature are difficult to design and evaluate. Rigorous quantitative and qualitative research was central to the success of every aspect of the SIMPlE study. In line with best practice our research strategy was designed and published as a study protocol prior to the commencement of SIMPlE (Duane, Callan et al. 2013). Our protocol outlined our intervention design, what change we were measuring (primary and secondary outcome measures), the methodology we were planning to use and our analysis strategy.

Meticulously designing our study protocol at the beginning had its advantages. For example, it allowed us to design a remote electronic data collection system which helped reduce the data collection burden on participating practices. This system was based on consultation coding a concept most GPs were familiar with even though they may not have been using it. By integrating our data collection system into the Practices existing patient management software we were able to reduce errors associated with manual data entry and perform additional analysis on our results (Galvin, Callan et al. 2015, Vellinga, Galvin et al. 2015). We were also able to focus on very specific research questions, i.e. what type of antibiotic GPs were prescribing for UTI and the frequency of prescription? We also had the opportunity to adopt novel approaches to overcome hurdles that took place when trying to collect data from acute patients, i.e. UTI patients who may visit the GP once but should not have to reconsult. As part of SIMPlE we developed both a two way text message evaluation system and an award winning smartphone application to collect data from patients in the days after their reconsultation (<https://www.youtube.com/watch?v=nW-Od-yC30Y&feature=youtu.be>). Both methods focused on patient symptoms (See Figure 4) (Duane S, Tandan M et al. In Press). It also allowed us to look at additional research questions such as reconsultation rates between male and female UTI patients (Tanden, Duane et al. 2016).

Figure: 4: UTI Diary App and patient text messages



Outcome Evaluation

SIMPLE's primary objective was to improve the quality of antibiotic prescribing for UTI patients according to guidelines. The results are discussed extensively elsewhere (Vellinga, Galvin et al. 2015). In summary, an absolute increase in the quality of prescribing of 20% was achieved for practices in the intervention arms, and patients attending an intervention practice were twice as likely to receive a prescription for a first-line antibiotic for their UTI as those attending a control practice. This change was 10% greater than anticipated. The changes made within general practices during the SIMPLE intervention period were also sustained during the five month follow up period. This indicator of success highlights that it is possible to improve the quality of antibiotic prescribing in general practice through designing interventions which reflect real life practices and the needs of the audience, in this case using interactive workshops and practice specific audit and feedback reports.

Although this intervention successfully improved the quality of antibiotic prescribing, an unanticipated consequence of the intervention was that the amount of antibiotic prescriptions increased during the intervention period (Vellinga, Galvin et al. 2015). This may be associated with message framing however, more research is needed to fully explain why.

Although RCTs are an excellent method of measuring the efficacy of new drugs, the complex nature of behavioural related health research leads to methodological difficulties, as researchers underestimate the importance of the person and the process in the behavioural change activity. Their classic experimental design makes it difficult for their application to be transferred outside the trial setting, this observation raises questions as to whether they are an appropriate method to evaluate complex interventions which involve multiple components interacting together within a specific environment (Stead and McDermott 2013). Taking SIMPlE as an example, the researchers were able to identify a positive improvement in the quality of antibiotic prescribing. However, the increase in quantity is harder to explain. To help with understanding the impact of such changes a process and economic evaluation were also undertaken.

Process evaluation

Our process evaluation provided insights into the observed effects of introducing different intervention components which could help when rolling out SIMPlE in the future (Duane, Domegan et al. 2017). A process evaluation was conducted consisting of face to face interviews with GPs (n= 15), telephone interviews with patients (n = 12) and observation throughout the intervention period. The results of this evaluation are published elsewhere however, SIMPlE was successful because it was built into routine care, we provided scientific evidence to support the changes we were implementing through practice specific audit and feedback reports and the intervention did not increase GP workload or overly burden the GP.

Economic Evaluation

Funders may look beyond clinical effectiveness when deciding to fund the implementation of changes within clinical practice. Expected cost effectiveness may also be taken into consideration when deciding the sustainability of complex interventions. Therefore the cost effectiveness of SIMPlE was also assessed as part of the suite of evaluation activities which were integrated (Gillespie, Callan et al. 2016).

Conclusion

To date the SIMPlE study is the largest non-pharmaceutical trial to have taken place in Ireland. It was successful on a number of fronts. Firstly, due to the rigorous formative research and situation analysis the researchers recruited all 30 general practices within a two week period. This is a very short recruitment period. All practices were retained for the duration of the intervention- we developed an intervention which rewarded the GPs with something they valued- an audit and feedback report. The change observed was double what we had estimated and changes in prescribing behaviours were sustained 5 months after the intervention period had finished. We even had general practices contacting us requesting further studies.

This was the first time that an electronic data extraction system had been implemented in a trial in Ireland- again this method was valuable as it was easy for GPs to use and reduced the data collection burden of participating in a study. Consultation coding (U71) resulted in over 3000 UTI patients' data being electronically extracted during the intervention period – data from these patients made it easier and more efficient to evaluate changes in the quality of antibiotic prescribing during the SIMPlE intervention.

This case study describes the steps taken within the design, implementation and evaluation of the SIMPlE study and how the choices made throughout this process positively and negatively impacted on the emerging results. The testing of such interventions has been identified as a weakness of social marketing in the past, which often rely on interviews and focus groups to evaluate change activities (Rundle-Thiele, Kubacki et al. 2013). The SIMPlE complex intervention was an RCT. RCT are a gold standard evaluation method which are frequently used in the health domain to measure the effectiveness of clinical outcomes, for example the type of antibiotic prescribing undertaken by GPs (Oakley, Strange et al. 2006). It is important that social marketers apply such rigorous evaluation methods, to ensure the sustainability of our change activities in the future (Gordon, McDermott et al. 2006, Rundle-Thiele, Kubacki et al. 2013).

For a summary of the SIMPlE intervention please visit
<https://www.youtube.com/watch?v=buyeYTt1uQs>

QUESTIONS

1. SIMPle successfully improved the quality of antibiotic prescribing within participating practices, however it also resulted in an increase prescribing. What changes in the strategy design would you implement to prevent this from happening?.
2. Like the SIMPle research team you have been tasked with evaluating a similar social marketing intervention. Design and describe how you would undertake a process evaluation to analyse the interaction between intervention components.
3. SIMPles intervention components were constrained as it was an RCT. Now that we have shown favourable results describe how you would scale up and out your social marketing activities.

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