Template Protocol for non-CTIMPs

How can we increase behavioural intent to take antibiotics “exactly as prescribed”? An online randomised behavioural experiment.

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Protocol authorised by:

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Sponsor

Imperial College London is the main research Sponsor for this study. For further information regarding the sponsorship conditions, please contact the Head of Regulatory Compliance at:

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Funder

There is no external funding for this study. IGHI and BIT are working in collaboration to conduct behavioural science studies related to AMR, and researcher time is provided in kind. IGHI are funding the use of the Predictiv Online Platform at BIT through internal funds, which includes small financial incentives for participants as outlined above.

This protocol describes the "Take exactly as prescribed" study and provides information about procedures for entering participants. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the study. Problems relating to this study should be referred, in the first instance, to the Chief Investigator.

This study will adhere to the principles outlined in the UK Policy Frame Work for Health and Social Care Research. It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate.

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KEYWORDS
Antimicrobial Resistance, Antimicrobial Stewardship, Behavioural Science

STUDY SUMMARY

TITLE	How can we increase behavioural intent to take antibiotics “exactly as prescribed”? An online randomised behavioural experiment.
DESIGN	Online randomised controlled trial
AIMS	Evaluate whether the framing of messages impacts intent to “take antibiotics exactly as prescribed”, and whether the mechanism of delivery of this message impacts behavioural intent.
OUTCOME MEASURES	Intent to take antibiotics exactly as prescribed, comprehension of instructions, comprehension of antimicrobial resistance (AMR), sentiment towards AMR.
POPULATION	7,000
ELIGIBILITY	Participants signed up to market research panels, population representative of UK population demographics
DURATION	6 months

1. INTRODUCTION

1.1. BACKGROUND

Antimicrobial Resistance (AMR) is recognised as an urgent global public health crisis (1). Due to misuse, overuse, and excessive reliance on antibiotics, bacterial resistance to pathogens like germs and viruses, is becoming increasingly difficult to control (2). As a result, infections that were once easily treatable are now harder to manage, increasing the risk of life-threatening illnesses and death. Without a clear understanding of how to combat AMR, it is projected that by 2050, up to 39 million people could be affected (3).

Human behaviour plays a crucial role in mitigating AMR. Promoting responsible antibiotic use can encourage the public to adopt practices such as completing the full course and avoiding seeking unnecessary prescriptions. The public may be unaware that their actions directly contribute to AMR or may have a basic understanding of the concept yet hold incorrect beliefs and attitudes. Despite some individuals possessing a high understanding of AMR and antibiotic stewardship, they may also experience cognitive dissonance, believing that they themselves are not at risk of being affected by AMR or related consequences (4). In 2024, the UNGA High Level meeting resulted in a political declaration, which included a commitment to strengthening antibiotic stewardship in healthcare settings and promoting appropriate antibiotic use among the public (5). However, implementation remains in its early stages, and there is an urgent need to better understand the behaviours and attitudes that influence antibiotic use. There are several behaviours that are important for antimicrobial stewardship, including “taking antibiotics exactly as prescribed”, language endorsed by UKHSA.

Using behavioural science-informed interventions to improve antibiotic stewardship has had mixed results in the past. In 2021, the COM-B model (a behavioural science framework that identifies determinants of behaviour including capability, opportunity and motivation) was applied to design an educational programme on infection prevention and antibiotic use for community youth groups, promoting the Antibiotic Guardian Youth Badge (6). Additionally, the Social Cognitive Theory has been implemented to create computer-delivered prompts to General Practitioners aimed at encouraging adherence to antibiotic prescribing guidelines (7). Both examples demonstrate the potential of behavioural science models to influence antibiotic-related behaviour. However, evidence regarding the effectiveness of interventions targeting the public to engage with the concept of AMR remains inconsistent (8). Thus, highlighting the need for further research into the barriers people face in adhering to antibiotic guidelines. From this, insights can support the development of more effective, evidence-based strategies tailored to real-world actions.

We are a team of behavioural scientists working to explore the behaviours that influence antibiotic use, aiming to co-design behavioural science informed interventions with the public to support positive behaviour change. As part of the Fleming Initiative, we are tackling AMR from several perspectives, including public engagement, behavioural science, policy and translational science. This unique setup has the potential to drive real change in public behaviour and empower the public to play a meaningful role in shaping research with global impact. However, to inspire behaviour change and mitigate the crisis of AMR, the public must understand exactly what it is and that how they take their antibiotics can directly contribute to the issue.

Our initial literature review explored research investigating how the public take their antibiotics. We identified a consistent pattern of common behaviours which contributed to misuse, showing that many do not “take as directed”. A key theme observed was an overall general lack of awareness of how to take their antibiotics, which then triggers a chain reaction of harmful behaviours, such as stopping the course early, incorrect disposal of antibiotics, and sharing them with other people (e.g. family members).

Previous research highlights that many individuals discontinue their antibiotics before completing the prescribed course. One study found that 78.1% of individuals stopped taking their antibiotics once they felt better (9). This tendency is particularly common among adolescents and males, with younger

individuals (16-18 years old) often perceiving antibiotics as a "cure-all" medication, ignoring the risks of AMR (10, 11). Stopping the course early not only increases the risk of re-infection (which leads to another round of antibiotics) but also results in leftover doses. A UK survey (12) found that 19% of 6,983 participating households had unused antibiotics, which were often stored for later use, shared with others, or improperly disposed of, contributing to environmental pollution and further resistant risks. Such behaviours maintain misconceptions around the purpose of antibiotics, creating a social norm that antibiotics can be taken anytime for whatever reason, ultimately contributing directly to AMR. Addressing these patterns of misuse is key to developing targeted inventions that promote better antibiotic stewardship and help mitigate the ongoing development of AMR (13, 14).

A 2023 online study further revealed that individuals who discontinued their course often chose to self-medicate at a later date for what they perceived as the same illness or shared their leftover medication with others (13). Contributing factors included prior negative experience with healthcare professionals, healthcare costs, and limited access to pharmacy locations. Interestingly, the study found that those who relied on medication leaflets or physician recommendations were less likely to self-medicate, suggesting that access to reliable information can positively influence antibiotic-related behaviours.

While previous research provides insight into current patterns of public misuse, there remains a gap in understanding the specific challenges individuals face when trying to adhere to prescriptions and discussing what can be done to improve them. Given that lack of awareness leads to harmful practices contributing to resistant infections, it raises the question of whether educating the public about the underlying causes of AMR could guide responsible antibiotic use. There is a clear need to further explore public attitudes towards antibiotics, assess whether AMR is widely understood as a global health crisis, and identify what we can do to change these attitudes and inspire behaviour change.

1.2. RATIONALE FOR CURRENT STUDY

It is widely recognised that behavioural science can be applied to the issue of antimicrobial resistance (AMR), meaning that the behaviours contributing to its development can be effectively addressed. While it is evident that individuals often misuse antibiotics, the reasons behind this are not fully understood. Studies have shown that many people stop their course early, dispose incorrectly, and that there is a general lack of awareness of AMR. However, there remains a lack of public engagement to gain a comprehensive understanding of what can be done to encourage the public to take their antibiotics as directed. This study aims to trial interventions that have been co-designed with members of the public in the UK, aimed at inspiring individuals to "take antibiotics exactly as prescribed".

As such, this study has been conceived to help answer the following research question: Can co-designed behaviourally informed interventions improve behavioural intent related to antimicrobial stewardship – specifically taking antibiotics exactly as prescribed.

We hypothesise that a co-designed intervention aimed at improving antibiotic adherence will encourage the public to take their antibiotics exactly as prescribed, enhance attitudes towards AMR, and influence future antimicrobial stewardship behaviours.

The null hypothesis for this study is that a co-designed intervention will have no impact on the public's behaviour towards taking their antibiotics as directed than the information already provided on the antibiotic packaging.

Intervention Design

Two broad categories of interventions were co-designed with public members through multiple co-design workshops. Prior to this, our research team conducted two focus groups with members of the public, capturing current behaviours and attitudes towards antibiotic usage, and identifying common themes related to antibiotic misuse. Insights from these discussions informed a series of three co-design workshops, where the public brainstormed potential solutions for improving antibiotic adherence, and

produced multiple ideas for interventions, targeting a range of antimicrobial stewardship behaviours. Throughout the workshops, intervention ideas were systematically refined based on feasibility and perceived overall effectiveness. Additionally, the research team worked closely with members of the public in a steering group to guide our engagement activities and trial design. The final selected target behaviour was "taking antibiotics exactly as prescribed". Three intervention ideas were selected, of which two were deemed suitable for testing in an online randomised experiment.

The final interventions form two broad categories, with three variations in each. They are focused on changes to the packaging of antibiotics, to provide the public with information about the target behaviour and AMR. Within each category, the intervention arms will explore different ways of presenting AMR to the public, to determine the impact of message framing.

2. STUDY OBJECTIVES

This study aims to gain a deeper understanding of how different ways of presenting information about desired target behaviours and antimicrobial resistance (AMR) on antibiotic packaging can influence the public's correct use of antibiotics, shape their attitudes towards AMR, and impact their intended future behaviour. Within the exploratory objectives, we will also use this survey to evaluate the participant population's opinion on text message reminders – the third intervention created in the co-design but not suitable for an online experiment, providing information for a future real-world study.

Primary Objectives
Change in behavioural intent to "take antibiotics exactly as prescribed". This will be measured as overall intent to take antibiotics exactly as prescribed (a composite measure made up of four individual behaviours relating to AMS)

Secondary Objectives
- Comprehension of how to take antibiotics
- Comprehension of AMR

Exploratory Objectives
- Change in behavioural intent for individual behaviours related to "take antibiotics exactly as prescribed" e.g. *finishing the course, number per day*
- Understanding that not taking antibiotics exactly as prescribed contributes to AMR
- Impact of message framing on behavioural intent to take antibiotics exactly as prescribed
- Impact of mechanism of delivery of intervention on behavioural intent to take antibiotics exactly as prescribed
- Impact on perceived personal responsibility
- Proportion of individuals who interacted with the QR code
- Impact of the interventions on sentiment towards information on the package itself
- Do participants perceive text message reminders would help them take antibiotics exactly as prescribed?

Sub-group analysis
The primary analysis will be repeated on three participant subgroups according to age, health confidence and baseline comprehension of AMR, to identify if there are differences in the impact of the intervention in these population groups.

3. STUDY DESIGN

This research study is a collaboration between the Fleming Initiative, housed within the Institute of Global Health Innovation at Imperial College London and the Behavioural Insights Team. Imperial College London will retain ownership of all data generated by the study.

This study has been designed as a seven-armed online behavioural experiment. This will be carried out using Predictiv (15), an online platform for running behavioural experiments built by the Behavioural Insights Team. There is a current contract in place between BIT and ICL for this work to be conducted on BIT's Predictiv platform.

The detailed user journey through the study can be viewed in Appendix 1, and will take the following steps. Figure 1 demonstrates the flow of participants through the online study.

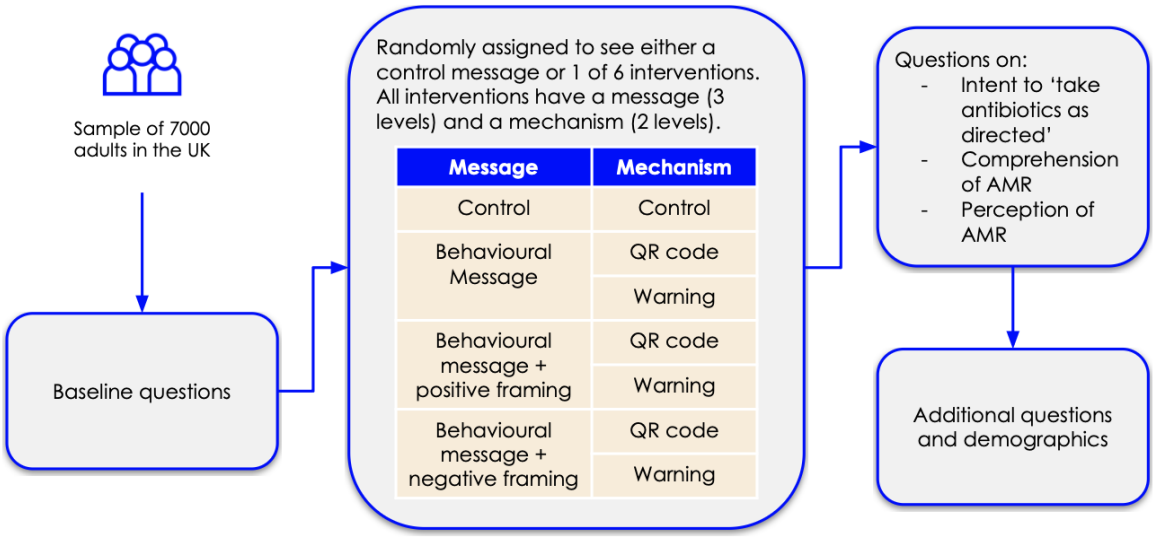

Figure 1: Participant flow through online experiment

1. **Access to survey.** Participants access the Predictiv online platform through an online link. This will be provided by their own market research panel company, that they have previously signed up to. Market research panels will be provided the survey by CINT, a panel aggregator. Since a panel aggregator is used, the study team do not work directly with specific market research panels. In similar previous survey studies, around 30-40 market research panels are typically contacted. The panel provider we use has access to over 500,000 participants who having completed an online survey in the last year. Participants must be at least 18 years old and live in the UK in order to participate in this survey. We will also set recruitment quotas across demographic criteria such as age, gender, region in the UK, and ethnicity, to ensure a nationally representative sample. This recruitment method was utilised in a previous Imperial – BIT study (Worktribe Application ID 6995049).
2. **Introduction slide.** This will orientate the user on the upcoming task (being told about a medical scenario they have, the resulting advice from the doctor, being shown some antibiotics, and that they will then be asked to answer some questions). They will be informed that completing the survey should take around 5 minutes, and that they are free to withdraw at any point by closing the survey window in their online browser. Participants will also be provided with a link to a summary Participant Information Sheet (Appendix 2).

3. **Attention check.** Participants will be asked a simple question to ensure they are reading the questions and can answer appropriately. If they do not answer the first attention check correctly they will be provided with a second simple question. If a participant answers both questions incorrectly they will be excluded from the study at this point.

4. **Randomisation.** The 7,000 participants will be randomised in a 1:1:1:1:1:1:1 ratio to one of seven trial arms. This will be done within the platform at the individual level and will be computer generated. Participants will be blinded to the study arm that they have been assigned to.
5. **Baseline measures.** Participants will be asked four questions to gauge their baseline understanding of AMR and antibiotic use.
6. **Scenario.** Participants will be shown information about an infection they have, and told they are being given antibiotics. They will also be asked if they would be willing to attend a pharmacy to collect this prescription. All participants will see the same scenario.
7. **Intervention.** Participants will then be shown one of seven images, according to their intervention arm. Each image will be of an antibiotic packet. Those in arms 2-4 will have a QR code that links to additional information. If participants choose to scan this QR code or click on the QR code itself, they will be shown a screenshot of a webpage that is tailored to the intervention arm. Those in arms 5-7 will be shown an antibiotic packet which has a warning message on it. Those in the control arm will be shown a standard antibiotic packet. The participant will be free to look at the image for as long as they wish to. Images of the control arm and two mechanisms of intervention can be seen in Figure 2. Detailed images of each arm can be viewed in Appendix 1.
8. **Survey Questions.** Once participants have looked at the images, they will click through a series of survey questions. The full survey can be viewed in Appendix 1. The survey questions have been designed to evaluate the following:
    1. Comprehension of “how to take antibiotics exactly as prescribed”
    2. Intent to take antibiotics “exactly as prescribed”, exploring why participants chose the answers they did
    3. Sentiment regarding the information on the packet and its relevance to the participant
    4. Personal responsibility related to a participant’s role in mitigating AMR
    5. Intention to scan QR code in real life (arms 2-4 only)
    6. Health confidence and knowledge of antibiotics
    7. Perception of text message reminders

    The survey incorporates some free text responses to further understand participants understanding of how to take antibiotics exactly as prescribed. It is possible that some anonymised quotes may be published in any resulting study publications. This is made clear in the summary PIS and on the introduction slide that the participant will see before engaging with the survey.
9. **Demographics.** Participants will be asked to provide non-identifying demographic data, including their previous antibiotic use and whether they work in the healthcare sector.

All questions within the survey will be compulsory. Once a participant has completed the online survey they will close the window. This will signify the end of their involvement in the study. No further contact or questions will be asked of the participants after this point.

Control Arm:

Arms 2-4: QR code shown on packaging

Arms 5-7: Warning message shown on packaging

Figure 2: Control arm and the two mechanisms of message delivery in the intervention arms

Participant Recruitment

The Predictiv Online platform already has access to a participant pool of 500,000 individuals, roughly representative of the general UK population (in terms of gender, age, location and income).

Participants are recruited via market research panel companies. The online survey will be uploaded to a panel aggregator who will subsequently distribute this to a range of market research panels. Examples of such panels include QMee and Prime Insights. The link to the survey will be provided by the individual market research panel, and will not be advertised directly by the research team.

Each individual market research panel will hold any personally identifying data and would have previously obtained consent to contact individuals in this way. If a participant responds to the advert, they will be invited to join the Predictiv Online platform via a link provided by their market research panel and take part in the study. No personal identifying data will be transferred to Predictiv, the Behavioural Insights Team or ICL, and it is impossible for these teams to access these data from the original market research panels. As such, for the purposes of this study, participants will be fully anonymous. Participants will be incentivised to participate in this study through a small financial incentive. This will be in the region of £0.70 per participant, although the amount may vary dynamically within a small margin depending upon recruitment. Payment will be made upon completion of the survey. This payment will be managed by the individual market research panel and not BIT or ICL. Funding for this payment will be provided by ICL, as part of the overall agreement for the work done by BIT. A contract is in place for this work between ICL and BIT, and BIT will invoice ICL for the work done as per this agreement. This invoice will include funds for participant payment. Payment to the panel aggregator company will be managed by BIT. BIT have a contract with the panel aggregator company, but not with the individual panel providers. The panel aggregator will invoice us for the number of completed surveys based on a preset charge per completed survey. The aggregator will then distribute the relevant payments to the relevant panels who will in turn reimburse the participants. This recruitment and participant reimbursement method was utilised in a previous Imperial – BIT study (Worktribe Application ID 6995049).

Recruitment will be open for specified covariates until the representative quotas are recruited, demonstrated in Table 1. Once the survey is advertised, survey completion and ongoing participant recruitment will continue in parallel. The recruitment window for the study will remain open until all participant groups are recruited at the defined size. If one participant sub-group is more difficult to recruit, the financial incentive for this sub-group will be raised as part of the pre-defined dynamic process.
Recruitment rates will determine the length of the recruitment and study period, however from previous experience we anticipate the total duration of the study to be 3 weeks.

The target for recruitment has been set at 7,000 participants based on power calculations for the primary outcome. Accepting a two-sided p-value of <0.05 as statistically significant, the study has been designed with 80% power to detect a minimal detectable effect size of 7 percentage points between trial arms, in line with previous research on attitudes and behavioural intent to antimicrobial stewardship. This is based on an assumption that the baseline will be approximately 70%, based on a previous similar study. The power calculation is corrected for 6 comparisons using a Bonferroni correction. Note that for our analyses we use a Benjamini-Hochberg correction to adjust for multiple comparisons; however, it is not possible to apply this correction prior to data collection and so for power calculations we use a more conservative Bonferroni correction.

Table 1: Participant recruitment targets to ensure representation of the U.K. population

Covariate	Proportion to be recruited
Gender	
Women	51%
Men	49%
Age	
18-24	11%
25-54	50%
55+	39%
Region	
South & East	32%
North	23%
Midlands	16%
Scot/NI/Wales	16% (each country represented proportionately)
London	13%
Ethnicity	
White	83%
Asian (or Asian British)	9%
Black (or Black British)	4%
Mixed / Other	5%

Consent to participate.
Participants will receive the link for study via their own market research panel, who will hold any personally identifying data. This will not be available to the research team at BIT or ICL. The research team will only access anonymous data provided within the survey itself and anonymised demographic data provided by the market research panel.
Accessing the link to the online experiment and continuing with the online survey will be taken as implied participant consent for this study. Participants will be informed that they are free to leave the survey at any point during the process, and given instructions as to how to do so.

Study Duration
The study will be launched on the 1st August 2025 and will stay open until participant recruitment has been fulfilled. Based on previous experience we anticipate the study duration to be 3 weeks. The participant will be involved in the study for approximately 5 minutes (the anticipated time taken to view the image and answer related questions), after which no further involvement will be required.

Data Storage
Aggregate anonymised data will be stored securely on ICL servers, only accessible by the ICL research team. This will be stored for 10 years in line with ICL policy on data storage.

4. PARTICIPANT ENTRY

4.1. PRE-REGISTRATION EVALUATIONS

To access our online survey, participants must be signed up to a market research panel that will receive the survey via a panel aggregator.

4.2. INCLUSION CRITERIA

Adults aged 18 and over
United Kingdom residents
Have passed the attention check at the start of the online survey.

4.3. EXCLUSION CRITERIA

Individuals who are not signed up a market research panel and therefore will not have access to the online survey.
Those resident outside the UK.
Those who fail the attention check at the start of the online survey.
Individuals aged under 18.

4.4. WITHDRAWAL CRITERIA

Participants can leave the study at any point by closing the online window. They will be informed of this within the information at the start of the survey. If a participant withdraws from the study their data will not be included in the analysis and will be deleted.

5. ASSESSMENT AND FOLLOW-UP

There will be no routine follow up of participants once they have accessed and completed the online survey in Predictiv's online platform. Participants are not asked any personal questions during this study or asked to relay any personal experiences, as such there is no requirement for follow up once the study has been completed.

6. STATISTICS AND DATA ANALYSIS

Data Analysis
Statistical analysis of anonymous survey data will be conducted by the named study team members at BIT, obtained directly from their Predictiv platform. This will be conducted at the individual participant level. The survey will initially be launched for 100 participants as a "soft launch", to check for any ceiling effects in the control group related to behavioural intent, and to check the rates of scanning on the QR code arms. The mitigation strategy for either of these outcomes can be seen in slide 37 of the deck in Appendix 1. The detailed analysis plan can be found in Appendix 1, and will cover the following key components:

1. **Primary Outcome** – Do the interventions increase intent to take antibiotics exactly as prescribed? This will be conducted using a quasibinominal regression model
2. **Secondary Outcomes** – Comprehension of how to take antibiotics and comprehension of AMR. These will be conducted using a quasibinominal regression model
3. **Exploratory Outcomes**. Each exploratory outcome will be analysed using either a quasibinominal regression model or a separate logistic regression for each outcome.

Regression will be adjusted for the following covariates: age, gender, income, region, ethnicity, education, employment status, whether they prescribe antibiotics in in their job, health confidence, whether they take multiple medications and English as a first language.

Aggregate anonymised data will be transferred to researchers at ICL via secure email for further analysis and write up of the findings. These data will be stored securely in a password protected folder within Imperial College London's Sharepoint.

7. REGULATORY ISSUES

7.1. ETHICS APPROVAL

The Principal Investigator has obtained approval from the Head of Department (Surgery and Cancer) and approval from the Research Governance and Integrity Team (RGIT). The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

7.2. CONSENT

Participants registered with market research panels will have historically consented to be contacted for use in future online studies at the point of signing up. If a participant decides to join this study following receipt of an advert by their own market research panel, them joining the online survey and participating in the questions will be taken as implied consent. No personal or identifying data will be asked or recorded by BIT or ICL as part of the Predictiv online survey. The right of the participant To refuse to participate without giving reasons will be respected. All participants are free to withdraw at any time whilst the survey is being conducted.

7.3. CONFIDENTIALITY

The Principal Investigator will preserve the confidentiality of participants taking part in the study and fulfil transparency requirements under the General Data Protection Regulation for health and care research. Data and all appropriate documentation will be stored for a minimum of 10 years after the completion of the study, including the follow-up period.

Data will be anonymised prior to transfer to ICL.

7.4. INDEMNITY

Imperial College London holds negligent harm and non-negligent harm insurance policies which apply to this study.

7.5. SPONSOR

Imperial College London will act as the main Sponsor for this study.

7.6. FUNDING

There is no external funding for this study. IGHI and BIT are working in collaboration to conduct behavioural science studies related to AMR, and researcher time is provided in kind. IGHI are funding the use of the Predictiv Online Platform at BIT through internal funds, which includes small financial incentives for participants as outlined above.

7.7. AUDITS

The study may be subject to audit by Imperial College London under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the UK Policy Frame Work for Health and Social Care Research.

8. STUDY MANAGEMENT

The day-to-day management of the study will be co-ordinated through Dr Kate Grailey

9. PUBLICATION POLICY

The findings of this study will be written up and published in peer-reviewed journals. We will also create a report detailing the process of intervention design (our public engagement and involvement (PPIE) work) which will be published as a report on the Imperial College IGHI blog. The study findings to be distributed to public members involved in this PPIE work as a written report.

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