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Shifting the practice and attitude of private doctors with respect to unethical benefits from pharmaceutical companies for prescribing medicines

Submission date
19/04/2022

Registration date
10/05/2022

Last Edited
03/02/2025

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
This study applies cutting-edge health policy and systems research to address a critical and poorly addressed global health challenge: conflict of interest (COI). COI, which we define as a situation whereby the impartiality of a healthcare provider's judgment may be influenced by a secondary interest, such as financial gain, can lead to a decision that is not in the patient's best interest and hinders improvements in the quality of care delivered by private healthcare providers. Studies show that private doctors prescribe multiple antibiotics when patients do not need them in order to receive benefits from pharmaceutical companies or make profits from the medicine sales.
Despite the scale and urgency of this issue which affects millions of people and drives antimicrobial resistance which can spread across the world, there is extremely limited evidence on strategies that are effective in contexts where resources and political support for the enforcement of rules are low. We focus on irrational prescribing of antibiotics by private doctors in Pakistan, the sixth most populous country in the world, where more than 80% of people first seek care at private doctors and where antibiotic usage is among the highest in the world. Training interventions focusing on increasing knowledge and skills to affect voluntary behaviour change in private providers is the most common approach used. However, these interventions have had limited success when irrational prescribing is mainly motivated by profit-generation rather a lack of knowledge; here norms and values associated with professional ethics are critical to address with interventions.

Our study aims to generate new evidence about the impact of a continuing medical education intervention with specially designed messages to sensitise doctors to professional ethics and COI, as well as provide critical insights about barriers that need to be overcome in order to facilitate scale-up of this intervention in the local health system.
Our study objectives are four-fold: firstly, to understand how COI and professional ethics is conceptualised by influential stakeholders in Pakistan; secondly, to investigate how private doctors decide what is ethically unacceptable and acceptable with respect to getting personal

benefits from prescribing antibiotics; thirdly, to understand how best to present messages that sensitise private doctors to professional ethics and the role of COI in driving irrational prescription of antibiotics; and fourthly, to assess the impact of our intervention on the behaviour and attitudes of private doctors with respect to unethical benefits from pharmaceutical companies for prescribing antibiotics.

Who can participate?
Qualified and licensed doctors working as general practitioners in Karachi, Pakistan.

What does the study involve?
The study involves continuing medical education on understanding COI in medical practice and provides a summary of the main policies for doctors on ethical practice. There will also be a series of reminders delivered directly to participants to reinforce the key educational messages. Finally, the study involves an unannounced assessment to provide participants with feedback to enhance on their professional practice, as well as to determine if the seminar was effective and find ways to improve its delivery in the future.

What are the possible benefits and risks of participating?
At the end of the seminars, participants should have gained new information that can improve their professional knowledge and practice, so that they may provide better quality care to their patients. Participation may have wider benefits as it will help the research team to design materials or policies that might improve ethical medical practice. Participating in this research should not cause any discomfort or hazards, and participants may withdraw at any time by letting a member of the research team know.

Where is the study run from?
London School of Hygiene and Tropical Medicine (UK)

When is the study starting and how long is it expected to run for?
June 2021 to July 2022

Who is funding the study?
The grant for this study was awarded jointly by the Foreign, Commonwealth & Development Office (FCDO), the Economic and Social Research Council (ESRC), the Medical Research Council (MRC) and the Wellcome Trust (UK).

Who is the main contact?
1. Dr Mishal Khan, Mishal.Khan@lshtm.ac.uk
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Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
26506

Study information

Scientific Title
Addressing conflict of interest driving irrational prescribing of antibiotics in pluralistic health systems: an interventional study in Pakistan

Study objectives
Evidence on the ‘know-do’ gap shows that conflicts of interest (COI) related to profit generation from medicine sales plays a critical role in prescribing decisions, as do values associated with professional ethics and altruism. This study thus hypothesises that a multi-faceted intervention, based on a 'soft' governance approach, can shift the practice and attitudes of private doctors with respect to unethical benefits from pharmaceutical companies for prescribing medicines (focusing on antibiotics).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/10/2021, London School of Hygiene & Tropical Medicine Observational /Interventions Research Ethics Committee (Keppel Street, London, WC1E 7HT, UK; + 44 (0)207 636 8636; ethics@lshtm.ac.uk), ref: 26506

Study design
Single-centre interventional blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
The practice and attitudes of private doctors with respect to unethical benefits from pharmaceutical companies for prescribing medicines (focusing on antibiotics)

Interventions
The study brings together different disciplinary perspectives to conduct a randomised controlled study to compare knowledge, attitudes and practice of doctors who receive the intervention package with those who attend placebo seminars with no mention of conflicts of interest (COI). The randomization process was conducted by a statistician independent of the study research team.

The intervention seminars will include the following core components:
• A short film designed to sensitively illustrate how doctors' relationships with pharmaceutical industry, specifically prescribing targets linked to gifts from sales representatives, can result in conflict of interest and a range of adverse impacts.
• A discussion-based case study on a common type of incentivization that occurs between doctors and pharmaceutical sales representatives, designed to make participants think through the different dangers or consequences of this type of incentivization.
• Educational presentations based on synthesised and clarified information on conflicts of interest that have been developed for doctors using existing national and international policies and regulations, with input from several experts in ethical conduct.
• A special address from the provincial regulator on actions they will be taking against unethical prescribing to indicate that there will be consequences for continued unethical practice.

Within one month of the last seminar, the intervention arm will also receive a series reminders to reinforce the key messages from the seminar. These reminders include:
• An activity-based reminder (via WhatsApp or SMS) to design a slogan that can motivate GPs

towards more ethical practice.
• A clip from the short film shown at the seminar (via WhatsApp or SMS) accompanied by a written reminder of one or more of the key messages from the educational presentations.
• An official letter from the seminar organizers summarizing all of the key messages from the seminar and attaching a hand-out for participants to keep.

We will generate robust evidence on the impact of our intervention on behaviour by using a novel objective assessment of doctors' interaction with Standardised Pharmaceutical Sales Representatives (SPSR) offering incentives for prescribing antibiotics. The assessment will take place between 2-4 months after the participants attended the seminar. This is an innovative extension of the well-established approach of using Standardised Patients to collect data on the behaviour of medical professionals that we will design based on data from our formative research interviews.

Intervention Type
Mixed

Primary outcome measure
The proportion of doctors who accept unethical benefits (according to the regulator's guidelines) for prescribing the SPSR's antibiotic measured using a questionnaire completed by the SPSR immediately following their interaction with the doctor at 12 weeks post-seminar

Secondary outcome measures
Knowledge and attitude shifts will be assessed by comparing mean scores in survey responses at baseline and endline (24 weeks)

Overall study start date
18/06/2021

Completion date
31/07/2022

Eligibility

Key inclusion criteria
Doctors with a formal training in medicine (MBBS), who are registered with Pakistan Medical Council (PMC) and work as primary care general practitioners (GPs) in Karachi

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
280

Total final enrolment
267

Key exclusion criteria
Doctors who only work in tertiary care facilities will be excluded, are consultants, run welfare clinics, or are non-allopathic professionals.

Date of first enrolment
01/09/2021

Date of final enrolment
31/03/2022

Locations

Countries of recruitment
England

Pakistan

United Kingdom

Study participating centre
London School of Hygiene and Tropical Medicine
Keppel Street
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Study participating centre
Aga Khan University
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Sponsor information

Organisation
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Sponsor type
University/education

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ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Government

Funder Name
Foreign, Commonwealth and Development Office

Alternative Name(s)
Foreign, Commonwealth & Development Office, Foreign, Commonwealth & Development Office, UK Government, FCDO

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Economic and Social Research Council

Alternative Name(s)
Economic and Social Research Council (ESRC), ESRC

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Wellcome Trust

Alternative Name(s)
Wellcome, WT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publications in high-impact peer-reviewed journals.

Intention to publish date

31/10/2024

Individual participant data (IPD) sharing plan

Due to the sensitive nature of the research and the potential legal/professional consequences for doctors for contravening codes of ethical medical practice, data has been anonymized and information/identifiers that risk damaging the reputations of specific doctors or groups of doctors have been masked. This is in line with our commitments to both the Aga Khan University (AKU) and the London School of Hygiene & Tropical Medicine (LSHTM) ethics committees. Therefore, all the data collected will be kept confidential and will stay with the AKU-LSHTM core team. Data can be made available upon reasonable request from the corresponding author Muhammad Naveed Noor (naveed.noor@aku.edu).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			11/08/2022	No	No
Protocol file			20/09/2022	No	No
Results article		15/01/2025	03/02/2025	Yes	No