

PHarmawareness
STUDENT SURVEY

PASS

STUDY PROTOCOL

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Project Summary

There have been a wide variety of studies examining the exposure of medical students (both at the preclinical and clinical level) to the wider pharmaceutical industry during their undergraduate degrees [1]. These examples, however, have been conducted primarily in the United States or countries within Europe including France and Germany. Only one study, conducted and published in 2005 has thus far examined the exposure of United Kingdom (UK) medical students to the pharmaceutical industry [2]. This study, conducted over a decade ago, used a sample size of only 29 students from one university.

The PharmAwareness Student Survey (PASS) aims to collate a fresh, large-scale dataset profiling UK medical students level of exposure to different aspects of the pharmaceutical industry, as well as assessing students' opinions on how appropriate they believe it is to be exposed to individuals promoting pharmaceutical products such as pharmaceutical reps, colloquially referred to as drug reps, early on in their careers.

A 31 item survey, available in both online accessible through a web browser, and paper format will be distributed across all 34 UK medical schools. Data will be collected during a 12 week period from the start of November 2016 (pending ethical approval). The survey will collect predominantly quantitative data on level of exposure, and attitudes towards, the pharmaceutical industry based on a series of statements.

General Information

| | |
|--|---|
| Full Title of Project | “Study surveying UK medical students on their exposure to, and attitudes towards, the pharmaceutical industry- PharmAwareness Student Survey (PASS)” |
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Rationale and background information

An evidence base exists concerning how medical students interact with the pharmaceutical industry. Austad et al's systematic review, published in 2011, is the most recent analysis and is useful in illustrating why we wish to conduct this study. [1]

Of the 1603 abstracts extracted from that team's search queries, 32 met their criteria for being included in the review. Published between 1971 and 2010, these 32 papers include 15 conducted in the US, 10 from EU countries and 1 from the UK with the remainder conducted in countries such as Canada. The sole paper from the UK included in that review was a study conducted in 2005 by Stanley et al. and asked the opinions of 29 students at one UK university following a pilot teaching module about the pharmaceutical industry [2].

A search analysis through PubMed of any papers published since either the 2005 UK paper or the 2010 systematic review reveals there have been no large scale studies conducted in UK medical schools that ask students about how they interact with the pharmaceutical industry and what their opinions are about that relationship.

Across the papers included in Austad et al's review, a range of between 61% and 100% of students described having “any interaction” with the the acceptance of gifts such as pens or mugs having an average of 81% uptake across the reported papers. These are

alarming levels, especially considering that some of these papers had results reported solely from preclinical students, students who aren't even regularly in a clinical environment. Even more alarming still was that the review reported that the majority of clinical students felt it was appropriate to accept any gifts from pharmaceutical representatives (henceforth referred to as "drug reps" in this protocol). Also interesting was that two thirds of students felt that they were immune to any influence that accepting such gifts may have on their future prescribing practices. This finding mirrors a similar study done in America in 2001 and published in the American Journal of Medicine that found that 61% of medical residents stated they felt accepting gifts wouldn't affect their prescribing practices but only 16% of respondents felt the same way about their colleagues [3].

There are other relevant studies published outside of the systematic review discussed so far. One large scale study, conducted in France in 2012 by Etain et al, received responses from 2101 students from across the country's 37 medical school [4]. 64% of those surveyed stated they had interacted with a drug rep and 62% stated they had accepted a gift. Similar to the studies in the Austad review, only 2% of responses stated they agreed that they thought accepting a gift would influence prescribing practices (though that result had a p value of 0.27).

After an examination of the current literature about this subject matter, the following should be noted:

- the Austad et al review is over 5 years old;
- the majority of the papers from that review are >6 years old;
- that there is only 1 paper conducted in 2005 asking medical students opinion in only one location on a incredibly small number of students
- all papers exploring student and pharmaceutical industry relationship demonstrate the two do interact and there are varying opinions on how appropriate such a relationship is

In light of this, we believe there is a need to conduct a study that will provide a dataset similar to that compiled by Etain and colleagues for the French paper. Our study will aim to give an objective estimate of the proportion of medical students in the UK that interact with the pharmaceutical industry; and allow an exploration of students' opinions about how appropriate they think it is to accept gifts given the evidence base from a systematic review carried out by Spurling et al in 2012 demonstrating there is an effect of prescribing practices [5]. The following protocol outlines how the PharmAwareness Student Survey (PASS) will be conducted.

Study Objectives

The study has a number of primary and secondary objectives.

1. Primary objectives:
 - a. Determine what proportion of UK medical students are exposed to pharmaceutical promotion/marketing throughout their medical education.
 - b. Examine UK medical students opinions about the pharmaceutical industry's practices and their beliefs on whether student's exposure to drug reps influences prescribing practices
2. Secondary Objectives

- a. Investigate what proportion of students being exposed to the pharmaceutical industry do and do not accept invitations to sponsored events or offers of gifts and examine why
- b. Assess the frequency that UK medical students are exposed to pharmaceutical promotion across each year of their medical degree
- c. Ascertain if there is an association between medical students exposed to pharmaceutical promotion and positive attitudes towards pharmaceutical industry practices
- d. Determine if there is a “dose-response” relationship between the frequency of an individual medical student being exposed to pharmaceutical promotion and their attitudes towards the industry
- e. Investigate medical students beliefs regarding the impact of pharmaceutical marketing on other people's prescribing practices

Study design and methodology

Following on from those studies outlined in our background information which had similar aims, PASS is first and foremost, a cross-sectional survey in nature. We aim to achieve our primary and secondary objectives through a 31-item survey split into 3 distinct sections. A number of the questions will ask participants retrospectively about their exposure to various elements of the pharmaceutical industry. A number of other questions will ask for participant's opinions relating to a number of statements.

We estimate the current population size of medical students in the UK to be approximately 38,330 (based on university intake data for the period 2012-2015 [6]).

For a cross-sectional survey of this nature recruiting participants primarily through online means, we would expect and are aiming to get at the very least, a 10% uptake throughout the total population resulting with a desired low-end estimate sample size of between 3800-4000. If we can optimize our participant recruitment methods, it is hoped we can reach 5000 responses which would equal, if not exceed, a number of similar papers published on the subject mentioned in the literature review above.

Details of survey items being used

Taking out the five demographic questions asked at the start of the survey, 22 out of the 26 items of the survey will collect quantitative data on the number of respondents answering different options to a stem. The other four questions will be “white space boxes” collecting qualitative data and allowing respondents to outline other opinions based on the statements given to them in the other questions.

The full survey being distributed to our population cohort can be found in [Appendix A](#) of this protocol.

Section 1 consists of five questions collecting a small number of demographic data points from each respondent that will help identify trends and options for sub-analysis of the survey results. The demographic information being collected is as follows (with rationale in parenthesis):

- Sex (to explore if there is a difference in rates of acceptance of free gifts and opinions on appropriateness between the two core genders. Identification of a correlation between male to female respondents and the proportion of each sex in the whole

student population should also give us an indication of our ability to generalise any conclusions)

- Current medical school (to identify if there is a geographical variance in the exposure of medical students to pharmaceutical reps and again to allow us to check we have an even distribution of respondents across our sample)
- Current year of medical school (to compare rates of exposure across the duration of a medical degree and ensure homogeneity in the survey responses)
- Indication of completing a degree prior to starting medicine (to compare opinions of student between “straight from school” students and postgraduate medical students)
- Whether their medical school identifies them as a “pre-clinical” or “clinical” medical student (we hypothesise that those who are undertaking almost full-time clinical exposure are more likely to encounter pharmaceutical reps than those who are predominately receiving their education in the university setting)

We consider the above 5 questions as the minimum demographic data points that should be collected from respondents to allow us to ensure our results are externally valid, and that we have a range of options for sub-analysis of our results.

Section 2 consists of 17 items collecting information from respondents on their level of exposure to the pharmaceutical industry in three domains.

Domain one (items 6-10) asks respondents to indicate the settings that they may have encountered the pharmaceutical industry in and whether they have accepted or refused such invitations. The rationale behind this domain is that we are very aware that students encounter the pharmaceutical industry in a variety of scenarios outside of just potentially being offered “a free lunch” and we feel it is important to quantify the number of students encountering these situations.

Domain two (items 11-17) asks respondents to indicate the physical things they may have been offered by representatives of the pharmaceutical industry in the same style as in Domain 1. The rationale behind this domain of questions again allows us as researchers to identify not only if medical students are being offered things like free lunches but identify what is the uptake on such offers.

Domain 3 (items 19 & 20) asks respondents to now quantify both the number of times they have encountered the scenarios outlined in domain 1&2 and the frequency of such encounters. The reason for asking these two questions is that it allows us to know objectively identify how often medical students are being put in the situation of having to refuse or accept gifts from drug reps. Whilst the investigators believe that students should never have to be placed in the situation, knowing whether it is once or twice a year or once or twice a month students are placed in this situation gives us an idea of the scale and level of acceptability there is within the medical student body.

The other questions found in Section 2 of the survey (items 18, 21, 22) are 3 questions we feel are important to ask the medical student body. Item 18 in particular is important to us. It is important for students to feel able to challenge seniors and voice their opinions about certain issues they may have with accepting things which pose conflicts of interest to prescribing practices. One of the investigators from personal experience has been viewed upon incredulously by seniors for voicing concerns about accepting something as a free lunch, despite the student being able to explain the evidence base behind their reasoning. Item 18 seeks to identify if this feeling is shared amongst any other students in

the UK. Item 21 seeks to explore the proportion of occasions where students are aware any sponsorship from the pharmaceutical industry of an educational event or meeting or conference has been disclosed prior to attending. We feel it is grossly unfair if students are expected to attend an educational event and the individuals running the event assume that anyone attending will be fine to accept the sponsorship from the pharmaceutical company. By not being able to make an informed decision prior to attending, we feel it places more undue pressure on students to conform with accepting the free lunch or attending the sponsored event anyway. Finally item 22 asks respondents if they are aware of any guidelines published by their medical school that outlines how students should deal with situations of Conflict of Interest like those presented by the pharmaceutical industry. Answers to this question again give us as investigators indication as to where we can focus our advocacy and follow up work.

Section 3 consists of 9 items (8 opinion statements and 1 white space question) for respondents to answer.

We have ensured that the statements we are asking for respondents opinions of have been worded in a neutral tone to reduce the amount of confirmation bias. Or, where possible, the statement is framed from a positive perspective. For example, in Item 29 where we have stated that “The pharmaceutical industry provides *accurate* and *reliable* information...” rather than in the more negative stance again to reduce our own inherent bias.

There are multiple reasons why we have chosen the statements in items 23-30 to seek opinions on. Not only do statements like Item 23 satisfy our primary objectives of the study, but they also seek to gain an explanation *behind* the behaviours examined in the Section 2 items. In particular, we hope to identify if there is a correlation between positive attitudes towards the pharmaceutical industry and accepting either drug rep free lunches or invitations to pharmaceutical industry sponsored events. Item 26 and 27 (“*Accepting a free lunch or small item like a pen or mug could impact MY PEERS current or future prescribing practices*”) meanwhile investigates a phenomenon described in a paper published by Steinman et al. that showed an “affects everyone but me” type attitude among doctors [3]. We hypothesise that the same effect may be present within the medical student cohort based on personal interactions with our peers at university.

Being able to explain the behaviours outlined from Section 2 responses will help us as investigators work out the best strategy for our follow-up advocacy and the degree of education which may be needed in the medical school curriculum to help better inform medical students about their choices.

Participant recruitment and inclusion criteria

We do not feel that a randomised selection of medical students within the UK is a viable option to pursue in recruiting participants. The technique for survey distribution will be a combination of multiple methods to maximise uptake:

- A link to access both the web and paper versions of the “survey” (which will actually be a link to the Participant Information Sheet and consent form allowing participants access to the survey items once the consent form is complete) will be sent to

contacts at all 34 UK medical schools accompanied by an invitation letter about the study for distribution through every year group mailing lists

- A medical student will be recruited from each medical school to act as a “local lead” of the study. These local leads, after receiving a short session on their role in the study, will actively engage with the medical student body during the data collection period, sharing the study “survey” to maximise the number of responses from each university. Each “local lead” will be incentivised to gain at least 125 responses from their university as they will then be granted part authorship on any academic paper published from the study results
- Finally, the two organisations coordinating the study will circulate the “survey” amongst their members directly and through social media to collect further responses providing they meet the inclusion criteria. We are very conscious, due to the nature of the organisations focus of work, that this method of participant recruitment has a high risk of including individuals that will increase the degree of measurement/confirmation bias in our results- hence we will ensure to not rely heavily on this method of recruitment and instead focus on the other two methods

The study has the following inclusion criteria:

- Participants must be a currently registered student at a UK-based medical school with a .ac.uk domain email address
- Participants may be at any stage of their medical degree including being on a year out undertaking an intercalated degree
- Participants do NOT have to have interacted with any of aspect pharmaceutical industry to be able to participate

The study has the following exclusion criteria:

- Participants must not have graduated from medical school as of August 1st 2016
- Participants must not be employed by a pharmaceutical company at the time of completing the survey

Timeline for study implementation

| Time Point | Deadline to be met |
|---------------------|---|
| 1st August 2016 | Application made to ethics committee |
| 1st August 2016 | Survey sent to pilot group for assessment of question validity and consistency |
| 15th August 2016 | Start of recruitment of local student leads for survey distribution |
| 30th September 2016 | Close of recruitment of local student leads |
| 30th September 2016 | Successful student leads contacted and briefed about role in survey distribution among local cohorts |
| 30th September 2016 | Expected last date by which result of ethics committee application should be known (hopefully known sooner) |

| | |
|--------------------|--|
| 1st October 2016 | Deadline for pilot responses analysis and modification of survey for final rollout on 1st November |
| 7th October 2016 | Last date for which round of formal letters sent to all 34 UK medical schools seeking permission to proceed with study in their student cohort. Period between this and start of data collection to be used to finalise arrangements for circulation of study. |
| 1st November 2016 | Start of 12 week data collection period. Online and Paper surveys circulated directly through medical schools, local leads and social media |
| 30th January 2017 | End of data collection period. Online and paper surveys links closed. |
| 28th February 2017 | Preliminary analysis of survey responses made |

Strategy for survey pilot

For a study of this nature, piloting the survey is a really important step to ensure that we get valid results from our data collection.

The purposes of our pilot will be to ensure that:

- Respondents can easily understand the questions being asked and are able to choose an answer appropriate to their experience as a student
- Data being entered by respondents can easily be analysed and where necessary disaggregated into sub-groups for efficient analysis
- Usability of the survey is appropriate for the target audience
- Respondents are able to give a range of answers within a normal distribution

We will be conducting the pilot by recruiting 30 individuals to answer the survey as well as 5 supplementary questions asking their opinion about:

- The ease by which they could complete the survey
- Their ability to understand the questions being posed
- Their opinion about the format and layout of the survey items

Individuals will be recruited from a variety of universities (we are aiming for at least 11 of the 33 universities being contacted), a variety of years within medical school and individuals both within and outside the student organisations organising the logistics of the study.

Strategy for analysis

For each of the objectives outlined earlier, a corresponding outcome/measure is expected to be attained from various items from the survey. For the majority of questions posed in section 2 and 3 the strategy for analysis will simply look at calculating the proportion of respondents who choose each corresponding option for the item using a student 1 tailed t-test to identify the statistical significance of each result.

Because of the demographic information collected in Section 1 of the survey, we will be able to disaggregate the data obtained from the survey (both for questions such as item by:

- Sex
- Year of Medical School
- Medical School location
- Country within the UK
- "School Leavers" vs Postgraduates
- Pre-clinical vs clinical medical student

Some of our secondary objectives will look to identify if there is a correlation between respondents exposure to pharma analysed in section 2 and their opinions about the industry analysed in section 3. Currently, our strategy will be to employ a linear regression model of number of exposures identified in item 19 against respondents selected answer to item 23 or 28 using simple rank spearman correlation coefficients to ascertain association between the two variables.

Dissemination of Results

Following analysis of the dataset we plan to disseminate the results on a number of platforms:

- An academic paper will be compiled for submission to a peer-reviewed, open-access journal such as the Public Library of Science (PLOSone).
- We plan to write to the authors of the key systematic review on this subject area, sharing our findings in the hope the dataset can be included in any update to the review
- Once we ensure the dataset is anonymised, we plan to upload the dataset to an open data repository to allow any researcher to openly test/replicate our analysis to hopefully draw the same conclusions. We also hope that uploading our dataset will allow future researchers to repeat the study in 5-10 years time
- The two key organisations who are coordinating the study (PharmAware-UK and Universities Allied for Essential Medicines) also plan to use the data to create visualisations and infographics that can be used as tools for advocacy and campaigns. Areas of work include increasing education around the ethical role of the pharmaceutical industry in healthcare education and encourage universities, where they haven't already, to produce guidelines on such interactions

Follow-up

At this stage, we do not have any plans to directly follow-up with any of the survey participants.

This survey is designed to be a distinct investigation with defined objectives and outcomes to be met. In our planning stages the investigators explored the possibility of having a series of online focus groups using respondents to the survey to explore a number of different themes based on opinions that would come out of the Section 3 items. However, after reflection and with the view of trying to be as specific as possible in our plans for this

investigation, we will forgo any plans in that regard until after analysis of the survey results. If any action was to be taken to set up a series of focus groups, a separate ethics application would be made.

As our plan for dissemination of results above outlines, we plan to use the results of the study to both advocate for change and help guide plans for introducing educational resources/potential changes to the medical school curriculum in the UK. Following any action taken based on our results, we hope to replicate the survey study in a similar sample size if possible, using a similar protocol to identify whether any changes have made a difference on the levels of exposure and attitudes towards the pharmaceutical industry.

Ethics

Ethical approval has been applied for from both Leicester and Edinburgh university Research Ethics Committee (REC). The outcomes of both ethics applications is pending. In the planning stages of this project, we gathered a range of opinions from REC's in different universities. This was to ascertain whether we would have 34 separate ethics applications to prepare or if gaining ethical approval at 1 or 2 REC's would suffice for the project. We came to the decision that formal ethical approval would be sought from 2 universities and informal approval to proceed would be gained from all universities where the survey was being circulated.

Furthermore, in light of the information above about follow-up, ethics has been specifically for the survey of this project. If we do proceed with carrying out focus groups, a separate application to an REC will be made.

Participant Information Sheets and Consent Form

The full Participant Information Sheets (PIS) and Consent Form to be used in the study can be found in [Appendix B](#) of this protocol.

As this study is designed to allow participants to fill out either an online or paper form of the survey, we will ensure that participants will not be able to access the survey items until they have read the full PIS and fill out the consent form. The link to either the online survey items or the paper form will never be distributed in isolation. If a survey response is somehow submitted without having completed an accompanying consent form, it will not be used in the analysis of the results.

Safety Considerations and Data protection

We do not expect there to be any specific safety concerns for study participants.

With regards to data protection, we have a number of measures to ensure that personally identifiable information is kept secure.

Firstly, the spreadsheet which will automatically collect the responses from the online survey will be password protected with only the investigators knowing the password to access the results. Whilst the spreadsheet collecting the survey data will be stored on the cloud storage service connected to the survey software, a backup of the data will be made at the end of each calendar week and stored on a password protected hard drive, again only accessible by the investigators.

For paper versions of the survey submitted by either post or email to the investigators, one of the investigators will input the survey responses directly into the same password protected spreadsheet collecting the online survey responses. Once completed, the paper copy will be destroyed by shredding the paper copy or deleting any scanned copies emailed to the study inbox.

We believe the only information that would be able to uniquely identify a study participant is the email address we are asking to be submitted. The reasoning behind asking for this piece of information is to allow us to confirm the status of a participant as a university student and ensure an individual isn't submitting more than one response to the survey. This piece of information needs to therefore be anonymised in the spreadsheet where the survey responses are being analysed.

At the end of each week of the data collection period, one study lead will access the spreadsheet, and give each submission a unique code. At the end of the data collection period, the list of responses will then be examined for any occasions where the same email address corresponds to more than one survey submission. Where this occurs, all duplicate sets of responses for that email address will be excluded from the dataset to be analysed. Once this process has been completed, the column on the spreadsheet that contains the email address field for each response will be deleted from the master dataset and all backups leaving only the anonymous code to uniquely identify a response.

As part of the consent form we are asking participants if they consent to the dataset being used for future research and, once anonymised, being uploaded securely as an open dataset that other researchers can use and analyse if they wish.

Problems Anticipated

The problems we anticipate with this study are common to cross-sectional surveys of this nature namely:

- Ensuring we capture a large enough sample size to satisfy the requirements for this study to be considered externally valid/representative of the wider medical student population
- Minimising the selection bias of respondents who may participate due to the fact the two key organisations coordinating the study have policy/strategic aims that try to limit the scope/influence of the pharmaceutical industry on health care professionals
- Trying to minimise confirmation bias that could arise in participants responses from the language and tone of the questions asked in the survey

We plan to overcome the outlined above through the following ways:

- Using a multiple approaches to participant recruitment to maximise our respondent rate through student society networks and mailing lists through universities coordinated at the local level by a network of student leads who know the best ways to contact students in their area
- By asking universities to distribute the survey on the investigators behalf to all students and reinforcing in our participant information that we are seeking individuals who have and have not encountered the pharmaceutical industry, we hope to minimise selection bias of respondents

- By piloting our survey questions with a group of medical students both involved and not involved in the coordinating organisations, we hope to ensure the tone of the questions asked, are such to minimise any confirmation bias that may be inherently introduced by the investigators

Financing

The budget for this study is relatively small as the investigators are not being remunerated for their time working on this study and participation in the study is entirely voluntary without an compensation. The expenditure associated with the project is estimated to be the following:

- £xxx for use of the survey software
- £xxx for buying of the website domain

You will note that a figure has not been listed for the costs associated with publishing any academic journal article that may be written. This expense will largely be determined by the journal approached and will be decided upon at a later stage.

The study has no specific sponsors to declare. The money raised to pay for the above expenses is from the internal resources of the coordinating organisations.

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