Internet Appendix A45: Pharmacy

A45.1 Illustrative Pitch Template Example on Quitting Smoking

This pitch is reverse engineered from the paper:

Zhu SH et al (2015) Quitting smoking before and after varenicline: a population study based on two representative samples of US smokers. Tobacco Control doi:10.1136/tobaccocontrol-2015-052332

Pitcher's Name	Sam Hollingworth	**FoR category**	Pharmacy	**Date Completed**	October 2015
(A) Working Title	Can I quit smoking with this medicine?				
(B) Basic Research Question	Do medicines for smoking cessation work in 'real world' people?				
(C) Key paper(s)	Walsh RA. Australia's experience with varenicline: usage, costs and adverse reactions. Addiction 2011;106(2):451-2 Kasza KA et al Use of stop-smoking medications in the United States before and after the introduction of varenicline. Addiction 2015;110(2):346-55 Langley TE et al Prescribing of smoking cessation medication in England since the introduction of varenicline. Addiction 2011;106(7):1319-24				
(D) Motivation/Puzzle	Medicines are generally tested for their effectiveness in randomised controlled trials. One group gets the medicine and the other gets some control comparison. The outcome of interest is then compared between the two groups. The people who participate in trials are often slightly different to the people in real world settings (e.g. they are usually 'healthier'). It's more likely that medicines are more effective in a trial than they are in real life. We want to support people who wish to stop smoking and one way is to use prescription smoking cessation medicines (SCM) such as nicotine replacement (e.g. patches), bupropion (Zyban®) or varenicline (Champix®).				
THREE	**Three** core aspects of any empirical research project i.e. the "**ID**io**T**s" guide				
(E) Idea?	Varenicline is known to have greater efficacy than other pharmacotherapy for treating nicotine dependence and has gained popularity since its introduction in 2006 in the United States. We will examine if adding varenicline to existing pharmacotherapies increased the population cessation rate.				
(F) Data?	The Tobacco Use Supplement (TUS) is a periodic survey attached to the Current Population Surveys (CPS) and administered by the U.S. Census Bureau. The CPS uses a multistage stratified sampling procedure to interview a nationally representative sample of households of the non-institutionalised civilian US population aged 15 and older. TUS surveys are conducted about every 3 years in conjunction with the regular CPS. The sample size is about 240,000 individuals in each survey period. We will examine two CPS-TUS surveys, one in 2003 and the other in 2010–2011: the former was conducted three years before varenicline came to the market, and the latter four years after its introduction. The 2003 survey had 183,810 respondents who were 18 years or older, including 34,869 smokers (smoked 12 months prior to the survey). The 2010–2011 survey had 171,365 respondents aged 18 or older including 27,751 smokers. The response rate for TUS (number of people who completed the survey divided by the number who were eligible) was 63.6% for the 2003 survey and 61.2% for the 2010–2011 survey. Participants were self-respondents aged 18 or older who answered "everyday" or "some days" to the survey question: "Around this time 12 months ago, were you smoking cigarettes every day, some days, or not at all?" The annual cessation rate, as well as the per cent of smokers who had quit for ≥3 months, was compared between surveys.				
(G) Tools?	Descriptive analysis using statistical software to obtain point estimates of demographic variables, use of medications, quit attempts, annual quit rates, and quitting for three months. Survival analyses were conducted to calculate the length of the last quit attempt using Kaplan Meier analysis. Separate analyses were performed for all smokers (daily and non-daily) and for daily smokers alone, since daily smokers are known to have lower quit rates than non-daily smokers. Ethics approval: This study is a secondary data analysis of publicly available data. Analysis of the population data set will require ethics approval.				

Template adapted from Faff, Robert W., Pitching Research (January 11, 2015). Available at SSRN: http://ssrn.com/abstract=2462059 or http://dx.doi.org/10.2139/ssrn.2462059

TWO	**Two** key questions
(H) What's New?	Using routinely collected data from large population surveys to see if these medicines are effective in real world populations (i.e. to help people to stop smoking). The critical measure for assessing the potential population impact of any new intervention is whether its introduction increases the quit attempt rate of the population. It is important to develop new therapies to help individual smokers quit the addictive and destructive habit of smoking. However, the ultimate goal of developing any therapy should be to increase the quit rate of smokers at the population level. A new efficacious therapy needs to lead to a greater usage of therapies overall and, more importantly, a significant increase in the quit attempt rate among smokers before it can have a real impact on successful quitting at the population level.
(I) So What?	People either have to pay considerable amount of money for these medicines or they may be subsidised by government schemes (e.g. Medicaid and Medicare in the US) or health insurance companies (e.g. Kaiser Permanente). The medicines were registered for use on the basis of data from clinical trials. Some organisations that subsidise medicines may also consider cost effectiveness (or utility) analyses. We need to know if these medicines are working as well in 'real world' populations (i.e. stopping people from smoking) as they do in trials and whether they represent good value for money.
ONE	**One** bottom line
(J) Contribution?	Information on the effectiveness of these medicines in real world populations may help to inform the use and possible subsidy or health insurance reimbursement for these medicines. It might help us know how to better use these medicines (i.e. target particular groups in the population that had a better chance of stopping smoking).
(K) Other Considerations	Is **Collaboration** needed/desirable? • Likely need grant funding to support this work. • Need collaborating with peers who are experts in the area + statistical expertise. **Target** Journal(s)? E.g. Tobacco Control, Addiction, etc. "**Risk**" assessment: low risk. Particular challenges are inherent in the topic - the fact that people often have a long and varied journey towards their final destination of stopping smoking. This can be hard to measure in survey data. Is the **scope** appropriate? Not too narrow, not too broad.

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