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The ethics of conducting observational tobacco research without providing treatment to people who use tobacco: a case example from South Africa

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INTRODUCTION

Tobacco use is responsible for approximately 7 million deaths and costs the global economy an estimated $1.4 trillion annually.[1 2] Tobacco use behaviour is frequently measured in research studies, including both those that focus on reducing tobacco use and those that assess its effects on health outcomes. Given the large health burden of tobacco use, its reversibility with tobacco cessation and the availability of efficacious treatments,[3 4] we discuss the obligation of researchers to provide tobacco cessation treatment to participants in prospective observational studies. We use a case example of a current study in which we measure tobacco use in South Africa[5] to describe considerations and options for researchers working in this area.

ANCILLARY CARE OBLIGATIONS

The 2021 Council for International Organizations of Medical Sciences ethical guidelines state that "Researchers have an ethical obligation to care for participants' health needs during research and, if necessary, for the transition of participants to care when the research is concluded."[6] The obligation can be met by the researchers directly providing care or by facilitating referral through local health services.[7]

Examples of providing ancillary care for hypertension and diabetes have been regarded as a standard in global health research.[8] Like hypertension and diabetes, if tobacco use is unaddressed, it can lead to cardiovascular disease and other health problems. Yet, obligations to provide ancillary care for tobacco use have rarely been described.[9 10] Although we cannot measure the overall prevalence of ancillary care in observational tobacco research studies, in our experience, it is not offered in most studies. Tobacco cessation treatment may be viewed as inadequately effective,[11] particularly in settings with limited access to providers with cessation treatment training.[12] Regardless of the rationale, 'exceptionalism' for tobacco use is problematic. Like hypertension and diabetes, evidence supports the efficacy of tobacco cessation treatments.[4] These treatments include inexpensive and simple to deliver options, and all are cost-effective.[4] Plus, there is an urgency to treat tobacco use. The earlier a person quits smoking, the sooner their risk of myocardial infarction, cancer and other diseases decreases and the more years of life expectancy they gain compared with persons who continue to smoke.[13]

Summary box

- ⇒ Tobacco is the leading preventable cause of death globally, causing approximately 7 million deaths each year.
- ⇒ No ethical standard exists to guide researchers considering their obligation and ability to provide treatment for study participants who use tobacco.
- ⇒ We propose that tobacco cessation treatment should be offered as ancillary care to interested study participants who use tobacco.
- ⇒ We share a case study in which we describe our approach to implementing a brief behavioural tobacco cessation intervention as part of an observational study of tobacco use patterns in South Africa.

STANDARD OF CARE FOR TREATING TOBACCO USE

Several factors warrant consideration when deciding on the appropriate ancillary care

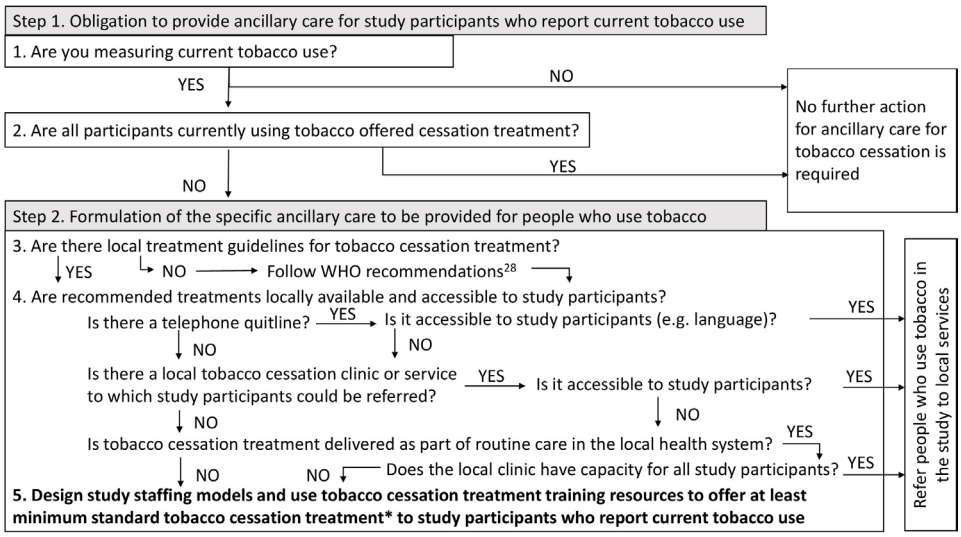

Figure 1 Schema for planning ancillary care for tobacco use. Footnote. *Minimum standard tobacco cessation treatment should be based on local treatment guidelines, if available, or WHO recommendations and should include brief advice in all healthcare sectors.

for tobacco cessation (figure 1). Brief advice to quit tobacco is universally recommended as standard care in clinical guidelines and can be offered anywhere, at minimal cost.[14] Telephone quitlines are another option in many low- and middle-income countries. The WHO Model Essential Medicines List names tobacco cessation medications including nicotine replacement therapies, bupropion and varenicline. International, national and local practice guidelines provide a useful context-specific framework for selecting a treatment standard.

Considering the local standard of care in ancillary care planning is a complex topic, particularly when the standard varies between high- and low-resource settings. While a full review of this topic is beyond the scope of this article, an important question relates specifically to tobacco cessation therapy referrals: If treatment is not available locally, should researchers nonetheless offer services? In their description of the benchmarks of ethical, global health research, Emanuel *et al* point out two responses to this: First, that researchers are not tasked with addressing the shortfalls of a country's healthcare system, and second, that researchers cannot ignore the health problems of their participants and should at least ensure access to care that meets national guidelines.[15] Furthermore, planning for ancillary care is part of building collaborative partnerships with mutual respect between researchers and the communities with which they collaborate.[15]

Nevertheless, since brief cessation counselling advice is effective and available in all settings, we believe ancillary care for tobacco cessation treatment—including, at a minimum, brief advice—should be obligated when tobacco use is uncovered as part of observational research. We next describe how we considered our obligations and implemented brief behavioural assistance for participants who reported tobacco use in an observational study.

TOBACCO CESSATION TREATMENT IN VUKUZAZI: A CASE STUDY

We are conducting a telephonic survey to assess tobacco use behaviours among people who participated in Vukuzazi, a community-wide multidisease survey conducted in rural KwaZulu-Natal, South Africa, between 2018 and 2020.[5] Through its initial field-based survey and ongoing community and health system engagement, Vukuzazi has built a collaborative partnership emphasising bidirectional benefit to the community and the advancement of science.

Following the design of our tobacco follow-up survey, our study team considered whether to provide ancillary care for tobacco use among survey participants. The rural district of uMkhanyakude in KwaZulu-Natal, South Africa, where our tobacco survey is being conducted, is a community with a high burden of communicable and non-communicable diseases for which tobacco use is a risk factor. Cross-sectional data from Vukuzazi showed 21.8% of participants had lifetime tuberculosis and 23.0% had elevated blood pressure.[16] The community also faces high levels of poverty and unemployment, which are associated with tobacco use. Notably, our initial field-based survey showed that 94% of persons who smoke had never been advised to quit by a healthcare provider (unpublished data). This suggested to us that even brief cessation counselling could be beneficial and that ancillary tobacco cessation treatment was warranted.

ASSESSMENT OF LOCAL STANDARD OF CARE AND AVAILABLE RESOURCES

To make an informed decision about how to offer tobacco cessation treatment to research participants, we assessed the national standard of care and the actual availability of care as delivered through the local health system. South Africa has a constitutionally mandated

national health system that defines healthcare guidelines to be enacted by provincial districts and local subdistricts. The Department of Health's national framework for tobacco use outlines that tobacco use should be identified during routine consultations with healthcare practitioners, and that people who use tobacco should be advised to quit and offered at least brief cessation assistance.[17] We conducted an informal assessment of the local standard of care through visits to primary healthcare clinics and discussions with district health representatives. This assessment revealed that tobacco cessation screening and cessation counselling were not routinely offered in the local healthcare system. This gap was attributed to the many burdens on local clinics, lack of training in tobacco cessation counselling and lack of resources in the rural setting. We then looked for descriptions of tobacco cessation resources elsewhere in South Africa and found only one public sector smoking cessation clinic in the country. This clinical service in Cape Town, over 1800 m away, was not accessible to our study population. Next, we assessed the services offered by two national quitlines: the Cancer Association of South Africa (CANSA) and the National Council Against Smoking (NCAS). CANSA offers an online support programme (https://cansa.org.za/how-to-quit-smoking-and-why/), but few individuals in our study population have internet access that would enable its use. NCAS (https://www.againstsmoking.co.za/) offers telephone-based services (call-back). This left us with a choice to refer participants to the telephone-based quitline service or to offer initial tobacco cessation advice ourselves plus a referral to the quitline as ancillary care. Since we would already be in telephonic contact with participants while administering the survey, we decided that offering direct tobacco cessation advice offered a substantive benefit to research participants that might be more beneficial than referral to the quitline alone.

RESOURCES REQUIRED TO PROVIDE TOBACCO CESSATION COUNSELLING

The decision to administer tobacco cessation counselling to study participants required us to consider available staff and whether survey personnel were appropriate providers of tobacco cessation counselling. In our case, the follow-up survey was conducted by a research nurse fluent in English and IsiZulu (the local language). The research nurse completed a certified online training course, Basic Skills for Working with Smokers, at a cost of US$175 (https://www.umassmed.edu/tobacco/training/ttscore/). The course equipped the research nurse with basic tobacco cessation treatment skills.

CARE PLAN AND REFERRALS

To align our tobacco cessation care with South African guidelines, our plan included brief cessation advice, referral to the NCAS quitline and telephone follow-up. Participants were those who reported current tobacco use in our ongoing tobacco survey. The research nurse provided brief advice and assessed readiness to quit. For those willing to quit, the nurse delivered brief counselling and provided the participant with the NCAS quitline telephone and WhatsApp numbers. Figure 2 displays the brief counselling script components. The nurse adapted language from a US-based counselling script and translated it into IsiZulu. A second IsiZulu-speaking research team member back-translated the script to ensure accuracy. To avoid introducing bias into the telephonic survey responses, the team administered the tobacco cessation care after completion of the research survey. Follow-up calls were conducted 1 and 3 months later to assess participant experience with the NCAS quitline and to offer additional cessation advice.

CONCLUSIONS

Tobacco use is a major health threat globally, and low-cost, internationally available interventions to promote

- ❑ **HEALTH RISKS AND BENEFITS TO QUITTING TOBACCO:**
  - ❑ Tobacco use is the leading cause of preventable diseases and death
  - ❑ No type or amount of tobacco is considered safe
  - ❑ Hundreds of toxic chemicals in tobacco increase risks of health problems, impacting nearly every organ in the body
  - ❑ Tobacco use contributes to many diseases
    - ❑ Hypertension, diabetes, heart conditions, stroke, emphysema, lung infections such as TB and pneumonia, cancers, erectile dysfunction and fertility problems
  - ❑ Health benefits of quitting are seen within minutes to hours of ending tobacco use, for example:
    - ❑ Heart rate and blood pressure are reduced within minutes of quitting
    - ❑ Senses of smell and taste improve within 2 days of quitting
  - ❑ Most people try several times before the final quit because of addiction caused by nicotine
    - ❑ Nicotine is the substance found in tobacco that causes dependence
  - ❑ Quitting tobacco reduces the risk of diseases, improves overall health, and saves money
- ❑ **STRATEGIES TO DEAL WITH BARRIERS TO QUITTING TOBACCO AND TO PREVENT RELAPSE:**
  - ❑ Barriers to quitting
    - ❑ Nicotine withdrawal symptoms, tobacco cravings, stress, alcohol use, spending time with others who use tobacco
  - ❑ Barriers can be addressed with good strategies
    - ❑ Methods for dealing with urges to use tobacco
      - ❑ Drinking a lot of water, physical exercise, eating fruits and vegetables, deep breathing techniques, good coping strategies for stress, stop alcohol consumption and stop drinking caffeine containing beverages
    - ❑ Seek support from family/friends
    - ❑ Avoid triggers
      - ❑ Limit time around people using tobacco
      - ❑ Remove tobacco products and related items (e.g. lighters and ashtrays) from the environment
  - ❑ Use of approved tobacco cessation medications may help to deal with withdrawal symptoms and promote success

Figure 2 Outline for brief counselling on tobacco cessation.

cessation are available. However, researchers commonly measure tobacco use but fail to offer assistance when tobacco use is identified among participants. We propose that tobacco use should be included in ancillary care considerations in prospective, observational research and that offering cessation treatment to research participants is feasible, even in resource-constrained settings.

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