

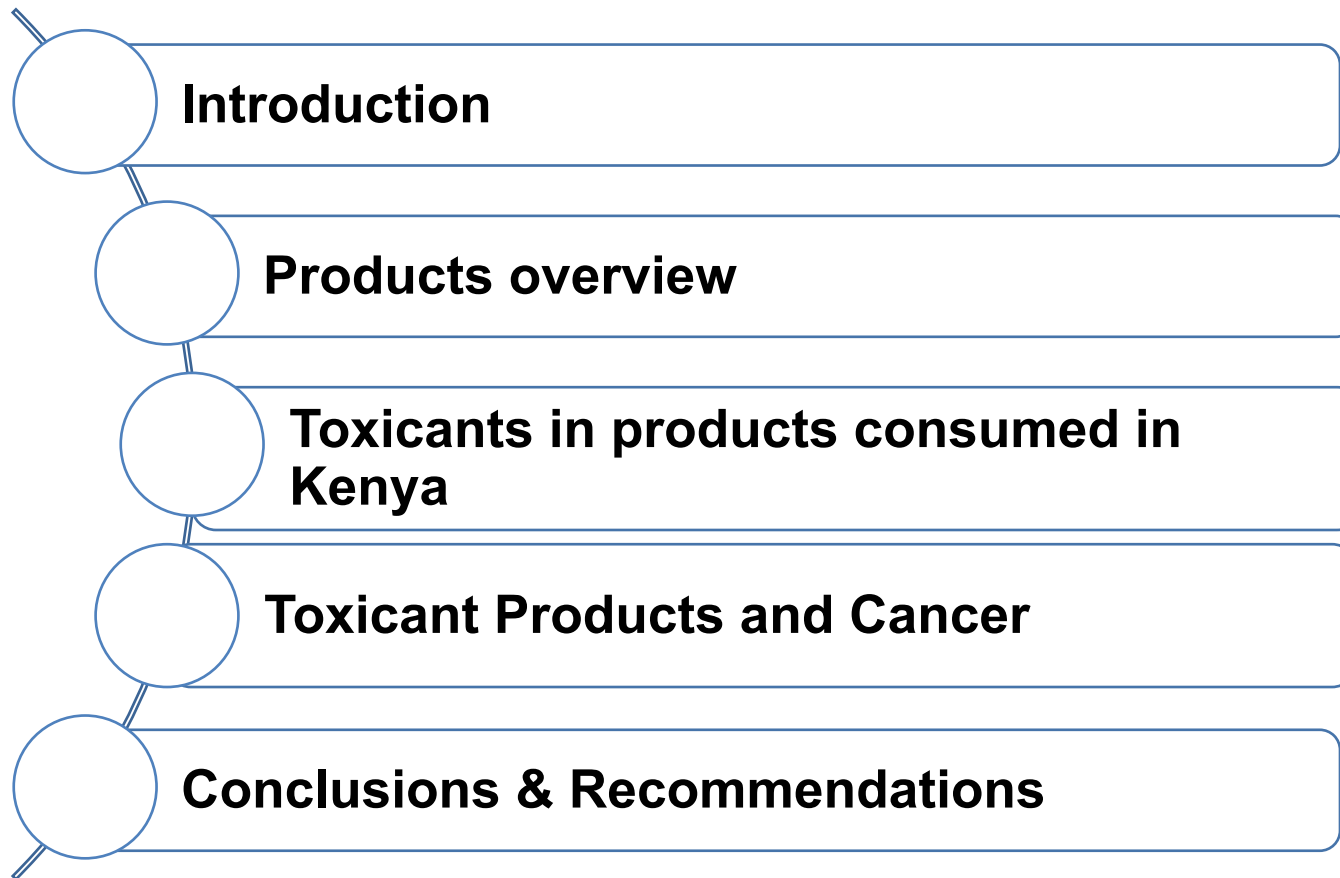


The Risks and Toxicants of STPs in Kenya

**Kenyans choosing oral and nasal
toxicant products with higher
cancer risk**

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Outline



Introduction

- Chewing tobacco, snuff, areca nut products (pan, gutkha), and khat (miraa) are the major legal Smokeless Psychopharmacologically-active Products (SPPs) used in Kenya



- The majority of SPPs consumed in Kenya are locally produced, **unregulated, and unbranded with little or no quality control** in terms of levels of toxicants or psychoactive ingredients.
- There is a lack of adequate studies demonstrating either the carcinogenicity of SPPs in controlled trials or their toxicant contents.
- This report aims to consolidate the limited information available on the types of SPPs used in Kenya and make recommendations for future work to clarify the toxicant levels and, hence, the health risks of Kenyan SPPs.

Product Overview.



- Most of the Smokeless Psychopharmacologically - active products used in Kenya are produced locally and a few imported.
- These include most oral and nasal tobacco products containing areca nut such as betel quid (pan, paan) and khat.
- The local chewing tobaccos and oral and nasal snuffs are made in small home workshops.

Product Overview.



- The products are not sold in branded packaging but are wrapped in desiccated banana leaves or pieces of paper.
- Imported products are mainly from India and include packaged chewing tobacco (khaini) and areca nut (gutkha).
- Retail sales of imported SPPs are relatively small, with most of the market being accounted for by unpackaged, unbranded, and unregulated products.

Demographics of products used in Kenya.

- **The use of smokeless tobacco increased steadily with age,** from 3.0% for the 30-39-year-old group to 8.9% for the 60-69-year-old group.
- A small proportion of the respondents (0.7% of males and 0.1% of females) smoked cigarettes and used STPs.

Demographics of products used in Kenya.

- The 2014 Global Adult Tobacco Survey found that **among males, 3.9% use nasal snuff, 1.9% use local chewing tobacco, and 0.3% use imported chewing tobacco.** In contrast, chewing tobacco (2.3%) was used more than nasal snuff (1.7%) among females.
- Among the urban respondents, chewing tobacco (1.8%) is more prevalent than the use of oral snuff (1.0%). Rural respondents use nasal snuff (3.7%) more than chewing tobacco (2.3%).
- Other forms of tobacco use, such as shisha (water pipe), are much less common, and, in December 2017, the import, manufacture, and sale of shisha was banned by Kenya ministry of health.

Oral and Nasal products used in Kenya

Product	Other terms used	Type of product/ mode of use	Ingredients	Notes
Ndovu	Dawa, dose, pembe, cuba, tambuu,	Chewing tobacco	Chewing tobacco	Contaminated with illicit drugs.
Chavez	In mombasa: ogoro, strong sugar, gwasma, zindegi. In machakos: rwara, mbaki	Snuff. Used orally or nasally	Finely ground tobacco, colored green or brown	
Pan	Paan, tambu, betel quid. Without tobacco: sweet pan, pan masala, tambu	Sucked, chewed, or held in the mouth	Areca nut, slaked lime, catechu, flavorings, sweeteners. Wrapped in a betel leaf.	Used widely in south asia and the indian subcontinent.

Oral and Nasal products used in Kenya

Product	Other terms used	Type of product/ mode of use	Ingredients	Notes
Gutkha	Gutka	Sucked or chewed	Areca nut, slaked lime, sun-dried, roasted, finely chopped tobacco	Imported from India.
Khaini	Kuber, Mirage.	Sucked or chewed	Sun-dried/ fermented tobacco),lime paste, areca nut, Menthol /aromatic spices.	Khaini is the most popular form of STP in India.
Khat	Miraa (veve), muguka (jaba, ketepa) muhulo, muirungi	Chewed	Leaves and twigs of Catha edulis	Khat has alkaloid cathinone, a stimulant-causes euphoria and loss of appetite.

Modern nicotine products

Nicotine Replacement Therapy (NRT) Products

- NRTs were developed to help people quit smoking by replacing the nicotine that would otherwise be obtained from cigarettes or other tobacco products.
- NRTs deliver nicotine in various ways: trans-dermally via patches, directly into the mouth by aerosol sprays, or chewed like gum or lozenges which can be flavoured
- **NRT products are safe with no evidence of lung, gastrointestinal and oral cancer associated with their use.** However, there have been conflicting reports about the relationship between NRT and cardiovascular disease.
- Using NRT does not increase the overall nicotine intake compared with smoking alone.

Modern nicotine products

Modern oral nicotine products (MONPs)

- Modern oral nicotine products have the potential to have a lower risk profile than the Swedish snus which is the STP with the lowest global risk profile.
- The flavors used must be generally recognised as safe (GRAS) .
- Some MONPs were marketed in Kenya on and off from July 2019 to mid-Oct 2020 and were regulated as pharmaceutical products.
- **They were later re-categorized by the Kenyan government as tobacco products, and it now falls under tobacco regulation.**

Toxicant products and cancer



Africa

- **The estimated age-adjusted incidence rates of oral cancer in Kenya for 2020 are 2.8/100,000 overall** (2.9/100,000 for males and 2.7/100,000 for females).
- These rates are lower than the rates reported for India and the US.
- These differences may be accounted for by differences in risk factors between these countries.
- Oral cancer rates in Kenya and other sub-Saharan African countries are underreported due to the limitations of the cancer registries in these countries.
- **In Kenya, the registry only covers 2.5% of the population (as of 2012)** and is skewed more to urban than rural populations.
- There have been few epidemiological and case control studies to help clarify the roles of the different risk factors for oral cancer in Kenya.

Toxicant products and cancer



Africa

- In Sudan studies showed a higher oral cancer risk from the the use of toombak, which in an STP.
- Kenyan and South African studies on the risk of nasopharyngeal cancer among user of nasal snuff were small.
- The Nandi of Kenya, who habitually use a liquid nasal snuff, was found to have higher incidence of nasopharyngeal cancer compared to others.
- The Bantu of South Africa who consume nasal snuff had low levels of oral cancer but elevated risks (not quantified) for cancer of the paranasal sinus.
- To our knowledge, there have been no case-control studies on the risk of oral cancer from the use of STPs within Kenya or other parts of Southern Africa.

Toxicant products and cancer

- **STPs, in general, have been classified by the IARC as carcinogenic to humans (Group 3).** Areca nuts, and SPPs that contain them, such as betel quid, gutkha, supari, and mawa, have also been designated as Group 1 carcinogens by the IARC.
- The major health risks reported from using STPs and SPPs include cancers of the upper respiratory and digestive tracts, particularly oropharyngeal cancers. There are also reported increases in the risk of pancreatic cancer, gastric cancer, and cardiovascular diseases.

Risks of Cancer from use of STPs

- There was no significant risk for oral cancer from STP use in North America and Sweden
- In contrast, STP users in India and Pakistan had much higher risks
- The low rates of oral cancer associated with STPs in the US are due to the increasing prevalence of the lower risk products: moist snuff and chewing tobacco, which have replaced the higher risk dry snuffs, which are no longer popular

Risks of Cancer from use of STPs

- In Sweden, STP consumers' near-universal use of snus is responsible for their low oral and other cancers risk.
- Studies on snus show that, **after adjustments for smoking**, snus had lower risk of cancer of the oropharynx, esophagus, stomach pancreas, lung or any other sites, or with heart disease or stroke.
- An oral condition termed “snuff dipper's lesion,” fairly common in STP users, is reversible and does not predict oral cancer.

Risks of Cancer from use of STPs



- The US Food and Drug Administration (FDA) has acknowledged the reduced risk of snus products by authorizing the marketing of eight Swedish Match snus products sold in the US as **modified risk tobacco products**.
- These products can now be labelled “**Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.**”

Tobacco-related toxicants

- **Group 1 human carcinogens by the IARC include:**
N-nitrosornicotine (NNN) and
4-(N-methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK), B[a]P,
formaldehyde, arsenic compounds, beryllium, and nickel.
- The US Food and Drug Administration (FDA) has also included other elements on its list of Harmful and Potentially Harmful Compounds in tobacco products: the Group 1 carcinogens, cadmium and chromium (VI), and the toxic elements lead and mercury

Tobacco Curing process

- **The curing process results in considerable chemical changes in the leaf.**
 - There are essentially four curing methods:
 - flue-curing,
 - air curing,
 - fire-curing, and
 - sun curing.
 - Flue-curing involves hanging the leaves in a tightly sealed barn (kiln) and heating the space indirectly via flues from propane or oil burners.
 - Flue-curing requires careful regulation of the heat and moisture in the barn over the 10-14 day curing time.
 - Air-curing, which takes 4-8 weeks, also involves hanging tobacco leaves in a well-ventilated barn, sometimes heated to control humidity.
- After the curing process, fermentation commences and involves bringing the tobacco leaves to about 20% moisture and forming them into bulk piles or placing them in cartons (box-sweating).
 - The inside temperatures in the fermenting pile are monitored and allowed to reach 60-65°C.

Tobacco fermentation

- Some sun-cured tobaccos, such as the N. Rustica used in Sudanese Toombak are fermented after curing.
- In contrast, Swedish snus is made from non-fermented sun-cured and air-cured tobaccos, which are ground and pasteurized to prevent microbial growth.
- During processes where high moistures and warm temperatures occur for extended periods, such as fermentation, “sweating,” and storage, microbes, particularly bacteria, can multiply rapidly.
- **Many of the bacterial strains produce nitrate reductase enzymes that can convert the nitrate in the tobacco to nitrite during air-curing and fermentation, which reacts with the tobacco alkaloids and amino acids to form nitrosamines.**

Areca nut toxicants

- Areca nuts contain several alkaloids, one of which is arecoline, which is a possible (Group 2B) human carcinogen but there is little evidence for the existence of pre-formed nitrosamines in areca nut.
- Tobacco and areca nut can take up minerals from the soil, including toxic elements or radionuclides, or be exposed to toxic airborne contaminants such as B[a]P.

Polycyclic Aromatic Hydrocarbons

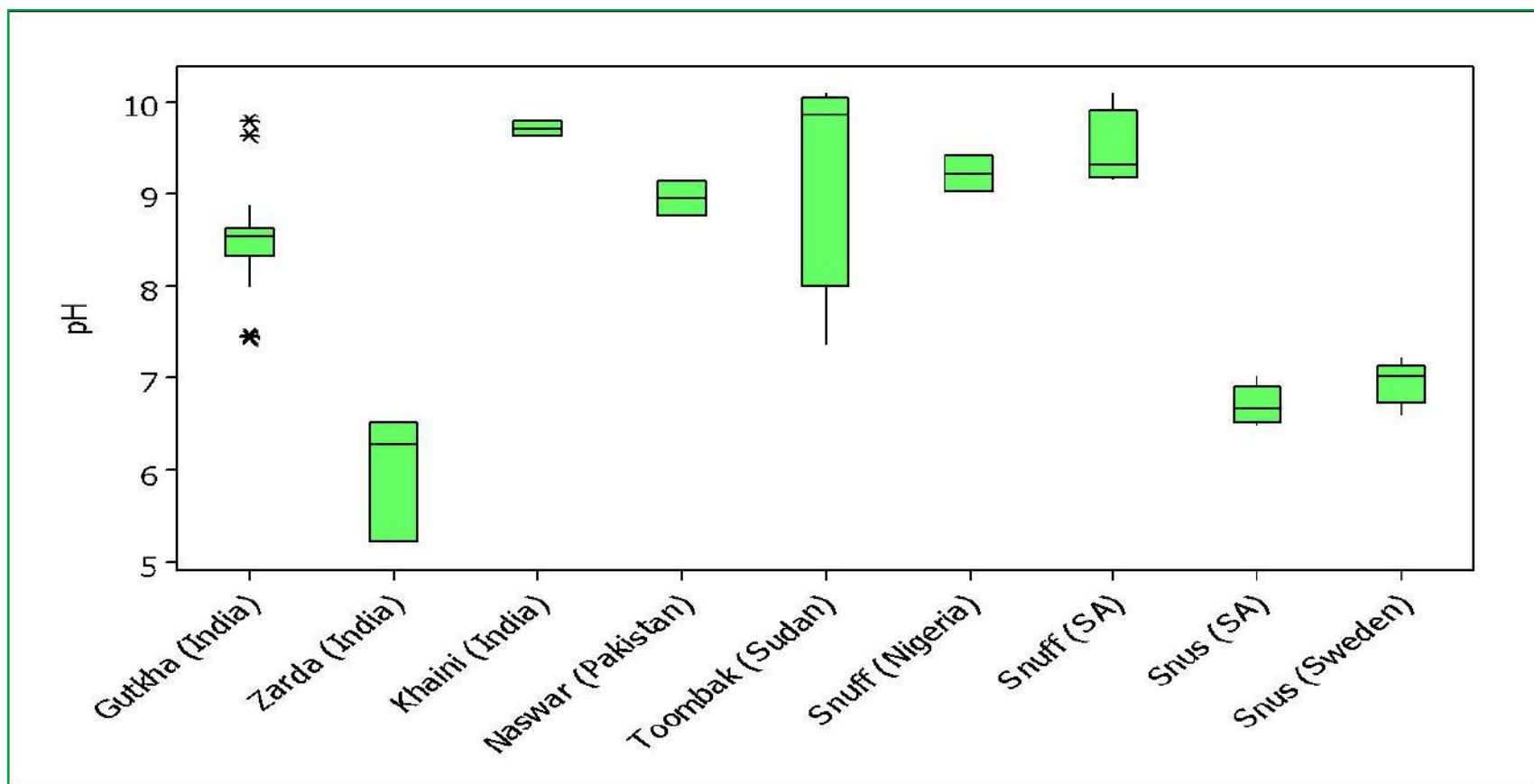
- PAHs do not occur naturally in plant material, and their presence is due to contamination from combustion sources.
- For tobacco, the curing process can introduce PAHs to the leaf if the tobacco is exposed to exhaust gases from heat sources such as oil or gas burning.
- In particular, the fire curing process, which involves exposing tobacco to wood smoke, can create high concentrations of PAHs on the tobacco leaf surface.
- Overall, there have been 86 PAHs reported to be present in tobacco. Only one of these, **B[a]P**, is classified as a known human carcinogen, although more than a dozen have been classified as probable (Group 2A) or possible (Group 2B) carcinogens.

Non - Gras Flavors

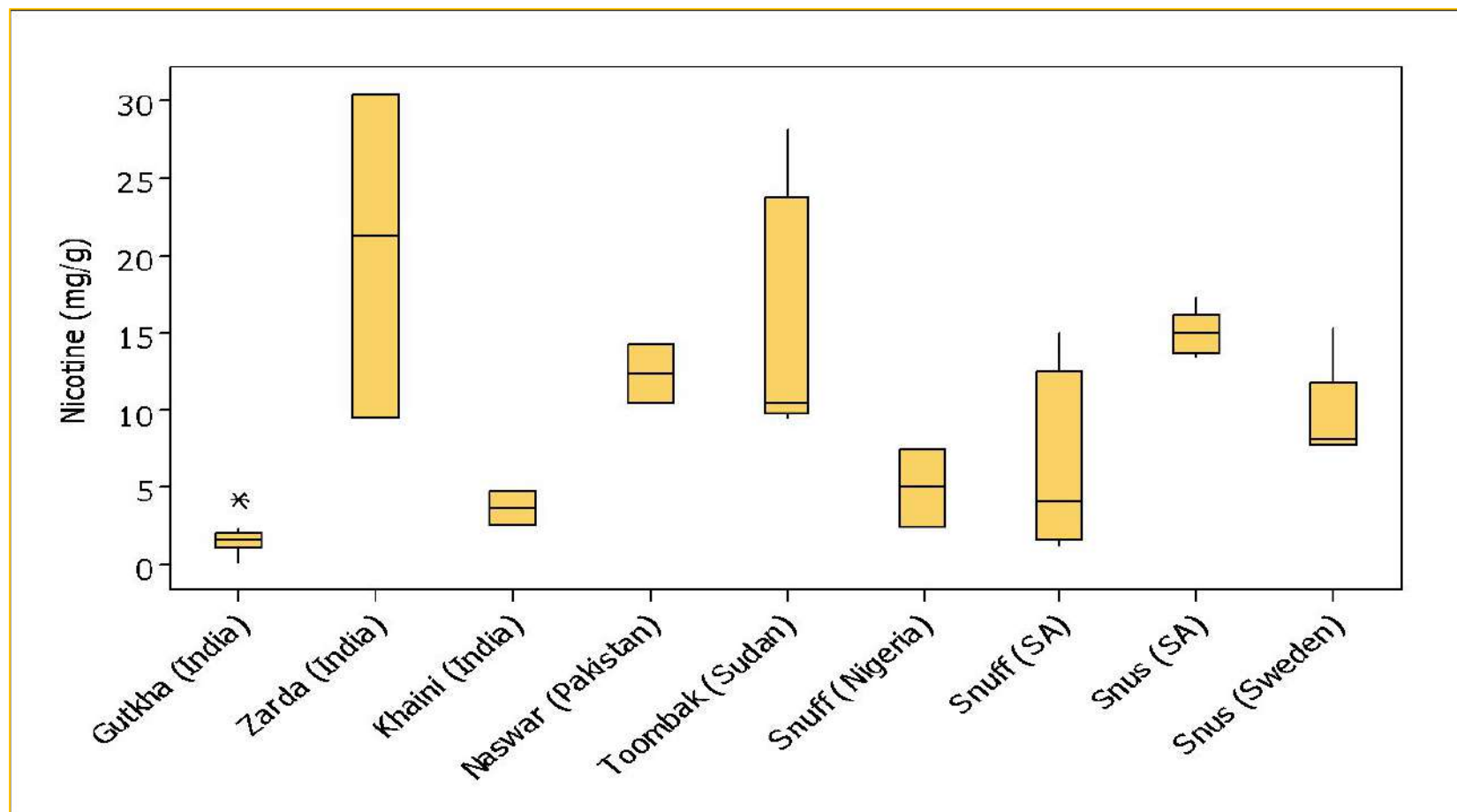
- These products are frequently flavoured for palatability.
- These flavours need to be generally recognised as safe
- Some flavours e.g. coumarin is hepatotoxic.
- The Kenyan government introduced a bill in parliament to regulate the use of additives in tobacco products



P.H from some STPs



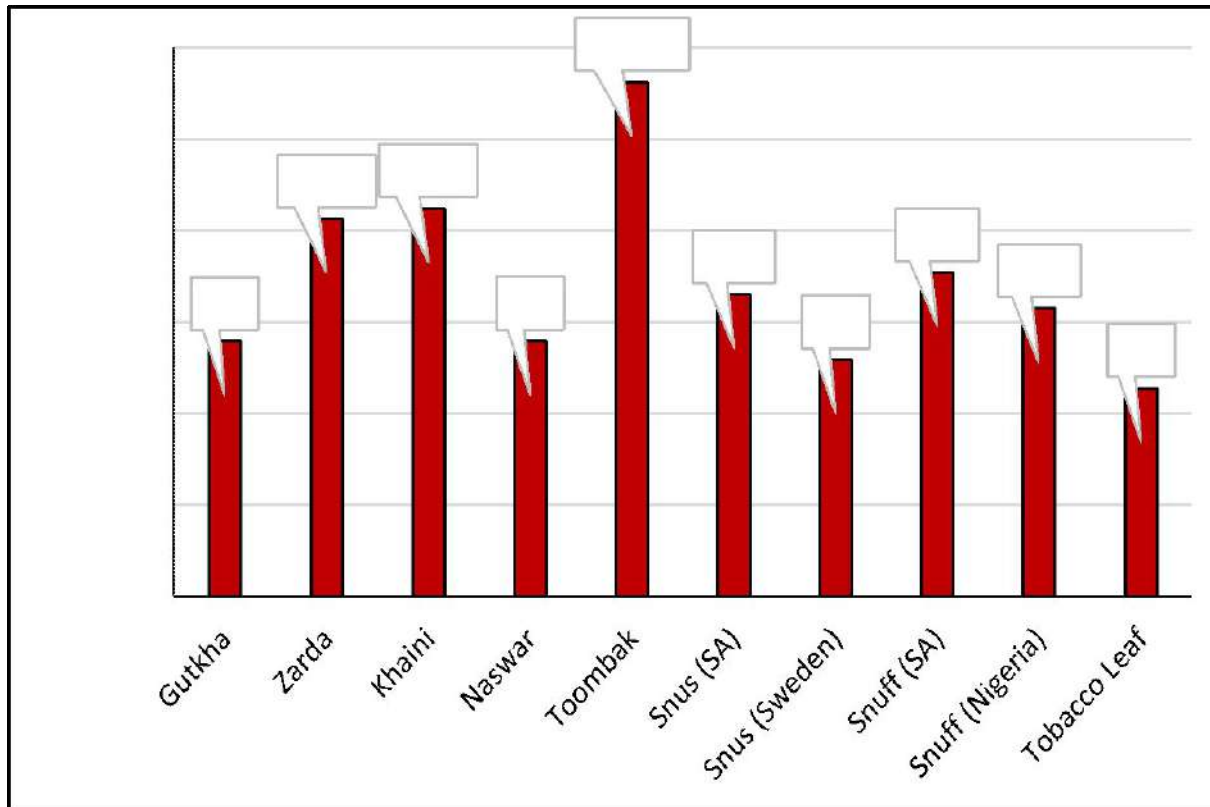
Nicotine Levels in some STPs



Nicotine Levels in Kenya STPs

Product	Other names	No of samples	Nicotine (mg/g ww)
Kuber (branded khaini)	Khaini	14	4.41
Other tobacco branded sachets	Khaini, gutkha	18	3.52
Ndovu	Formulated kuber/tambo	22	3.49
Chavez	Snuff	22	3.95

Average NNN+NNK levels (ng/g ww) in some STPs from Asia, Africa and Sweden



Overall, the **highest values for NNN+NNK** reported by Stanfill *et al.* (2010) were found for Sudanese toombak with average levels of 421 $\mu\text{g/g}$.

Conclusion

- SPPs and STPs are not one product but many different products with different ingredients, different chemistries and different health risks.
- Globally, risks for oral cancer range from extremely low or negligible for Swedish snus, through very low for US chewing tobacco and moist snuff, **to high for some Indian products such as khaini and gutkha, and Pakistani naswar, and to very high for Sudanese toombak.**
- These risks correlate approximately with the levels of carcinogens, particularly the TSNAs, in the product.
- The risk is also dependant on how the product is used e.g. frequency of use, amount of product in each dose and the length of time held in the mouth, as well as exposure to other risk factors such as tobacco smoking, alcohol, and human papilloma viruses



Recommendations

Carry out an in-depth review of quantities and types of imported and locally produced smokeless tobacco, areca nut and khat products in Kenya.

Study the ingredients and perform toxicant and alkaloid analyses for all smokeless tobacco, areca nut, khat, tobacco-free nicotine products on the Kenyan market.

Initiate case-control studies to determine the health risks from the use of these products.

Monitor for the presence of other drugs in local products to confirm anecdotal reports spiking with illegal drugs such as heroin, cocaine etc



Recommendations

Undertake an environmental in-depth study of the effects of smokeless tobacco, areca nut and khat products growth and production, distribution and consumption.

Lobby for the government to regulate all smokeless tobacco, areca nut and khat products.

Undertake a study on the of effects of smokeless tobacco, areca nut and khat products on the exposed non users and affected such as family members and the community.

Asanteni
/Thank you

