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1. CLINICAL POPULATION HEALTH – LITERATURE REVIEW

1.1. Results

The review identified 3 non-US-based studies (Japan, Germany, and Italy) [1-3]. Two of the studies [1, 2] were part of the 2022 Annual Report submitted to the US FDA. All the 3 studies were based on simulation models [1-3]. The quality of the studies was classified as strong in 1 of the studies [1] and moderate in 2 [2, 3].

1.1.1. Impact of THS Use on CC prevalence

One study analyzed the impact of THS use on the prevalence of CC smoking in Italy using the Systems Dynamics Model [2]. The model was based on populations aged 0-100 years and over a 100-year period (2001-2100). Results showed that THS use would result in lower prevalence of CC smoking in Italy (4.7% vs 11.3%).

1.1.2. Impact of THS Use on Mortality, LYL, and Life Expectancy

Three studies assessed the impact of THS use on mortality and LYL [1-3]. Camacho et al [1] used the Systems Dynamics Model to evaluate the impacts of THS use (vs CC only) on SADs and LYL in Japan. The model was based on populations aged 20+ years. Results showed that in a worst-case scenario, population health gains would be seen with THS risk being about 50% lower than that of CC smoking. THS use would result in 13 million fewer LYL by 2100 compared with CC smoking only. In a similar analysis but with populations aged 0-100 years in Italy, Camacho et al [2] reported that THS use would result in about 10.7 million reductions in LYL as compared to CC smoking only in Italy.

Rytsar et al [3] used the Population Health Impact Model developed by PMP S.A. to quantify the impact (SADs and LYL) of NNTP (THS and electronic cigarette use) over a 20-year period in Germany (1995-2015). The model was based on populations aged 30-79 years. In the base scenario (CC smoking only), it was estimated that there would be 852,000 SADs (42,600 per year) and 8.61 million LYL. Had all smokers ceased CC smoking in 1995 and with no NNTP use, these numbers would be reduced by 217,000 and 2.88 million, respectively. Compared to the base scenario, the estimated reductions in SADs and LYL were 159,000 and 2.06 million, respectively, for an immediate complete switch to THS and 179,000 and 2.34 million for 50% of CC smokers immediately switching to THS and another 50% to electronic cigarettes.

2. REFERENCES

1. Camacho, O.M., et al., *Modeling the population health impacts of heated tobacco products in Japan*. Tobacco Regulatory Science, 2021. 7(3): p. 221-231.

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2. Camacho, O.M., et al., *Investigating the Health Effects of 3 Coexisting Tobacco-Related Products Using System Dynamics Population Modeling: An Italian Population Case Study*. *Frontiers in Public Health*, 2021. **9**.
3. Rytsar, R., et al., *Estimated Public Health Gains From German Smokers Switching to Reduced-Risk Alternatives: Results From Population Health Impact Modelling*. *Contrib Tob Nicotine Res*, 2022. **31**: p. 35-51.

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