INNOVATIVE SOLUTION TO AN AGE-OLD PROBLEM: CONSIDERATIONS WHEN DEVELOPING AGE-GATED TECHNOLOGY

Lillian Ortega, Lise Fraissinet, Ed Carmines, Bryan Burd, Kevin Burd - Chemular Inc, Hudson MI, USA

Poster 75

ABSTRACT

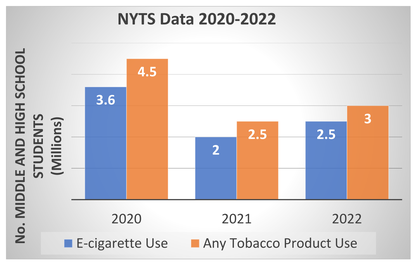
According to the National Youth Tobacco Survey (NYTS), over 3 million U.S. youth reported using a commercial tobacco product in 2022. The most used tobacco product in middle and high school aged students were e-cigarettes with 85% using flavored (I.e., menthol, mint, clove or spice, alcoholic drinks, candy, fruit, chocolate, or any other flavor other than tobacco) e-cigarettes. The Food and Drug Administration's Premarket Tobacco Application (PMTA) authorization decisions are based on a public health standard that considers the risks and benefits of the product on the population. To date, the agency has not authorized any flavored e-cigarettes and denied millions of applications due to lack of evidence demonstrating an added benefit to adult smokers that outweighs the substantial risk of youth initiation and use of flavored e-cigarette products. The tobacco industry has few options to provide evidence that flavored e-cigarette products benefit adult smokers and outweigh the risk of youth initiation and use. One potential option is age verification technology. Tobacco manufacturers are considering and, in some cases, have developed technology to solve a problem that predates the Family Prevention and Tobacco Control Act keeping tobacco products out of the hands of underage purchasers. This poster tackles the enduring challenge of preventing youth access to Electronic Nicotine Delivery Systems (ENDS) though age gating technology with insight informed by the agency's strategies for medical device software technology. It covers ISO standards for software development and delves into the risk-benefit balance in the design parameters of ENDS software, specifically targeting the restriction of youth access. Additionally, it shares valuable lessons gleaned from actual user study focused on age-gating technologies for e-cigarettes.

YOUTH USE OF TOBACCO PRODUCTS

An estimated 3.08 million U.S. middle and high school students reported current use (defined as use on ≥1 day during the past 30 days) of any tobacco product in 2022, representing approximately one in six high school students and one in 22 middle school students.

The FDA collaborates with the Centers for Disease Control and Prevention (CDC) to administer the NYTS to middle and high school students annually. The agencies use it to monitor a variety of aspects of tobacco use, including trends in current tobacco use, exposure to tobacco marketing, susceptibility to use and use of flavored tobacco products amongst other uses. Interpreting the data from the NYTS over the past three years presents a nuanced perspective on the ongoing challenge of youth tobacco use.

Figure 1: NYTS Comparison E-cigarette and Any Tobacco Use (2020-2022)



In 2020, an estimated 3.6 million middle and high school students reported using e-cigarettes within the past 30 days, with any form of tobacco use reaching over 4.5 million students.

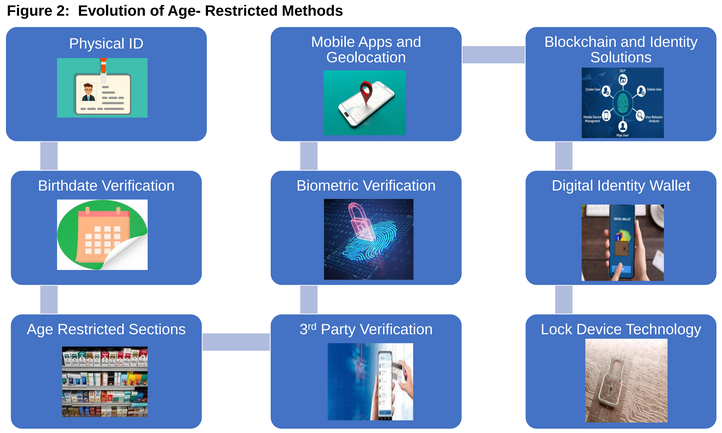
In 2021, these figures showed a slight decrease, with more than 2 million students using e-cigarettes and over 2.5 million engaged in any tobacco use within the past 30 days.

However, by 2022, the usage of e-cigarettes among students increased, with estimates surpassing 2.5 million, while any form of tobacco use within the past 30 days extended beyond 3 million students.

HISTORY OF AGE-RESTRICTION METHODS

In an ever-evolving landscape of consumer goods and digital engagement, ensuring responsible access to age-restricted products remains a paramount challenge. Particularly in the tobacco industry where curbing underage initiation and use is of utmost importance. From the physical scrutiny of identification documents to the contemporary realm of digital age verification, below (Figure 2) are some of the steps taken to balance the accessibility of tobacco products with the obligation of protecting our youth.

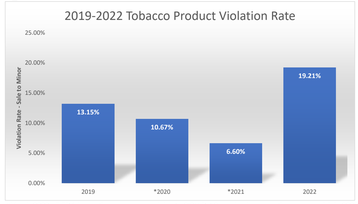
Figure 2: Evolution of Age- Restricted Methods

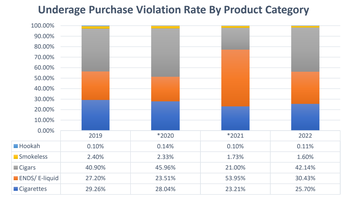


RETAILER COMPLIANCE CHECKS

FDA enforcement efforts to prevent underage access to tobacco products involve retailer compliance checks by trained minors working with commissioned FDA inspectors, attempting to purchase regulated tobacco products. By actively monitoring retailers' compliance with age restriction laws, the FDA reinforces the importance of maintaining stringent verification methods and has contracts with States and Territories to assist with retailer compliance checks.

Figure 3: Retailer Violation Rate 2020-2022





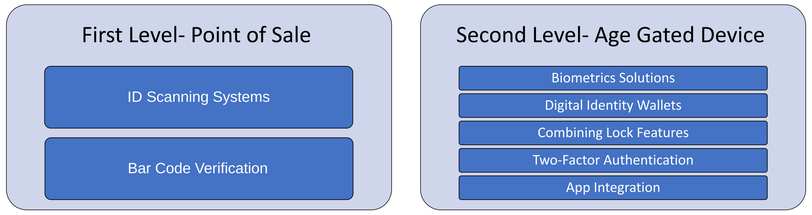
	2019	*2020	*2021	2022
Hookah	0.10%	0.14%	0.10%	0.11%
Smokeless	2.40%	2.33%	1.73%	1.60%
Cigars	40.90%	45.96%	21.00%	42.14%
ENDS/ E-liquid	27.20%	23.51%	53.95%	30.43%
Cigarettes	29.26%	28.04%	23.21%	25.70%

*March 2020 all FDA inspections were paused due to COVID-19 pandemic. Inspections resumed July 2020 based on priority and domestic and international COVID restrictions. July 2021 FDA resumed all inspections without travel restrictions.

In 2022, approximately 20% (Figure 3) of the retailer compliance checks conducted by the Agency resulted in the successful purchase of a regulated tobacco product by an underage buyer. ENDS represented over 30% of the products purchased.

TECH SOLUTIONS FOR CURBING YOUTH USE

This section delves into the realm of leveraging technology to tackle this complex challenge head-on, with a particular spotlight on ENDS. With an unwavering focus on the staggering toll of 480,000 deaths annually and diseases attributed to cigarette use, these innovative strategies aim to bridge the gap, enabling a responsible shift towards less harmful alternatives while guarding against the initiation of the next generation into harmful habits.



Biometric solutions, such as fingerprint and facial recognition, provide a personalized approach, guaranteeing that the user matches the registered adult profile. **Digital Identity Wallets** serve as secure repositories for users' verified age and identity data, ensuring seamless and trustworthy user authentication. Some systems merge **Lock features**, where devices remain non-operational until verified, further enhancing security measures. **Two-Factor Authentication** (2FA) adds an extra layer of security by requiring users to provide two types of identification before access is granted. Finally, **App Integration** facilitates the coordination of these features, streamlining the age verification process and creating a user-friendly experience while upholding stringent age restrictions.

INSIGHTS FROM MEDICAL DEVICE STANDARDS

Technology is reshaping healthcare, the FDA's guidance and international ISO standards is significant for regulated industries venturing into the digital space. Particularly relevant is the ENDS sector, where age-gated devices have emerged as a solution to curb underage usage of tobacco products creating an "Iron" store clerk approach, even after a underage sale is made, additional verification steps are in place on the device. By aligning with FDA's focus on risk assessment, cybersecurity and software validation, tobacco manufacturers can develop age-restricted devices that not only reduce the risk of youth initiation but also provides software standards FDA utilizes in other commodities.

Table 1: Key Industry Practices in Medical Device Software: Ensuring Safety and Quality

Medical Device Software Practice	Recommendation
Risk Assessment	Comprehensive risk analysis ensuring age verification solutions effectively address the risks of underage usage and unauthorized access.
Validation and Verification	Rigorous testing and validation processes to demonstrating software functions as intended and provides accurate age verification results in real time.
Human Factor Engineering	Testing user experience by considering factors such as user interface design, readability, and ease of interaction.
Cybersecurity Testing	Robust security framework including Security Requirements assessments, Threat Mitigation measures, Vulnerability Testing, and Penetration Testing.
Useability Testing	Leverage usability testing methodologies to assess the effectiveness and ease of use of the age verification software.
Data Security and Privacy	Collect only the necessary data required for age verification. Minimizing the amount of data collected reduces the potential impact of a data breach and ensures that user privacy is respected.

LESSONS FROM USER TESTING OF AN AGE-GATED DEVICE

The research poster presented at the 75th TSRC showcased a comprehensive study testing an age-gated device (GLAS G2 Device), drawing participants from diverse regions across the U.S. Individuals of varying ages, from 16 to over 50, and representing different sexes and racial backgrounds were invited to partake in the study. As a baseline criterion, each participant was mandated to possess a government-issued ID. The study process was methodically designed to emulate real-world usage of the device. Participants initiated their involvement by downloading the relevant application onto their smartphones. Subsequently, they were directed to create user accounts on the sponsor's website. The age verification step entailed participants providing a snapshot of their government ID alongside a selfie for enhanced authenticity. Once verified, participants progressed to activating the ENDS device and were finally asked to take a puff from the device. The study demonstrated all subjects below the legal age were consistently denied access, demonstrating the effectiveness of the age verification process, regardless of their race, gender, or ethnicity.

Lessons from the comprehensive study offer valuable considerations for the ongoing development and implementation of advanced age-verification software for ENDS:

- **Effectiveness Across Demographics:** The study confirmed that the age verification was effective across all demographic groups, reinforcing the potential for biometric solutions and digital identity wallets to provide a uniformly reliable mechanism for age verification.
- **Image Matching Algorithms:** Some participants had difficulty verifying their identity due to discrepancies between selfies and government-issued ID photos. This highlights the need for improved facial recognition algorithms in biometric solutions, making them more adaptable to variations in appearance.
- **User Interface and Experience**: Issues like an inability to take a selfie or scan a driver's license reflect user interface (UI) and user experience (UX) design aspects that could be optimized. Streamlined app integration can be instrumental in providing a user-friendly interface, thereby minimizing user errors.

KEY CONSIDERATIONS

As ENDS manufacturers navigate the complexities of developing age-gated devices, below are some questions:

- Mode of age verification: Should the device adopt a continuous age-gating mechanism, requiring regular user verifications, or would a single unlock system be more conducive to a seamless user experience? While the continuous verification might cause friction with current smokers, it would bolster confidence in preventing underage youth from using the product.
- Amplify the age-gated technology itself, incorporating advanced biometrics, machine learning, or other cutting-edge innovations to ensure foolproof age validation?
- How can the device's defense layers be fortified without making it cumbersome? Scrutinizing potential vulnerabilities is equally vital: Where might the system's weak spots lie, and how can they be preemptively addressed?
- Does the device offer a user-friendly experience tailored for its intended audience, ensuring they aren't deterred due to technological intricacies?

Navigating these multifaceted questions is crucial for producing an age-gated device that harmoniously blends security, innovation, compliance, accessibility and user privacy.

CONCLUSIONS

- The limitations of relying solely on retailers to prevent sales to individuals under 21 are evident, as highlighted by the 20% violation rate. Manufacturers are proactively taking bold strides to address both the issue of youth use of ENDS products and the concerning 1 in 5 retailer violation rate.
- Harnessing the potential of Age-Gating Technology, these steps signify a concerted effort to safeguard against underage access and promote responsible usage.
- Leveraging medical device software standards and heeding the lessons from real-world studies, will pave the way for a more secure and responsible future for ENDS, effectively curbing youth access while serving the needs of adult smokers seeking less harmful alternatives.

REFERENCES

Carmines, E., Fraissinet, L., & Steele, A. (2022). Actual User Testing of E-Cigarette Age Gating Technology. Poster presented at the 75th Tobacco Scientific Research Conference, September 2022.
Gentzke AS, Wang TW, Jamal A, et al. Tobacco Product Use Among Middle and High School Students — United States, 2020. MMWR Morb Mortal Wkly Rep 2020;69:1881–1888. DOI: http://dx.doi.org/10.15585/mmwr.mm6950a1
Park-Lee E, Ren C, Sawdey MD, et al. Notes from the Field: E-Cigarette Use Among Middle and High School Students — National Youth Tobacco Survey, United States, 2021. MMWR Morb Mortal Wkly Rep 2021;70:1387–1389. DOI: http://dx.doi.org/10.15585/mmwr.mm7039a4
Park-Lee E, Ren C, Cooper M, Cornelius M, Jamal A, Cullen KA. Tobacco Product Use Among Middle and High School Students — United States, 2022. MMWR Morb Mortal Wkly Rep 2022;71:1429–1435. DOI: http://dx.doi.org/10.15585/mmwr.mm7145a1
Food and Drug Administration Compliance Check Inspections of Brick and Mortar Tobacco Product Retailers (FY2020-2022) Compliance Check Inspections of Brick and Mortar Tobacco Product Retailers (fda.gov)
Food and Drug Administration. (2022, April 8). Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Draft Guidance for Industry and Food and Drug Administration Staff. [Document ID]. Retrieved from https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cybersecurity-medical-devices-quality-system-considerations-and-content-premarket-submissions
IMDRF Software as a Medical Device (SaMD) Working Group. (2014, September 18). "Software as a Medical Device": Possible Framework for Risk Categorization and Corresponding Considerations. Final Document.
International Organization for Standardization. ISO 13485:2016: Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes. ISO, 2016.
International Organization for Standardization. ISO/IEC27001:2022 - Information technology - Security techniques - Information security management systems: