

Unplugged - Challenges in Setting up a Study

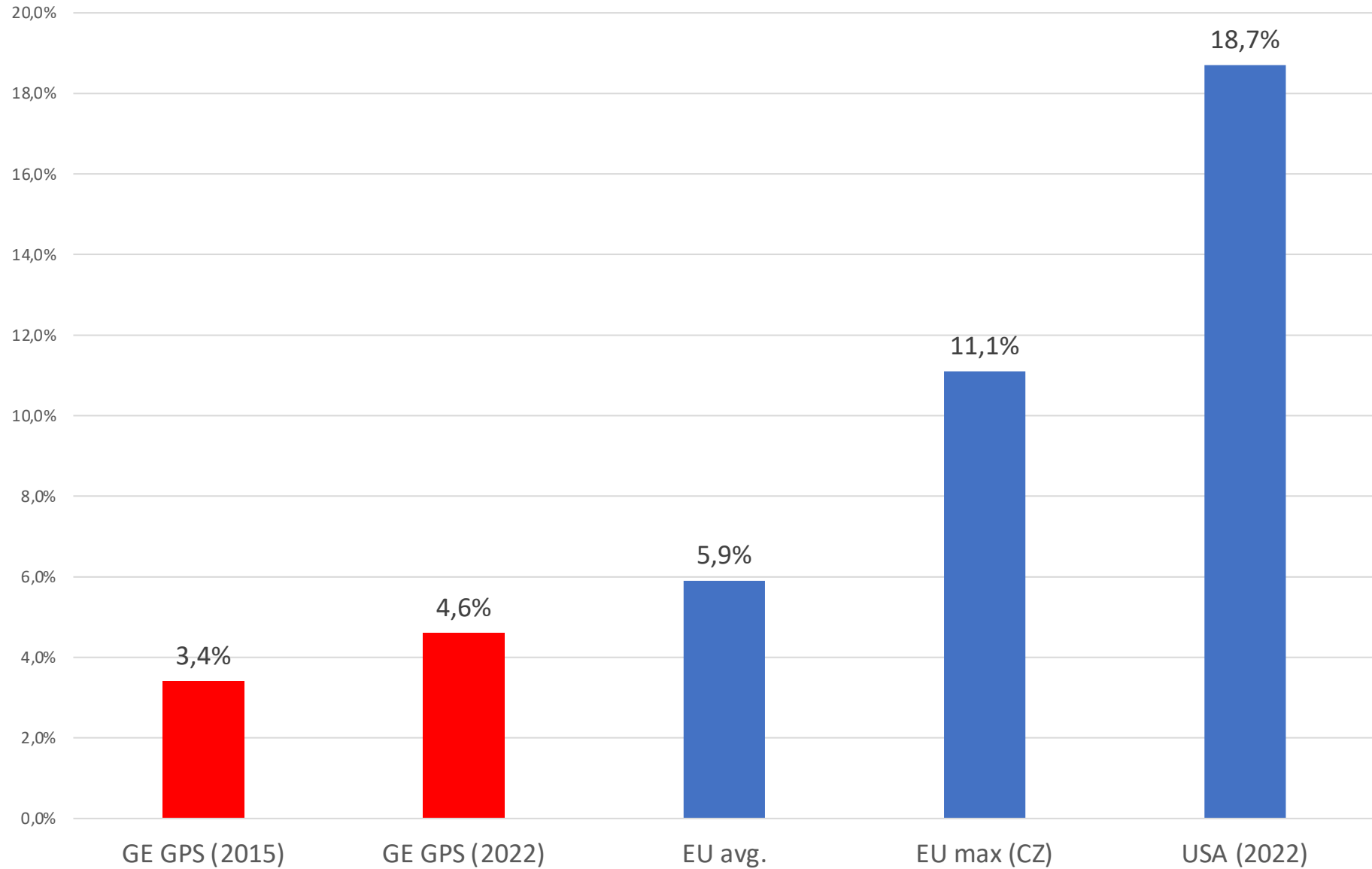
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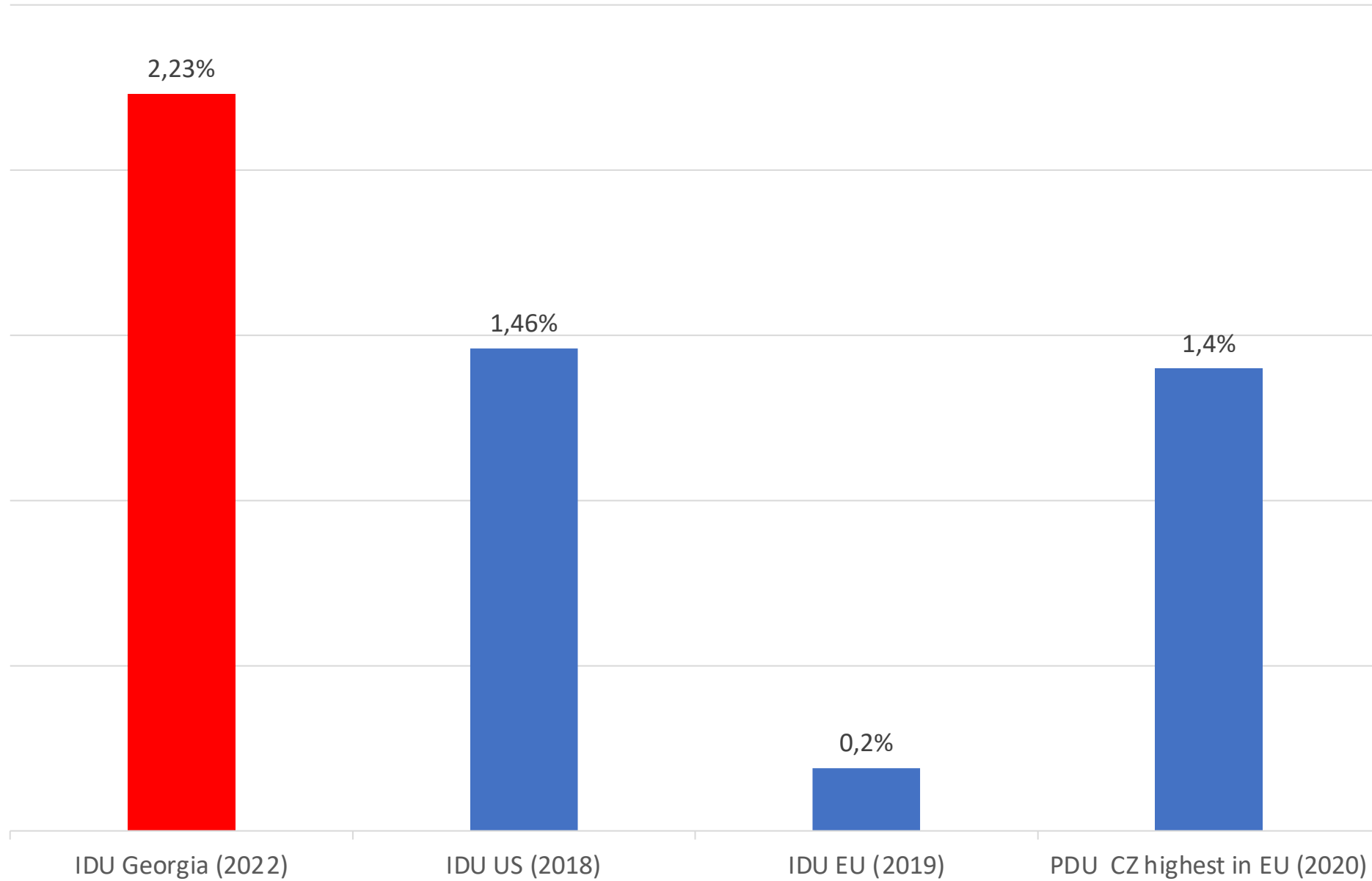
Accelerating Impact: Immersive Summer Bootcamp in Implementation Science and Biostatistics

July 10-12, 2024

LY cannabis use among adults in GE, EU, USA



LY prevalence of IDU/PDU in GE, US and EU



LY cannabis use among school students in GE, EU, USA

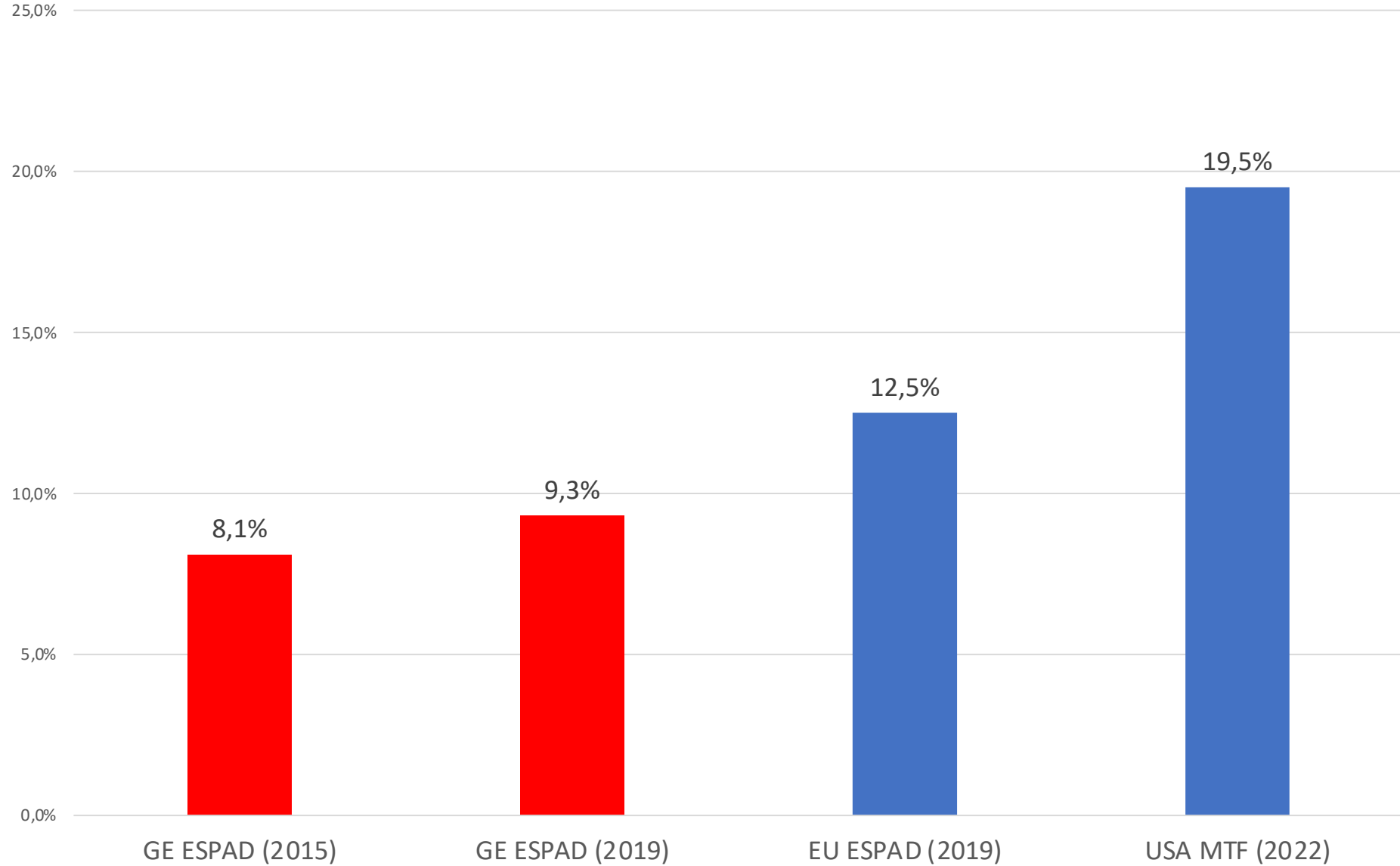
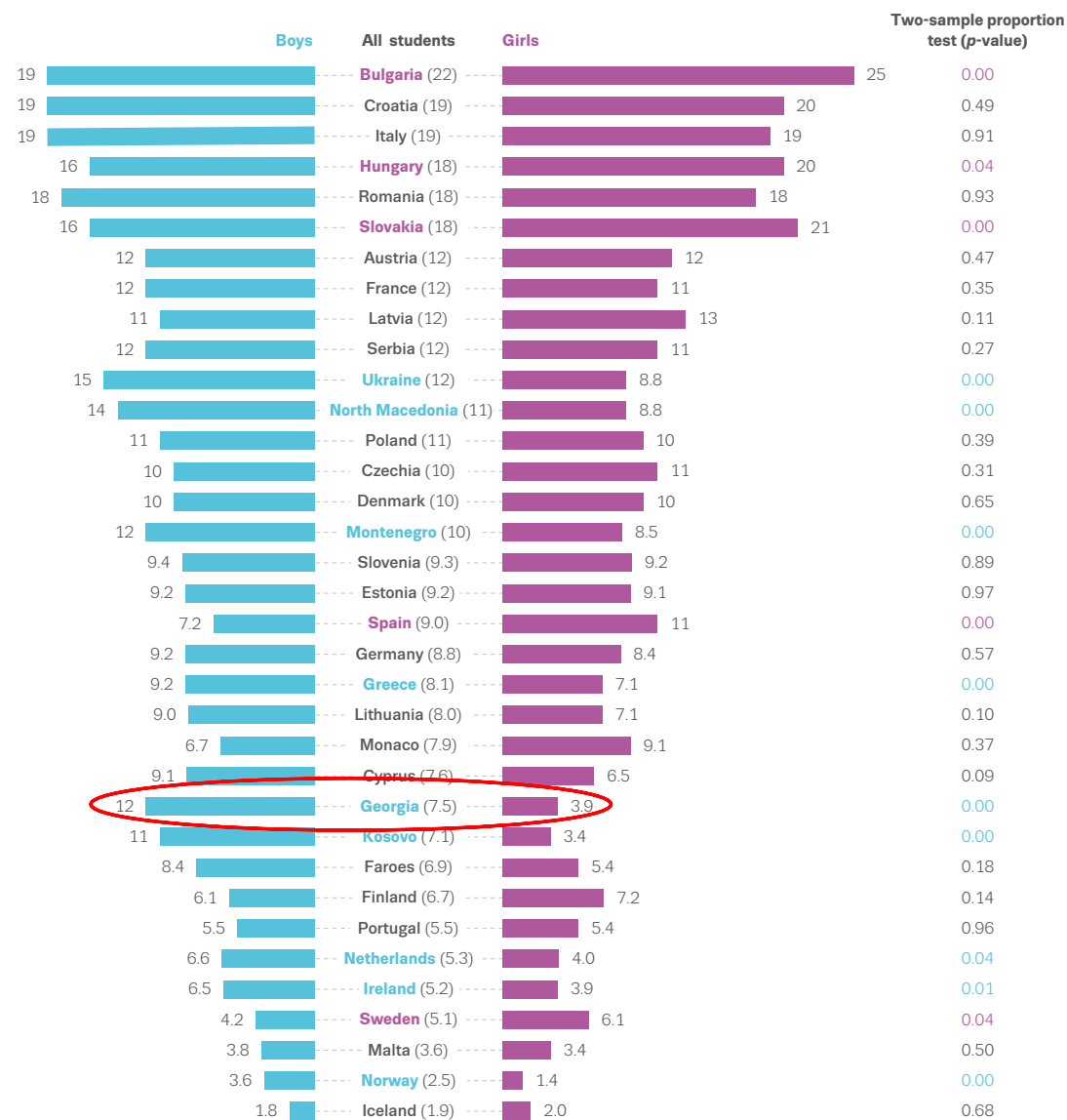


Figure 1b. Daily cigarette use: prevalence in the last 30 days by gender (percentage)



Colour indicates significant difference between boys and girls. Statistical significance levels are reported for each country.

Figure 6b. Prevalence of heavy episodic drinking (five or more drinks on one occasion; one drink contains approximately 2 centilitres of ethanol) at least once in the last 30 days by gender (percentage)

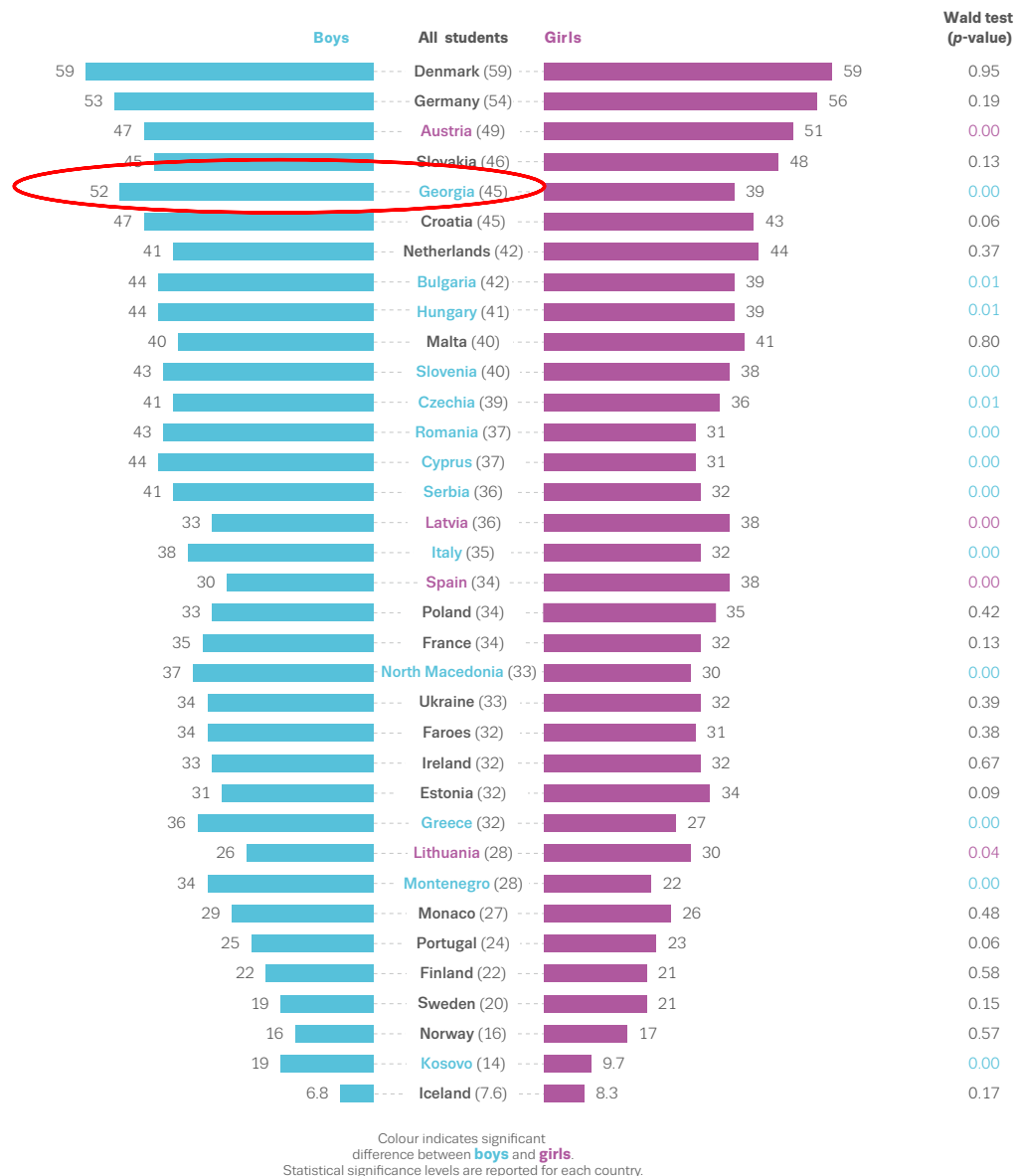
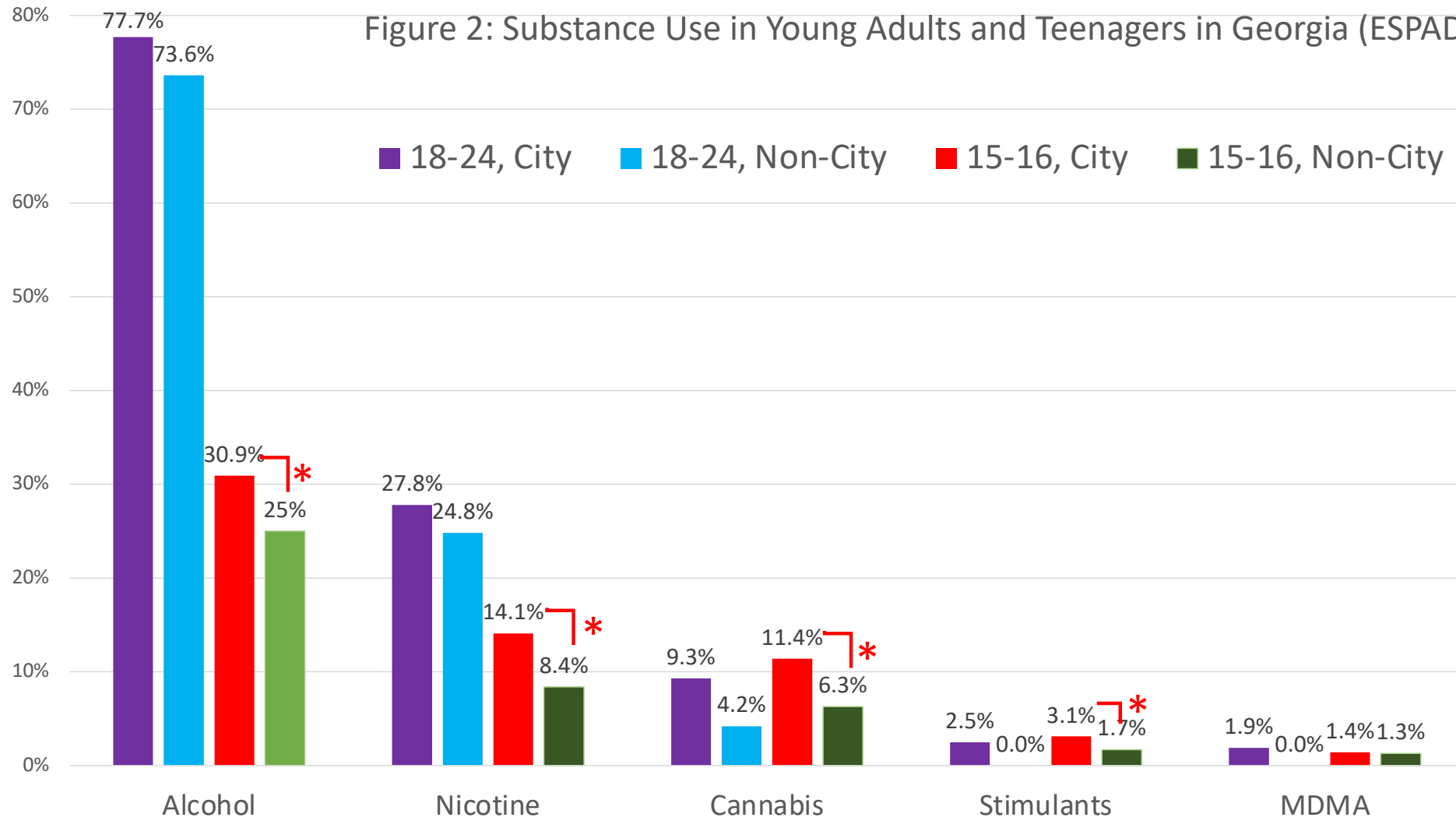
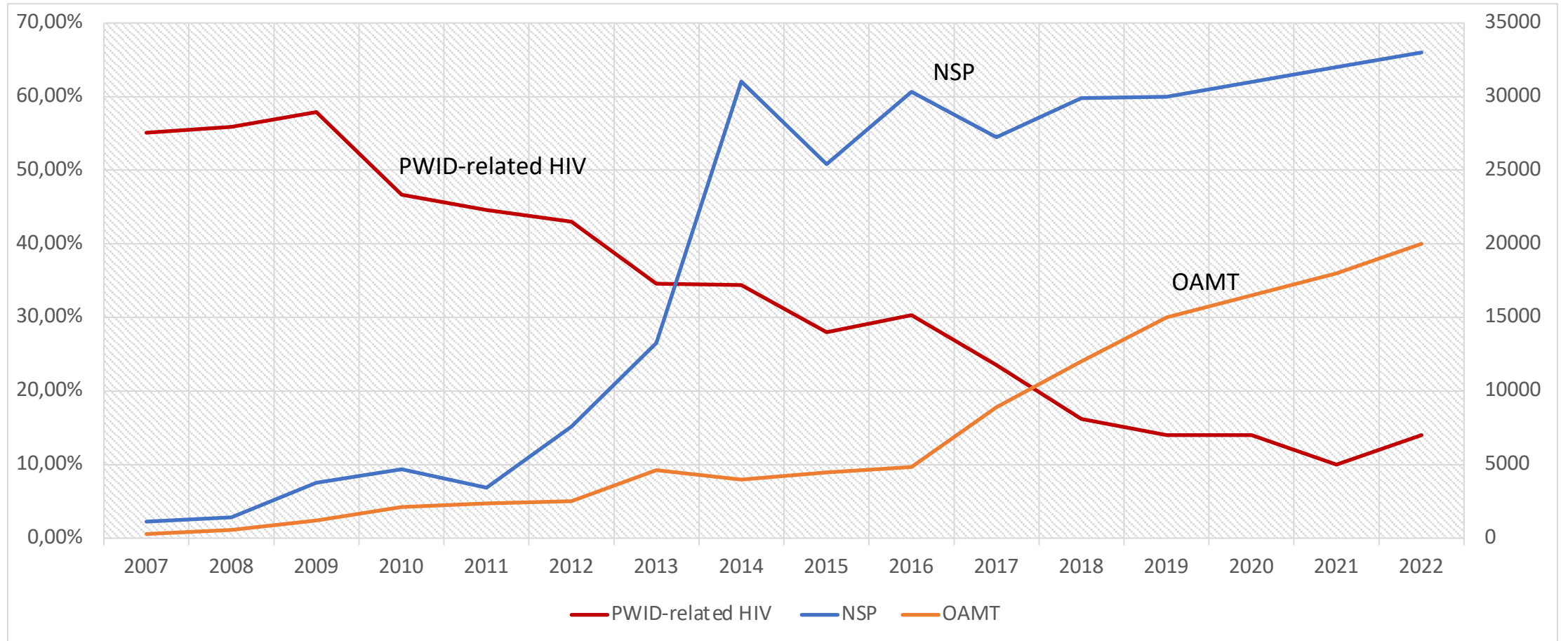


Figure 2: Substance Use in Young Adults and Teenagers in Georgia (ESPAD)



OAMT and NSP coverage and proportion of PWID-related transmission in new HIV cases, 2007-2022 Georgia



Are we doing anything to prevent substance
use?

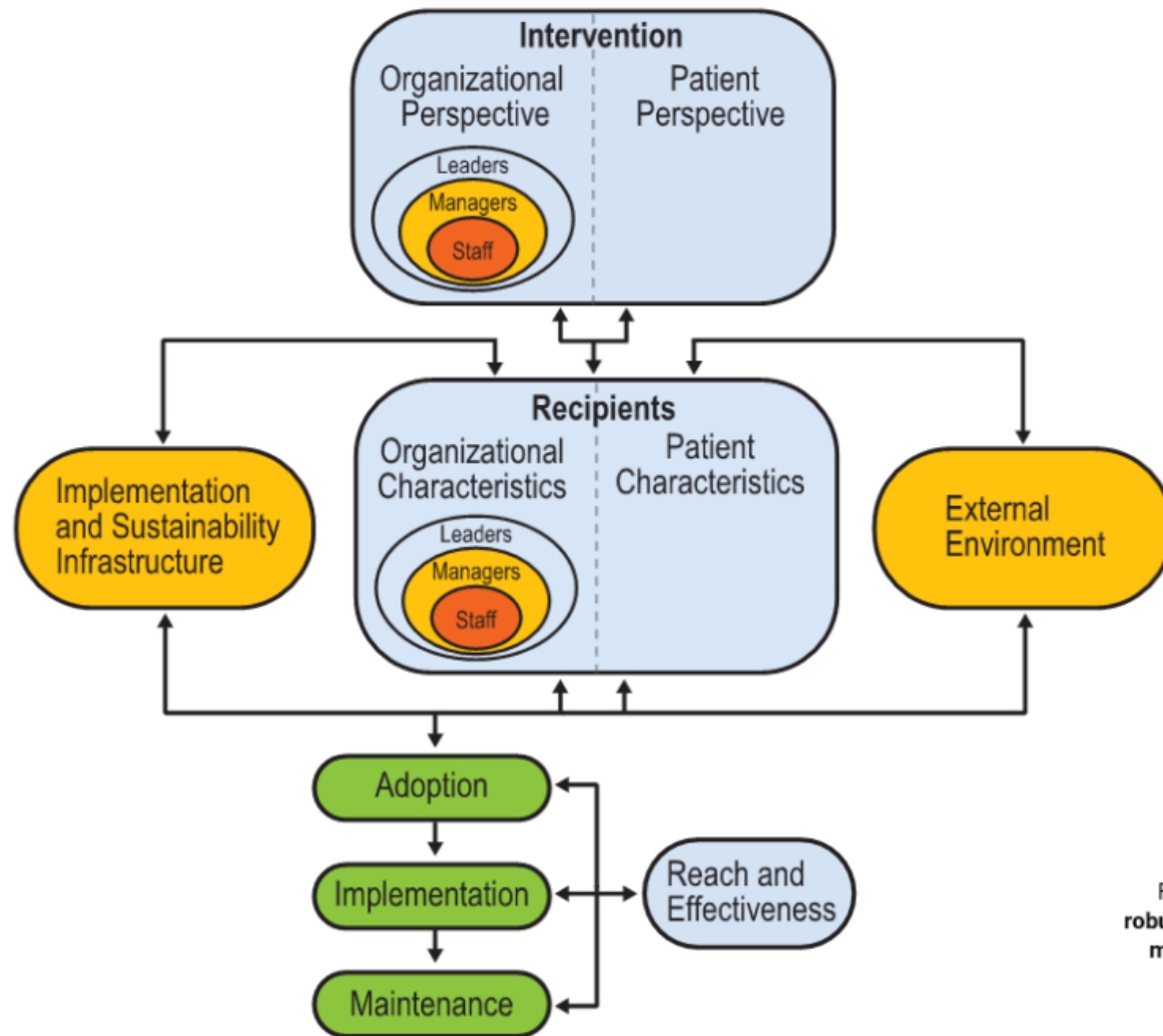
Not much!!!

School-based interventions – what does evidence say?

- Systematic reviews show that the most effective strategy to prevent SUDs is to intervene early during the transition from childhood to adolescence
- A systematic review of reviews suggests that school-based interventions are most effective for reducing *nicotine, alcohol and other drug use*

UnPlugged

- Curriculum is based on Life Skills Training (LST) within the Comprehensive Social Influence model
- Focus on enhancing interpersonal and intrapersonal skills using highly interactive teaching methods, such as small groupwork, discussions, role-plays and group games
- Develops critical thinking, decision-making, problem solving, effective communication, self-awareness, coping with emotions and stress, and knowledge about the harmful effects of substances
- Primary teachers deliver (PTD) the 12, 45-60 minute units over 3 months after 3 days of training
- Efficacy - EU-DAP cluster RCT of 7,071 students (age 13 years/7th grade) in 78 schools in 7 European countries
- UnPlugged was disseminated to 4 LMICs (Nigeria, Brazil, Peru, and Chile),



Feldstein AC¹, Glasgow RE. **A practical, robust implementation and sustainability model (PRISM) for integrating research findings into practice.** *Jt Comm J Qual Patient Saf.* 2008 Apr;34(4):228-43.

Implementing School-Based Substance Use Prevention for Adolescents in Urban Settings in Georgia

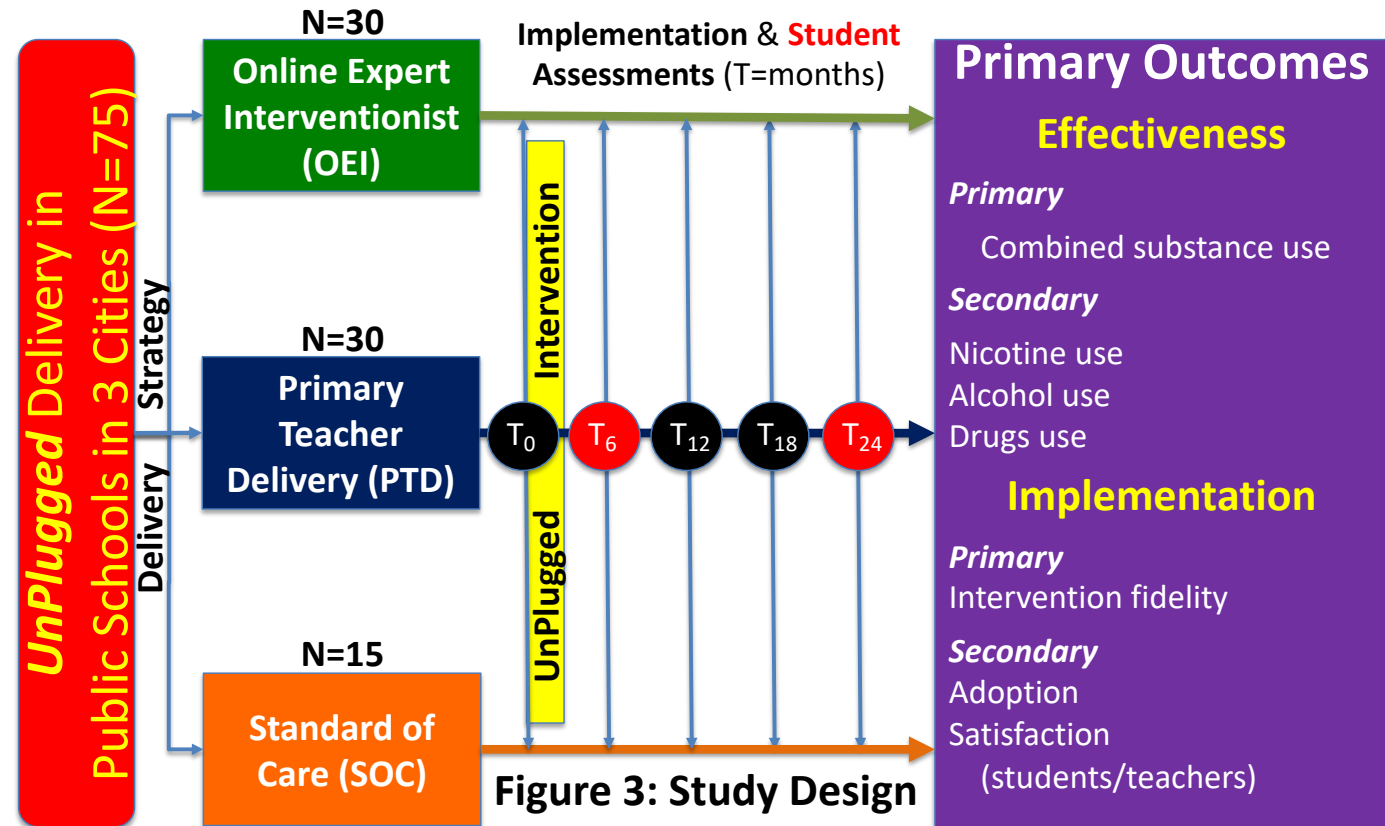
Innovation

- Online Delivery by an Expert (OEI): *UnPlugged* has not been delivered online, but many of the elements like informational sessions, roleplay, and group interactions can be conducted using Zoom with its whiteboard and anonymous polling functions. If *UnPlugged* can be successfully delivered remotely, it will reduce cost and can be scaled-up more broadly – in Georgia, in Europe, and worldwide.
- A systematic review of 71 meta-analyses from 1733 studies - outstanding outcomes through online delivery of behavioral interventions for substance use, mental health, diet and physical activity, making *UnPlugged* ideally situated for online delivery. Pedagogical changes worldwide due to the COVID-19 pandemic have shown that online psychosocial interventions are extremely effective.
- Use of a multi-wave, cluster randomized trial using a Type 2 Hybrid Design: While cluster RCTs typically represent the strongest design, this trial involves a multi-phase design in which schools have the potential to “learn” over time (each year is a wave resulting in 3 waves) through repeated delivery. Experience from the previous year may boost confidence and competence in intervention delivery over time).

Potential challenges for UnPlugged implementation in Georgia

- Teacher motivation (not part of curricula, payment..)
- Teacher confidence in delivering UnPlugged
- Fidelity
- The difficulty of inserting a program module into the lesson grid and the problem of finding time and space
- Parents' awareness

- **Aim 1:** To conduct a rapid, exploratory sequential mixed methods assessment using surveys, one-on-one interviews and nominal group technique (NGT) of the multi-level (students, teachers, school administration and MoE) barriers to effectively deliver the adapted *UnPlugged* EBI to adolescents in urban public schools in Georgia
- **Aim 2:** To conduct a Type 2 cluster, randomized controlled implementation trial with 75 schools in 3 cities and 20,250 students over 3 waves of implementation to compare two implementation strategies for the 12-session *UnPlugged* intervention, standard primary teacher delivery (PTD) and an online expert interventionist (OEI) to the standard of care (SOC) and compare primary efficacy (nicotine, alcohol and drug use) outcomes and implementation (fidelity) outcomes after 6 months; secondary efficacy and implementation outcomes will be assessed after 24 months



Research Quality Assessment

We will employ several strategies from previous studies to ensure fidelity and assess “intervention drift” among staff delivering *UnPlugged*:

- 1) Training of teachers: We will provide a 3-day competency training just before each fall semester;
- 2) Quality Improvement: All *UnPlugged* sessions will be digitally recorded and reviewed for content by experts and attendance will be recorded for fidelity - 10% of randomly selected sessions and correlation with the written fidelity checklist completed by teachers for: 1) was the unit started; 2) was it completed; 3) how long was it; and 4) were role playing and social interactions involved? Feedback will be provided to PTD and OEI deliverers;
- 3) School site visits and quality improvement: We will interact with sites at baseline and every 6 months to meet with teachers and administrators at each site to discuss challenges and their experiences in delivering *UnPlugged* and assess quality and fidelity of implementing the intervention. We will assess organizational factors based on what is working, not working and goals for improvement;
- 4) Technical assistance: Teachers will have access to our Quality Assurance Expert and our Master Trainer to respond to questions throughout the program as well as the support provided to implementers at pre-specified time points during *UnPlugged* delivery (which will be maintained and reviewed at CAB meetings).
- 5) Regular review of process measures data: Rapid collection of process measures via our electronic data management system with real-time input will allow us to monitor implementation of the intervention and assess many primary, secondary, and process outcomes. This information will be provided to the CAB for feedback and implementation refinement.