SOP Template 2: developing self-testing policies

**Establishing self-testing policies**

* Relevant HIV planning committees or processes should consider the adaptation of national policies and regulations for self-tests.
* Clear, supportive policies and regulations are needed for effective scale-up of ST and access to quality-assured ST products to achieve impact
* National guidelines are often a pre-requisite for implementation, scale-up, development of regulations, procurement, and importation of products
* When reviewing policies, minimize the gap between policy development and product availability

**What should be included in the self-testing policy**

* A clear definition of self-testing and emphasize that it is about testing yourself
* Include the message that current evidence on HIVST shows that social harm is very rare.
* Describe your priority populations for Self-testing.
* Clearly articulate the legal age of consent for the self-testing strategy.
* Clear ST strategy and diagram that links to the national testing strategy.
* For HIV, indicate ST is considered a test for triage and cannot replace the first test within the validated national testing algorithm.
* Nonreactive (negative) self-test results should be considered negative with no need for immediate further testing to confirm a negative diagnosis.
* Include re-testing frequency guidance for various categories of individuals based on risk.
* Outline the ST distribution models to be used in the country.
* Develop a minimum communication package with key messages for all self-testers and community.
* Those officially distributing ST kits require a well-established minimum training package.
* Minimum standards and requirements for procurement and distribution of ST kits
* System for quality assurance and post-market surveillance.
* Monitoring and evaluation indicators and plans, including a reporting system for complaints, adverse events, and cases of social harm.

**National registration and regulations**

Have a clear and transparent national registration pathways for ST:

* **Market authorization** (registration) – this is a process through which a test kit is released onto the market after its quality, safety and performance has been assessed.
* **Premarket controls** - The system a manufacturer should employ once the product is on the market to ensure monitoring continues with the aim of identifying and addressing potential complaints, including adverse events.
* **Market control**
* **Post-market surveillance**
* **Market surveillance/control**