2022 CLA CASE COMPETITION

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Case Title:

Using CLA approaches to institutionalize health technology assessment in Ukraine

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Dr. Rabia Kahveci, USAID SAFEMed Senior Technical Advisor, presents an introductory HTA course for HTA Department staff from the Ukrainian Ministry of Health, May 2019. Credit: Management Sciences for Health: SAFEMed Project

Summary:

Health technology assessment (HTA) is a multi-disciplinary process countries use to systematically make policy decisions about health technologies (from medicines and devices to procedures and health interventions). No health system can afford every new medicine or device, and countries face difficult choices, often in the face of limited resources and competing interests, which opens the door for corruption. As Ukraine works toward universal health coverage, and its citizens demand better quality health care, the country recognized that use of HTA processes would guide decision-makers to select medicines systematically, using evidence to determine the best value for the health care system. Management Sciences for Health (MSH), through the USAID/Safe, Affordable and Effective Medicines for Ukrainians (SAFEMed) Project partnered with Ukrainian health authorities to introduce HTA as an evidence-based decision-making process. Over the course of this work, SAFEMed systematically applied collaborating, learning, adapting (CLA) approaches relying on a wide range of stakeholders and regular reflection and adjustments that resulted in Ukraine's full institutionalization of HTA in just over three years.

Notably, an HTA roadmap incorporated CLA to guide the successful formation of the institutions, policies, human resources, and methodical and open processes to select medicines that bring the best value to Ukrainian patients. While Russia's invasion of Ukraine in February 2022 slowed the pace, the Government of Ukraine's HTA department continued to function and even assessed four new medicines. Meanwhile, SAFEMed has continued to build the capacity of local stakeholders to make evidence-based policy decisions related to access to essential medicines.

Which two subcomponents of the Collaborating, Learning & Adapting (CLA) Framework are most reflected in your case? Please reference them in your submission.

- Internal Collaboration
- External Collaboration
- Technical Evidence Base
- Theories of Change
- Scenario Planning
- M&E for Learning
- Pause & Reflect
- Adaptive Management
- Openness
- Relationships & Networks
- Continuous Learning & Improvement
- Knowledge Management
- Institutional Memory
- Decision-Making
- Mission Resources
- CLA in Implementing Mechanisms

1. WHAT: What is the general context in which the case takes place? What organizational or development challenge(s) prompted you to collaborate, learn, and/or adapt?

High medicine prices, low budget allocations, corruption, and unregulated and non-transparent procedures have traditionally created substantial barriers to treatment for Ukraine ' s 41 million people. Diverse governmental bodies at national and local levels participate in setting policies, allocating resources, and procuring the medicines for state-funded programs, and local and international pharmaceutical producers and distributers have a sizable stake in which technologies get included. In addition, patients and groups that represent them advocate for medicines that will meet their needs. Each of these actors contributes to ensuring access to lifesaving medicines for Ukrainians yet have diverse and sometimes rival interests.

In 2016, the Government of Ukraine embarked on ambitious health care reforms to increase health system transparency and efficiency and decentralize services to the regional level. Given that a substantial amount of the state budget on health goes to medicines (recent estimates suggest about 68%), and the selection, procurement, and distribution of medicines had been rife with corruption for many years, the Ministry of Health (MOH) embraced a range of measures to tackle these shortcomings. In 2018, with SAFEMed technical, legal, and operational support, the MOH and other stakeholders began the journey of learning about and introducing HTA as not only a way to select best-value lifesaving products but also to grow trust in the health system by improving accessibility, equity, and accountability. HTA brings science to the decisions on which medicines to publicly cover that requires a cultural change of how decisions are made. While the country needs to improve its technical capacity to systematically use evidence in decisions, all actors in decision-making also need to be ready for the openness of a corruption-free ecosystem and stakeholder-engaged processes.

2. WHY: Why did you decide to use a CLA approach? Why was CLA considered helpful for addressing your organizational or development challenge(s)?

Having used CLA in other projects, MSH, through the SAFEMed Project used that experience from the start to convince Ukrainian leaders that instituting a national HTA function—needing time and resources—would accelerate Ukraine's push toward universal health coverage and that evidence-based decision-making would produce reliable results. We also used CLA approaches to systematically identify and address challenges to HTA while using internal and external collaboration to prevent stalling by monitoring progress and pivoting immediately to adapt to another approach if needed.

Too often, health reforms fail due to weak political will, competing priorities, and vested interests that benefit from the status quo. SAFEMed recognized that to create a fully transparent HTA system that increases access to best-value medicines, external stakeholders across multiple sectors must be involved meaningfully during every step to create a common vision and commitment; therefore, from early on, SAFEMed partnered with the MOH to conduct widespread outreach to institute HTA within the health system. Such stakeholder-driven platforms included formal MOH technical working groups; regular roundtable meetings to raise awareness, gather perspectives, and agree on common action; and annual forums where a larger group could gather to track progress, celebrate successes, and renew momentum. We also introduced the use of an HTA roadmap developed in 2019 then consultatively reviewed and revised during roundtable meetings, relying on CLA approaches such as pause and reflect. Moreover, successful health reform requires adaptive management to continually review experience, adapt the vision and process for advancement, and learn from each step.

3. How: Tell us the story of how you used a collaborating, learning and/or adapting approach to address the organizational or development challenge described in Question 2.

Upon the Minister of Health's committing to HTA, SAFEMed began helping to design the legal framework needed to establish the HTA Department. We helped define the Department's mission, strategic goals, and operational model and build staff capacity. The project then supported the MOH to establish a technical working group whose first task was to oversee the draft of the roadmap that defined areas essential for progress. Officially endorsed by the MOH, the roadmap goals included establishing an HTA-informed health care decision-making ecosystem in Ukraine; creating an independent HTA entity; and developing a robust legal framework, communication/engagement plan, and capacity-building program.

Engaging external collaboration with stakeholders to inform HTA establishment: SAFEMed helped stakeholders determine the best model of HTA implementation for Ukraine by hearing from international experts and discussing how to adapt this learning to the Ukrainian context—step by step. We organized quarterly roundtables and annual forums. The meetings helped focus on specific topics (e.g., ethics in decision-making, the value of an independent HTA agency, hospital-based HTA), review activities and options, and determine next steps. Here, the MOH heard different voices so it could base next steps on broad input and avoid uptake challenges.

Adaptive management through the HTA roadmap: SAFEMed instituted CLA to make consistent progress entailing ongoing meetings to consider stakeholders ’ views on strategic directions and implementation. In quarterly roundtables throughout 2020-2021, participants representing multiple sectors including patients and industry discussed important decisions such as whether to create an independent HTA agency or continue to embed the function within the state regulatory body. Stakeholders learning together and making adaptations smoothed the transition toward an evidence-based system of decision-making. Our early stakeholder engagement focused on understanding the context and raising awareness, but then we used lessons learned to adapt management toward a more sustainable direction. In addition, the annual forums hosted by the MOH built consensus around important topics—the last one in September 2021 had over 200 participants, and during that meeting, there was overwhelming support to establish an independent HTA agency, following international best practice.

Continuous learning and improvement and encouraging openness in the HTA process: Recognizing the knowledge and capacity gaps in many stakeholders interested in HTA and wanting to maintain reform momentum, especially during COVID-19 restrictions, a series of 15 online webinars over two years, averaging 50 participants from across Ukraine, addressed those gaps. Post-webinar surveys demonstrated that more than half of the information received was new for more than 90% of all respondents and that 74% could make immediate use of it. We identified topics to address areas of stalled progress; for instance, as a result of a popular webinar on patient engagement in HTA, government counterparts asked the project to build additional patient capacity in the process.

Pause and reflect to update the HTA roadmap: After implementing for two years and receiving legislative approval for HTA, the MOH and SAFEMed decided to pause and review the roadmap through stakeholder consultations, resulting in a version 2.0 adapted to new strategic directions. The HTA roadmap 2.0 process built on gains, prioritized actions, and reenergized political will and stakeholder involvement. In the next year, after the HTA department had functioned for three years, the MOH together with SAFEMed again paused to review the HTA journey and receive stakeholder input through a series of interviews. Results showed that stakeholders felt engaged and were 100% satisfied with progress. They also made recommendations to modify next steps.

4. ORGANIZATIONAL IMPACT: How has collaborating, learning and adapting affected your team and/or organization? If it's too early to tell, what effects do you expect to see in the future?

In 2018, little was known about HTA in Ukraine. Remarkably, since then, HTA has been legalized and institutionalized within the MOH. Not only were stakeholders oriented to HTA and its potential benefits, but a dedicated government department within the regulatory authority was established from scratch. The MOH, the HTA department, and other HTA stakeholders have come to appreciate the power of CLA approaches to drive health system changes.

Had SAFEMed not chosen to use external collaboration, adaptative management, continuous learning, and encouraging openness in decision-making and resource allocation for HTA, the likelihood of lasting changes in the health system decision-making processes would have been limited. The project regularly relied on these approaches, especially at times when it appeared that enthusiasm on the part of different government actors was waning, or when stakeholders who were benefiting from the status quo were gaining influence.

As a result of three years of HTA creation and implementation in the shadow of the COVID-19 pandemic and the war, by using CLA approaches, an influential government-funded HTA Department was established, technical capacity was built, a capacity-building program and communication strategy created, legislations approved, more than 100 rapid assessments conducted, and more than 20 recommendations on new medicines released. Based on HTA, the MOH expanded the lists of essential and publicly reimbursed medicines that eventually led to more patients accessing lifesaving medicines. Awareness of HTA in Ukraine increased through numerous national and international events and the publication of many articles detailing the country ’ s HTA success story. Intensive stakeholder collaboration produced ownership of the HTA function—so much so, that the HTA Department published four recommendations within two months after Russia ’ s invasion. Clearly, CLA approaches not only helped create and develop the HTA Department but also ensured its sustainability and resilience.

5. DEVELOPMENT IMPACT: How has using a CLA approach contributed to your development outcomes? What evidence can you provide? If it's too early to tell, what effects do you expect to see in the future?

By using CLA approaches to help Ukraine introduce and institutionalize HTA within the health system, the Government of Ukraine and the broad network of stakeholders fully embraced the use of HTA's transparent, science-based methodology for rational health decision-making. As a result, Ukraine has achieved the following:

? The Government of Ukraine establishing the regulatory framework to create and fund the HTA Department. As of May 2022, the fully operational and influential HTA Department has a director and 29 staff.
? The main policy-making body, the Government of Ukraine Cabinet of Ministers, passed a decree in 2020 (drafted in close consultation with SAFEMed and the MOH Technical Working Group) mandating HTA ’ s use for all publicly funded medicines and the establishment of an independent HTA agency by 2023 (moving from a department within the drug regulatory body).
? Support to develop and continue updating Ukraine ’ s National Essential Medicines List, including adding newer lifesaving medicines that were previously unavailable. For example, the HTA review of new medicines for kidney cancer led to the government procuring these new medicines competitively in the open market. This resulted in treatment coverage for 100% of patients with this particular kidney disease and also significant savings for the government.
? HTA International, the global HTA society, conducted its regional meeting in Ukraine in September 2020, where neighboring countries in the region saw Ukraine presented as an outstanding example of HTA functioning in an emerging setting.
? Expansion of external stakeholder collaboration and capacity building through 15 webinars, 5 HTA roundtables and 3 annual fora. The Department also shared its experiences through international events; for example, at the 2020 HTA international conference, Ukraine presented their HTA experience on a panel titled “ Finding the Right HTA Roadmap: How Learnings from Eastern European Countries May Inform HTA Implementation Strategies. ”

6. ENABLING CONDITIONS: How have enabling conditions - resources (time/money/staff), organizational culture, or business/work processes - influenced your results? How would you advise others to navigate any challenges you may have faced?

Although COVID-19 shifted priorities and resource allocations for HTA, Russia's invasion of Ukraine in February 2022 remains the most sizable obstacle to implementing the valuable CLA approaches needed for ongoing institutionalization of HTA. However, though some activities paused, the strength of the nascent HTA system allowed the Department to continue working and engaging stakeholders. Enablers and obstacles to using CLA approaches to establish HTA and guarantee its success in Ukraine include:

Resources--Adequate financial resources: USAID remained an active partner, both financially and technically—recognizing that continued funding for collaboration and continuous learning (regular roundtables and other forums) built health system capacity to increase access to medicines. The Government of Ukraine ' s commitment to funding the HTA Department was also a major boon for implementation; time needed to fully use CLA approaches while introducing reforms: Health reforms take years to enact and to see real benefit or risk failure. USAID and SAFEMed ' s sustained support to the nascent HTA Department and the focus on building capacity to keep interest high produced impressive progress in less than three years.
Culture--Lack of transparency with deeply rooted corruption: SAFEMed sometimes faced obstacles in applying CLA to reforms that threatened the status quo. However, CLA ' s consultative and systematic nature allowed SAFEMed to continually realign tactics that helped counterbalance these threats; existence of committed reformers yet limited understanding of HTA capacity: Ukraine ' s dedicated health reformers embraced CLA methodology, such as reflecting, learning, and adapting the roadmap, and recognized their own value in advancing a common vision. This led to inclusive collaboration that secured political commitment and ownership.
Processes--Expertise in using CLA approaches to guide processes: The Ukrainian government is committed to aligning with European Union practices, and SAFEMed was able to call on international HTA experts to strengthen the HTA Department, who further advanced the HTA process.