Question 1: *How have systems thinking approaches and tools been incorporated in activities to improve health equity? Were these approaches useful in achieving health equity goals? If so, what are the pathways by which these approaches helped to address the root causes of inequity?*

SAFEMed and the Affordable Medicines Program in Ukraine: Reducing inequities in medicine access

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HEALTH SYSTEMS STRENGTHENING ACCELERATOR

Context

Before 2017, Ukrainians struggled to access needed medicines with severe wealth inequities. The context is continually evolving as a pandemic and military invasion have had drastic effects on the population's health and needs.

Insufficient funding and inefficient prescribing…

Low Public Spending on Health: The Government of Ukraine (GoU) spent 2.9% of the GDP on health in 2015, below the average of countries in the WHO European Region (5%) and EU (6%), despite taxing for health coverage. Other financing mechanisms, such as private health insurance, are rare.

Inefficient prescribing practices: Patients were often prescribed numerous medicines, brand-names instead of generics, and non-indicated medicines.[1]

…Led to inaccessible and unaffordable medicines.

High Out of Pocket (OOP) Expenditures: Medicines accounted for 56.5% of total spending on health in 2015. 96% of those who were prescribed outpatient medicines paid for them OOP. Outpatient medicines are the largest driver of OOP payments in health care.

Low consumption of medicines: The consumption of medicines per capita was half the amount of peer countries in 2017, due to medicine unaffordability. In 2015, 11.2% of people in Ukraine had been diagnosed with coronary heart disease, but only 0.45% received any type of statin (an important cholesterol lowering medicine), well below the anticipated need.[2]

Ukraine needed a systemic intervention using market solutions to lower prices, engage the private sector, prioritize essential medicines, refine prescribing practices, and offer financial risk protection to Ukrainians with the highest burden of disease.

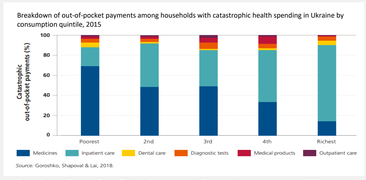
Inequitable access: OOP spending on medicines drove catastrophic health expenditure for the poorest households

Inequities among wealth quintiles: Among the poorest quintiles, medicines accounted for over 70% of household spending on health.

Catastrophic health expenditure (CHE): Spending on medicines was a significant driver of financial hardship for Ukrainian citizens, representing 46% of OOP payments among all households with CHE in 2015.

The most vulnerable are most affected: OOP spending on medicines accounted for 69% of expenditures in poorest quintile households that experienced CHE in 2015.[3]

Unmet needs: 25.4% of households reported they were unable to afford needed medicines in 2015 (30% in the lowest quintile and 17% in the highest).



1. Goroshko, Alona, Natalia Shapoval, and Taavi Lai. "Can people afford to pay for health care? New evidence on financial protection in Ukraine." (2018).
2. Iakovleva, L, O. Tkachova, O. Mishchenko, O. Gerasymova, N. Bezdilko, O. Kyrychenko, and N. Matyashova. "Analysis of affordability and consumption of statins in Ukraine in 2015." Value in Health 19, no. 7 (2016): A660.
3. World Health Organization. "Evaluation of the affordable medicines programme in Ukraine." (2019).

Activity Description

The GoU established the Affordable Medicines Program (AMP), also known as the State Reimbursement Program, in 2017 to answer inequities in medicine accessibility. The USAID SAFEMed project offered technical support on pricing strategy, identifying priorities, monitoring, stakeholder engagement, and communication. The National Health Service of Ukraine (NHSU), the national payer, took over management of AMP in 2019 and introduced an innovative e-prescription component to the program. SAFEMed continues to offer technical and legal support to the AMP.

THE AFFORDABLE MEDICINES PROGRAM

Step 1: Family or specialty doctor prescribes the medicines to a patient

Step 2: An e-prescription in a code format is sent to a patient's mobile phone (with written prescriptions allowed in active conflict zones).

Step 3: Pharmacy fills the prescription for a patient for free or with a reduced co-payment

Step 4: NHSU reimburses the pharmacy twice a month for prescriptions filled.

Prioritizing medicines and standardizing patient care plans

The program covers medicines for chronic conditions based on burden of disease, prevalence, and availability of effective and cost-effective treatments. It started with medicines for cardiovascular diseases, type 2 diabetes, and bronchial asthma and has grown to covering nine diseases and 58 different international non-proprietary names (INNs) or active substance. The AMP plans to expand to pain relief, diabetic testing supplies, and several other disease areas in the next several years. For each condition, NHSU works with the clinical community to develop patient care plans that guide treatment.

Enrolling Private Pharmacies

Pharmacy participation is voluntary but highly encouraged to ensure broad patient access. Enrollment in the program requires an accreditation process and annual renewal. They must also participate in the e-prescription program. Private pharmacies play an essential role in ensuring medicine is accessible.

To address in the inaccessibility and high OOP costs of medicines, SAFEMed and the GoU utilized the control knobs framework of health systems. By pressing on the key levers of financing, organization, and regulation, we improved the quality, efficiency, and access of healthcare, resulting in better financial risk protection and customer satisfaction.

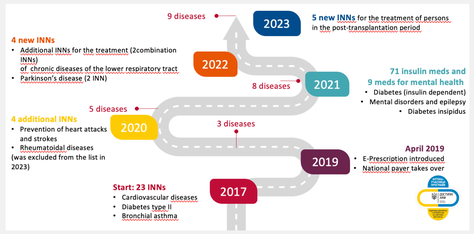
Setting competitive prices based on market research

Step 1: The median of the registered price (per defined daily dose, or DDD) of the active substance (INN) is collected in five reference countries: Czech Republic, Hungary, Latvia, Poland, and Slovakia. These prices are used to define a median reference price, above which any generics will not be reimbursed.

Step 2: For each reimbursed INN, the cheapest generic price becomes the reimbursement reference tariff (after including regulated retail margins and VAT)

Step 3: When the reimbursement reference tariff is defined, drug companies interested in the reimbursement scheme are given a five-day window to perform a reverse auction to have their generic fully reimbursed.

Step 4: If a generic is priced below the median reference price, but above the reimbursement reference tariff, the patient must co-pay the difference up to the median reference price. medicines above the median reference price are not reimbursed at all.



Activity Impact

Control Knobs (levers to impact the health system)

Organization: The NHSU contracts with each pharmacy directly. To obtain medicines through the AMP, the patient must receive the prescription from a primary or secondary care provider.

Financing: The GoU has expanded annual funding for the AMP from $26M USD in 2017 to $148.4M in 2022.

Behavior: Physicians have been prescribing more medicines that are reimbursed, and therefore more likely to be dispensed. Patients are more likely to fill prescriptions for conditions that require high-priced medicines.

Payment: Pharmacies are reimbursed twice a month at the agreed and published price. As of December 2022, 12,867 pharmacies were enrolled in the program (60% of all pharmacies in Ukraine).

Regulation: Reimbursement prices are set using external reference pricing. A legal framework was established to allow for more competitive pricing.

Intermediate Performance Measures

Access: Before the AMP, GoU set up targeted regional drug reimbursement programs, but they were recognized to be ineffective. Now, the entire population is eligible to use the AMP and select their hospital and doctor in any region and use any participating pharmacy.

Prescribers stated many new patients had come for treatment now that they could afford medicines and did not feel guilty for taking money away from the family budget.

Greater increases of medicine consumption were seen in poorer districts under the AMP, indicating that the AMP allowed people in poorer districts to receive needed medicines.

Quality: As part of the AMP, providers must use care plans that direct appropriate use of medicines. The AMP operates through the primary (PHC) and secondary health care sector, strengthening and establishing essential preventive and integrated care. As part of overall PHC reforms, all patients must be registered with a primary care physician. Health care providers rely on patient care plans that guide prescribing practices.

Efficiency: E-prescriptions have streamlined reporting and reduced concerns of corruption, including false prescriptions. Price negotiation has produced lower prices in medicines: insulin available through AMP is 11% less than in retail sales.

Performance Goals

Customer Satisfaction: Prescribers report being satisfied with the AMP. They saw an increased number of patients being treated, with increased loyalty and adherence to treatment. Patients reported being satisfied with the medicines available under the AMP.

Financial Risk Protection: $144M USD (5.2B UAH) has been reimbursed since the beginning of the program.

The proportion of OOP spending to total spending on medicines has been reduced from 86% in 2017 to 65.6% in 2023.

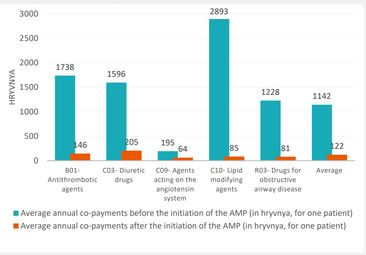
Health outcomes: 42.2M prescriptions have been filled for 3.7M unique patients since 2017.

On categorical average, 72% of dispensed packages of eligible medicines are dispensed under the AMP

There has been a 419% increase in pharmacies dispensing insulin since AMP inclusion in October 2021; currently, 120,000 insulin prescriptions are prepared monthly for 215,660 patients (100% of the estimated insulin-dependent population).

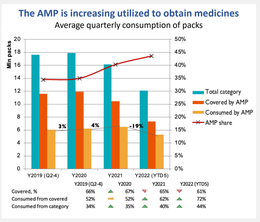
Evidence

A sharp decrease in prices…



On average, the AMP led to an 85% reduction on previous co-payments required to access medicines.[4]

The AMP is increasing utilized to obtain medicines

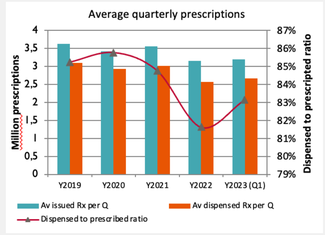


The increase in AMP share indicates increasing utilization of the AMP program for medicines that are covered. This results from increased participation of pharmacies, patients, and providers, as well as greater availability of medicines.

…Led to increased consumption of medications.

Increases in Consumption by Daily Defined Dose Gross Rate						
Medicines and Class	2016 (Baseline)	2017	2018	2019	2020	2021
Simvastatin (C10)	100%	1314%	2534%	3486%	3764%	3218%
Clopidogrel (B01)	100%	380%	570%	648%	703%	538%
Losartan (C09)	100%	109%	327%	561%	665%	622%
Budesonide (R03)	100%	313%	461%	498%	471%	519%
Hydrochlorothiazide (C03)	100%	293%	337%	420%	434%	404%

Inclusion of an INN in the AMP leads to significant growth in sales and increased consumption. Simvastatin, clopidogrel, losartan, budesonide, and hydrochlorothiazide (important medicines for the care and prevention of cardiovascular disease, cardiovascular incidents, and pulmonary disease) demonstrated the fastest growth in consumption of daily defined dose (DDD) gross rate.



The "dispensed to prescribed ratio" is the average number of prescriptions dispensed by pharmacies divided by the total number of prescriptions in the AMP issued by prescribers. This is an integrated indicator of patients' compliance to prescribed medicines and medicine availability.

4. World Health Organization. "Evaluation of the affordable medicines programme in Ukraine." (2019).

Facilitators

A New Single Payer System

The National Health Service of Ukraine (NHSU) was established in 2018 to facilitate contracting and payment for health care and to coordinate pooling and purchasing policies. The NHSU was able to take over the management of the AMP in 2019, with SAFEMed continuing to offer technical support. SAFEMed also coordinated collaboration between MOH, Medical Procurement of Ukraine (MPU), Center for Public Health (CPH), State Expert Center, and patient groups to strengthen the pharmaceutical sector.

Legal Reform

Multiple legal reforms paved the way for regulation, with many more evolving to support and adapt the program, even during wartime. Some landmark acts include :

- Law of Ukraine "State Financial Guarantees of Medical Service to the population" (Oct 2017)
- Cabinet of Ministers Decree "Certain Issues of Reimbursement Contracts" (Feb 2019)
- Cabinet of Ministers Decree "Certain Issues of Implementation of the Program for State Guarantees of Medical Service to the Population in 2022" (Dec 2021)

Technology Advances

SAFEMed supported the development of e-prescription (launched in 2019) which allowed for more accurate, timely, and complete reporting and reduced corruption risks.

An improved health information system allowed for financial planning, contract development, and performance management. A private medicine data firm, SMD, contracted by SAFEMed, offered ongoing analysis of imports, production, and retail data, providing feedback to NHSU for program improvements.

Private Sector Engagement

The ability to reference prices and offer "reverse auctions" (companies can offer lower prices after the reference price has been set) has lowered prices overall, matured the market by reducing the number of market players, and engaged the private sector to expand their market by offering more affordable medicine. While the AMP works to lower prices, the government depends on the private pharmacies to ensure medicines are available to the public. Such a partnership harnesses the potential of the private sector to provide medicines that are affordable and accessible.

Challenges

Russia's Invasion (February 2022-Current)

The AMP was able to adapt to the needs of Ukrainians migrating during the war.

- Paper-based prescriptions were allowed as an emergency mechanism
- All insulins in the AMP were free of charge for all categories of patients during martial law period (6 months)
- Internally displaced patients were able to receive their medicine without needing a new prescription from a new prescriber
- NHSU continued to pay the contracted 12,568 pharmacies in 2022, adding 461 pharmacies after March 2022
- More than 1.5M patients continued to receive their chronic disease medicines in 2022
- Ukrainians were previously required to go to the primary care provider (PCP) they registered with to receive medicines through the AMP; currently, they can see a PCP anywhere.

The AMP continues to operate during wartime, even in occupied territories. The production capacity, retail sales, government procurement, consumption of medicines, and overall AMP volume throughout Ukraine dropped in 2022 but rebounded in 2023.

To support the AMP in wartime, SAFEMed:

- Embedded consultants to bolster the NHSU IT department operations
- Supported the development of patient education videos about accessing prescriptions through the AMP during the war
- Offered expanded support through data analytics firm SMD to track impact of the war on the program and identify ways to modify
- Provided just-in-time legal support to draft necessary regulations to ensure patient access.

Geographic Access

The distance between the place of prescription (clinic, hospital, etc.) and where medicines are dispensed can be a barrier to filling prescriptions. The AMP has a goal to reduce the distance to 1 km. Currently, 40% of the pharmacies are located less than 1km from the place the scripts were written. 9% of the pharmacies are greater than 16km away. 83.6% of the pharmacies are in a city, but 11.6% are in a village and 4.8% are in an urban-type settlement. During wartime, SAFEMed has been advising the GoU on other ways to expand pharmacy access through use of mobile pharmacies (particularly in rural areas and conflict zones) and regulatory reforms and program expansions that would incentivize all pharmacies within health facilities to participate in the AMP.

Covid-19 Pandemic

The AMP continued to expand during the Covid-19 pandemic and offered remote prescription ability for chronic medicine refills so patients could avoid potential exposure to COVID-19 at routine health facility visits.

Lessons Learned

Tap an underutilized resource by engaging actors in the private sector

The private sector plays an important role in advancing legal, political, or societal reform. By giving private sector actors an important part to play in making medicines safe and accessible to Ukrainians, SAFEMed has harnessed their potential to effect change on a systemic scale. SAFEMed and NHSU host bi-annual reimbursement program forums to illicit feedback and steward relationships.

Launch a new initiative using a staged implementation approach

Several failed attempts were made to reimburse insulin before the AMP program. To integrate insulin into the AMP, the NHSU and SAFEMed decided to apply a step-wise approach to launching the program during 2019-2021:

- Update standardized treatment plans and ensure medical records of treatment plans for diabetic patients were registered in the eHealth system prior to becoming mandatory.
- An NHSU Academy-developed training program for physicians was designed to prepare participants to work with new electronic tools.
- Fully launch insulin reimbursement package in October 2021. Before inclusion in the AMP, 2,179 pharmacies sold insulin, but insulin was given by providers. Currently, 11,307 pharmacies sell insulin, with 70% of prescriptions provided free of charge.

Technological Interoperability

SAFEMed IT experts worked with NHSU to ensure their data platforms (encompassing e-prescriptions, pharmacy contracting, payment terms, etc.) were interoperable with the GoU's wider eHealth systems and contained accurate data to be used to inform decision-making.

Navigating Leadership Transitions

There have been multiple leadership changes at the MOH, NHSU and other governmental agencies over the years. To ensure the continued operation, funding, and expansion of the AMP, it was necessary to spend time and effort

- Build an understanding of new priorities, challenges, and opportunities and be responsive and flexible with new directions.
- Secure buy-in and understanding of project activities, achievements/progress made, and strategies moving forward.
- Establish consensus and align on the essentials.

Capitalizing on Political Will

The AMP would not have been possible without important legislation to pave the way for funding allocation, governmental agency collaboration, and prioritization. Advocating for legislation and increased annual state budget allocations was an essential part of this program's success and continues to be an important activity.

Data Feedback Loops

If the AMP had waited until every process was perfect, it would have never launched. Feedback loops were installed from the beginning to capture data and improve processes for continued efficiency and INN expansion. By hiring the pharmaceutical data firm SMD, SAFEMed was able to support the AMP to analyze market data to inform subsequent iterations of the AMP and continue to expand coverage, both geographically and pharmaceutically.

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