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THE IMPACT OF THE WAR IN UKRAINE ON ONCOLOGY PATIENTS

Overview and recommendations for European and Ukrainian health authorities and policymakers

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INTRODUCTION

The war in Ukraine has impacted Ukrainian citizens, infrastructure, markets, healthcare professionals and patients. It created new crises, reprioritization, and an appreciation for the solidarity of the global community.

Within the healthcare sector, cancer patients and their care are indicators of the challenges faced by Ukrainian patients with chronic conditions before, during, and after the war. Efforts to support both current and future patients will benefit from a structured plan on how to aid the country's essential recovery.

This study encompasses expert interviews from the start of the war in February to November 2022, and will retain relevance by explaining Ukraine's pre-war healthcare, and oncology care landscape in depth.

This report provides a timely view of the levels of, and trends in, oncology epidemiology, care, prescribing patterns, diagnosis, and clinical trials in Ukraine and the neighbouring countries (Hungary, Poland, Romania and Slovakia) who are currently providing essential care for Ukrainian refugees. The results are sourced from research with 26 experts, starting in June 2022 and completed in November 2022, to show the progress in the first 6 months of the war and collect perspectives on the immediate and long-term challenges for Ukrainian cancer patients.

The study was produced by IQVIA as a public service and acknowledges the funding provided by the European Federation of Pharmaceutical Industry Associations (EFPIA) Oncology Platform.[1]

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THE STATUS OF HEALTHCARE IN UKRAINE PRIOR TO THE WAR

This study focusses on the impact on cancer patients, yet the status of the healthcare system provides the backdrop to the care that patients were receiving. The Russian invasion and its consequent damage to critical infrastructure, relocation of Ukrainian citizens and disruptions to care aggravated long-standing issues in the Ukrainian healthcare system.

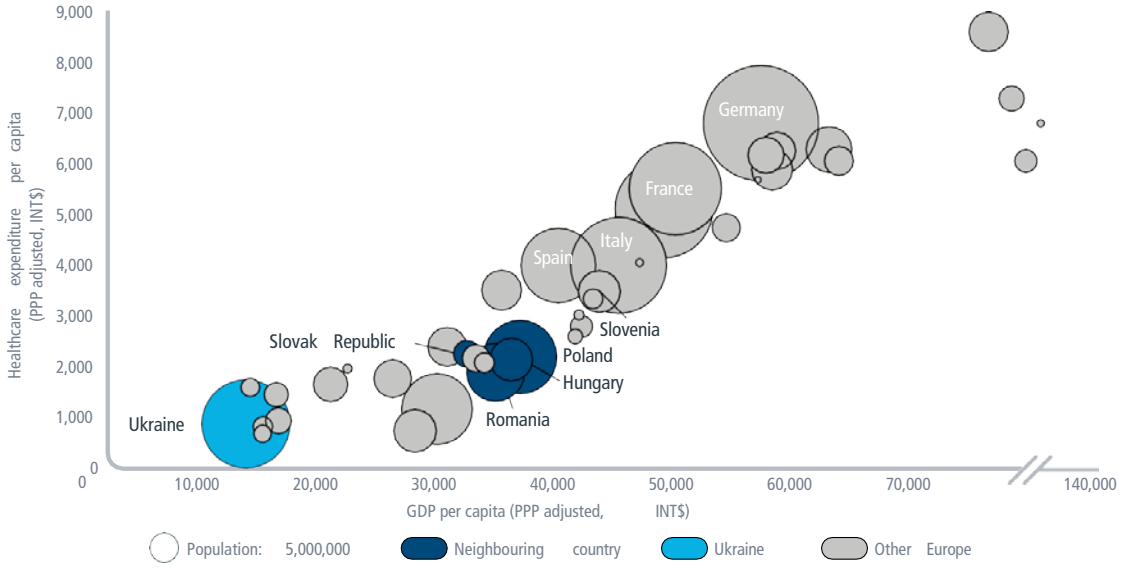
PATIENTS IN UKRAINE WERE TREATED BY AN UNDERFUNDED HEALTHCARE SYSTEM

Located in the Eastern part of Europe, Ukraine is the 8th largest European country with a population of 43.8 million people. Despite significant pressure to treat a large and rapidly aging population, the Ukrainian healthcare expenditure per capita is the lowest in the region, and often less than 20% of what a Western European economy spends on healthcare.[2]

The country's GDP per capita (PPP adjusted) is one of the lowest in the region, and the lowest of its neighbouring countries in Central & Eastern Europe (CEE).

Before the war, ambulances and staffing constraints were an on-going issue for the healthcare system. This was documented in 2016[3] and compounded by reports of attacks directed at ambulances during the early stages of the war. In response to these constraints, countries and public groups from around the world[4] donated vehicles to support both front-line

FIGURE 1: Overview of the European markets



Source: WorldBank data from the most recent period (2019, and 2020 combined).

troops with all-terrain ambulances, and day-to-day ambulances.

In 2014, the World Bank Country Director for Belarus, Moldova, and Ukraine described the healthcare system as, "poor… [and] requiring a comprehensive set of reforms", and despite loans such as the World Bank's 2014 loan of $215 million via the "Serving People, Improving Health" initiative[5], and the European Investment Bank's post- COVID recovery investments of over $1 billion[6], the healthcare system was not meeting the needs of the Ukrainian population prior to the war.[7]

THE SYSTEM WAS ATTEMPTING BROAD REFORMS WITH VARIABLE SUCCESS

Since the country became independent in 1991, following the collapse of the Soviet Union, Ukraine has been catching up to Western approaches to treatment, guidelines, and medicines. It had also been undertaking significant reforms in the healthcare sector, since 2014. The reforms included reconfiguring primary care financing and essential medicines reimbursement under the newly formed National Health Service of Ukraine, raising the remuneration of health professionals, introducing a transparent, merit-based, process for medical university admissions, and initiating development of an eHealth digital records system.

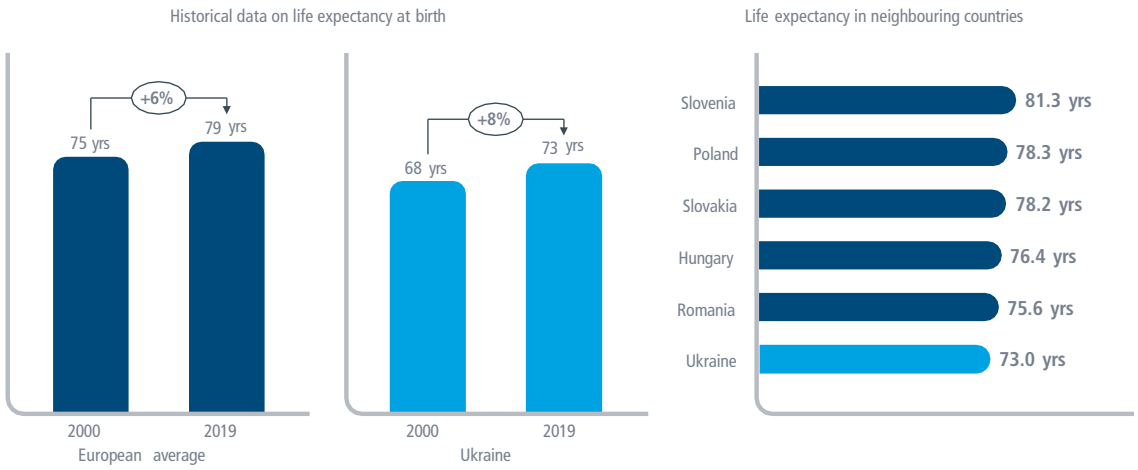
By 2020, these reforms had led to initial improvements by "reducing the number of acute medical events, and increasing patient satisfaction with their care providers".[8]

The structure of Ukraine's healthcare system is comprised of 25 administrative regions. Prior to reforms in 2017[9], clinical protocols were created at a local level, leading to wide variation, outdated approaches, and unnecessary workloads for stretched systems. With a backdrop of a deflating currency, inflation, and despite an overall 0.5% decrease in GDP expenditure on health since 2013[10], improved access to essential medicines had led to a reduction in the total number of acute events, such as heart attacks or strokes.[11] However, the starting point was far behind the rest of Europe.

AS A RESULT, LIFE EXPECTANCY WAS SIGNFICANTLY LOWER THAN NEIGHBOURING COUNTRIES BUT IMPROVING

At 73 years, Ukrainian citizens have the lowest life expectancy (at birth) among most Eastern European countries. This figure is also significantly below the European average of ~78 years. Low healthcare spending and a struggling economy are two of the main underlying factors. Between 1990 and 2015, public health expenditure in Ukraine decreased gradually from US $86 per capita to US $58 per capita.[12]

FIGURE 2: Life expectancy in Ukraine is significantly lower than other European countries



Source: WHO, 2020.
Notes: Europe defined as the European geographic region as defined by the WHO data set parent location code (EUR).

> At 73 years, Ukrainian citizens have the lowest life expectancy (at birth) among most Eastern European countries.

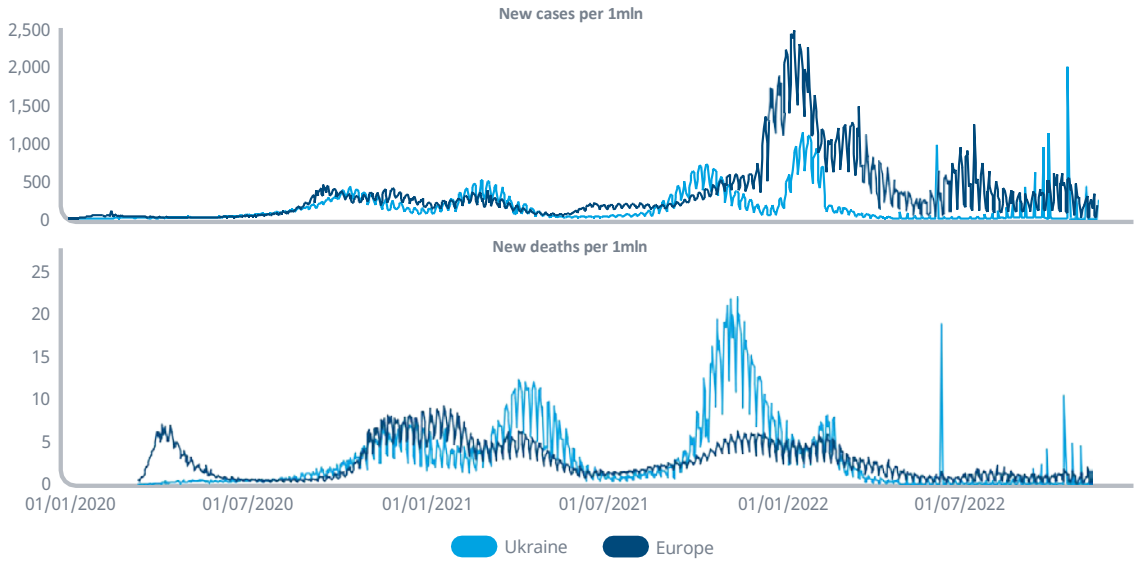
COVID-19 HIGHLIGHTED, AND ADDED, TO HEALTHCARE SYSTEM CHALLENGES

The COVID-19 pandemic added significant challenges to an already stretched healthcare system. Official data show that Ukraine had one of the lowest rates of infection in Europe, highlighted by a significantly lower number of population-adjusted cases throughout the pandemic compared to neighbouring countries. Despite this, the number of associated deaths is significantly higher than other countries, suggesting a higher mortality ratio for COVID-19 patients in Ukraine. As in many other countries, this discrepancy likely reflects inadequate testing in many places as well as the difficulty of attributing cause of death with precision. Although cases linked to the BA.2 variant are significantly lower (1:4) at their peak in early February than those seen within the European region, deaths are 400% greater.

Excess mortality data in Ukraine suggest around 160,000 -170,000 pandemic-related deaths, substantially higher than the official COVID-19 data.[13]

Prior to the war, Ukraine had fully vaccinated around one third of its population, making it the least-vaccinated country in Europe due to widespread vaccine skepticism among the population.[14] Since the war began, the ability to measure vaccination rates within Ukraine is understandably challenging, and figures are no longer available.[15]

FIGURE 3: Daily new confirmed COVID-19 cases and deaths (per mln)



Source: Our World in Data (last accessed November 2022).

PRE-WAR STATUS OF CANCER CARE AND TREATMENTS IN UKRAINE

Challenges to the provision of care for cancer patients in Ukraine were already high before the war, and the epidemiology and treatment of cancer in Ukraine is different to its neighbours due to historical reasons. Therefore, it is important to understand the status of cancer care in Ukraine prior to the war started in February 2022. The information included in this section can help to assess the direct damage to the system, and the subsequent prioritisation of solutions and recovery plans.

UKRAINE HAD A HIGH BURDEN OF CANCER PATIENTS PRIOR TO THE DISRUPTION OF THE HEALTHCARE SYSTEM

Cancer is the second most common cause of mortality in Ukraine, behind cardiovascular diseases, with 1.2 million active cases and more than 160,000 new diagnoses in 2020 alone. This represents nearly 3% of the total population. Available data shows that before the war, an estimated 139,000 Ukrainians were living with newly diagnosed cancer, and approximately 1,000 children were receiving active cancer treatment.[16]

FIGURE 4: Overview of Ukraine's cancer burden

~1.2 Mln Number of registered people with cancer

~60–80 K Number of deaths from cancer every year

Most frequent types of cancer in men

Cancer type		
Trachea, bronchi and lung cancer	20,3%	14,8%
Prostate cancer	12,4%	22,2%
Non-melanoma skin cancer	9,9%	3,3%

Most frequent types of cancer in women

Cancer type		
Breast cancer	20,3%	27,8%
Non-melanoma skin cancer	12,9%	3,6%
Cervical cancer	9,5%	9,8%

Source: Global Cancer Observatory (Last accessed November 2022).

> Basic indexes of cancer diagnostics and treatment in Ukraine were 2 to 2.5 times worse than high-income countries[19], and the Mortality Incidence Ratio (MIR) is one of the highest in Europe [...]

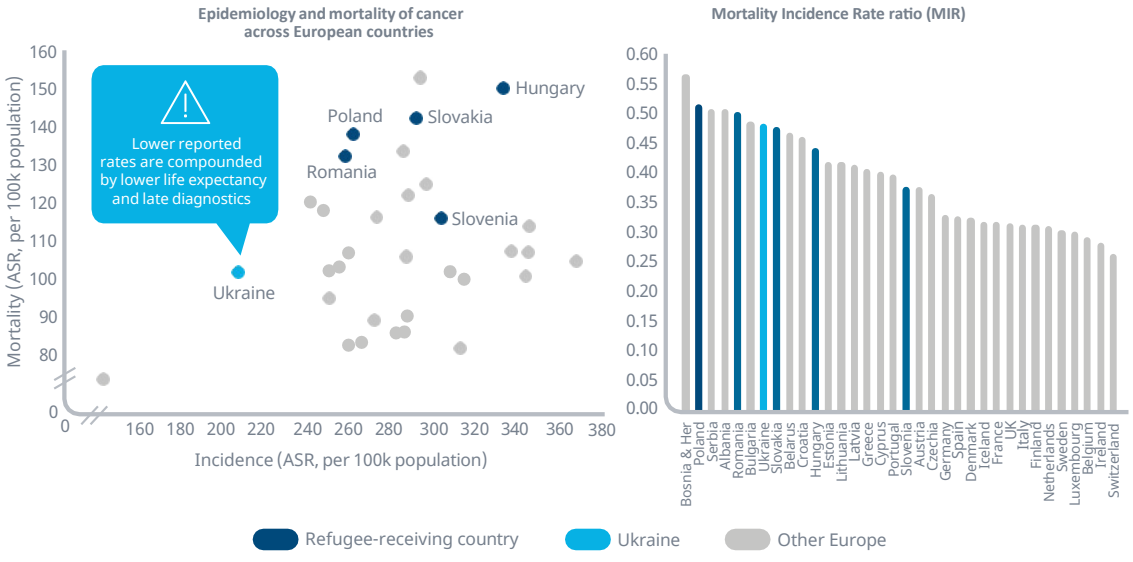
The distribution of cancer types varies between Ukraine and the other European countries. Between 2020 and 2021, the most common type of cancer for men in Ukraine was trachea, bronchi and lung cancer (20.3%), followed by prostate cancer (12.4%) and non-melanoma skin cancer (9.9%)(Figure 4). The high rates of lung cancer among Ukrainian men have been previously linked to the high prevalence of smoking in this population group and higher risk of exposure to airborne carcinogens through occupational activities.[17]

For women, the most common type of cancer was breast cancer (20.3%), non-melanoma skin cancer (12.9%) and cervical cancer (9.5%). In these instances, rates are either lower or equivalent to EU averages, however there are data limitations (discussed below).

UKRAINE HAS HIGH MORTALITY RATIO IN CANCER DESPITE DATA LIMITATIONS

Survival rates of cancer patients in Ukraine are up to 5 times lower than in European countries or the US.[18] Basic indexes of cancer diagnostics and treatment in Ukraine were 2 to 2.5 times worse than high-income countries[19], and the Mortality Incidence Ratio (MIR) is one of the highest in Europe despite the data gaps which would likely worsen the overall outcome.

FIGURE 5: Ukraine has a low cancer incidence, but high mortality ratio compared to other European countries



Source: Global Cancer Observatory (Last accessed November 2022).

Ukraine could be expected to have prioritised oncology care following the 1986 Chernobyl nuclear disaster, but studies on the long-term impact of the accident are unsatisfactory to draw conclusions upon. This event had the temporary effect of increasing certain cancers (notably thyroid cancer) among children and young adolescents who were in the contaminated areas of Ukraine. Thirty years on from the event[20], the Chernobyl accident can be seen to have increased rates of reporting and diagnosis. This event can also be linked to the introduction of screening ultrasound examinations of the thyroid, abdominal and kidneys as part of a routine medical check-up.[20]

Existing organizational barriers and lack of clear health policies in Ukraine meant that cancer diagnosis and treatment were often delayed or foregone. Weak financial protection mechanisms for patients undergoing chronic treatment are a likely cause of a higher fatality ratio in this country. Forgoing diagnosis and treatment are described as 'individual-level coping strategies' in response to the organisational and financial failures of the Ukrainian health care system.

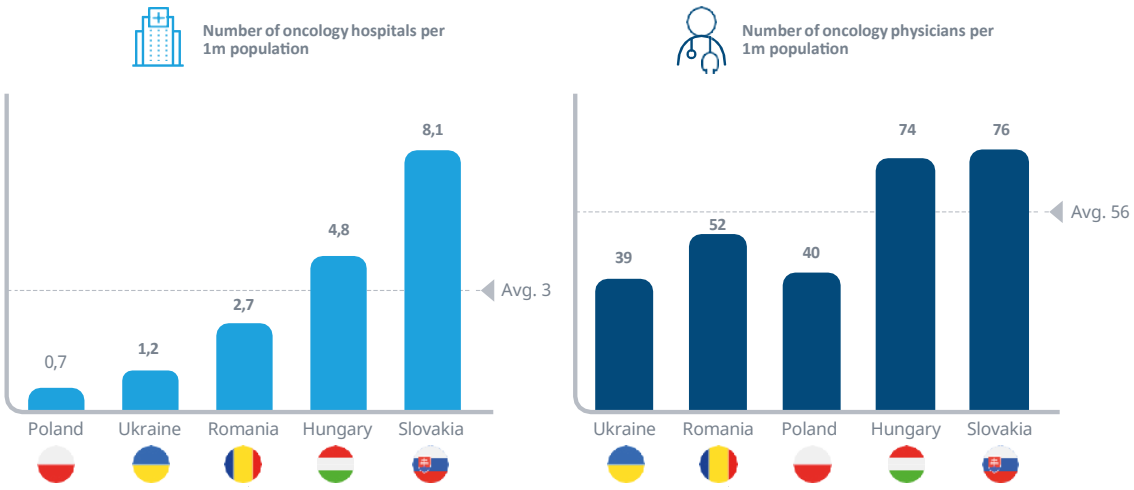
As a result, Ukraine appears to have a below average burden in cancer epidemiology statistics when compared to most neighbouring countries in Eastern Europe (i.e., Poland, Slovakia, Hungary and Romania), but this is not representative of the complete pre-war picture.

UKRANIAN PATIENTS HAD 70% FEWER ONCOLOGY HOSPITALS AND 35% FEWER ONCOLOGISTS COMPARED TO NEIGHBOURING COUNTRIES

Poor access to cancer treatment and low rates of treatment success might also underscore the high fatality ratio. Compared to neighbouring host countries, Ukraine lags behind most of its counterparts in population-adjusted cancer centers and oncology Health Care Professionals (HCPs).

Among the CEE countries studied, Slovakia and Hungary exhibited the highest amount of oncology physicians while the lowest number was recorded in Ukraine and Poland. If the war becomes protracted, the scarcity of healthcare professionals, combined

FIGURE 6: Cancer care capacity in Ukraine and refugee-receiving countries



Source: IQVIA OneKey Database, desk research, IQVIA analysis.
Notes: Data for Poland only includes oncology hospitals and does not capture hospitals with oncology wards.

with an increasing patient volume is likely to compound difficulties in cancer care delivery in the country. Higher psychological stress and displacement of vulnerable individuals have also been reported to cause a surplus of cases with unfavorable outcomes in the immediate post-war period during past conflicts.[21]

UKRAINIAN PATIENTS RECEIVE OLDER TREATMENTS TO OTHER CEE COUNTRIES

Total spending on oncology medicines in Ukraine is estimated at €85 million. When normalized by population density, IQVIA data shows that this is approximately 80 times lower than average spending in Germany and 28 times lower than CEE countries. As a result, patient access to new innovative products might be limited, owing to significant differences in total pharmaceutical spending. This may be the consequence of varying budgetary commitments.

Major components of oncology-related pharmaceutical expenditure in Ukraine are protein kinase inhibitors. Conversely, monoclonal antibodies represent the largest group of oncology drugs used in Central and Eastern European (CEE) countries by value.

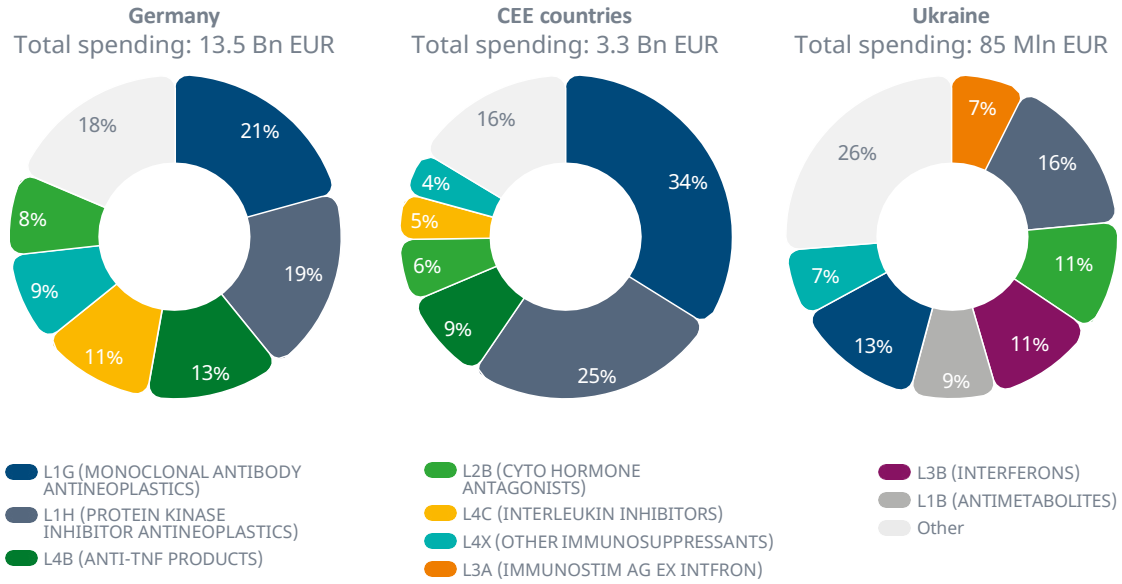
Ukraine consumes a larger proportion of older therapies, including cyto-hormone antagonists, antimetabolites and alkylating agents, compared to CEE countries.

Low consumption of modern therapies places Ukraine among the last CEE countries to benefit from the latest anti-cancer treatments. Despite this notable gap in access to cutting-edge innovation, interviews with healthcare professionals in Ukraine suggested that access to modern therapies unexpectedly improved during the war, thanks to increased delivery through humanitarian aid.

CLINICAL ACTIVITY IN THE REGION WAS INCREASING AND PROVIDED PATIENTS ACCESS TO INNOVATIVE TREATMENTS

Clinical research had increased significantly in Ukraine in recent years. Over 2,500 clinical trials were conducted in this country between 2011 and 2021, and 549 oncology trials in 2022.[22] In 2021, the majority of oncology trials took place in Western Europe (2,355), but of the remainder that were run in Eastern Europe (454), Ukraine accounted for a large share of active trials (42%). These figures

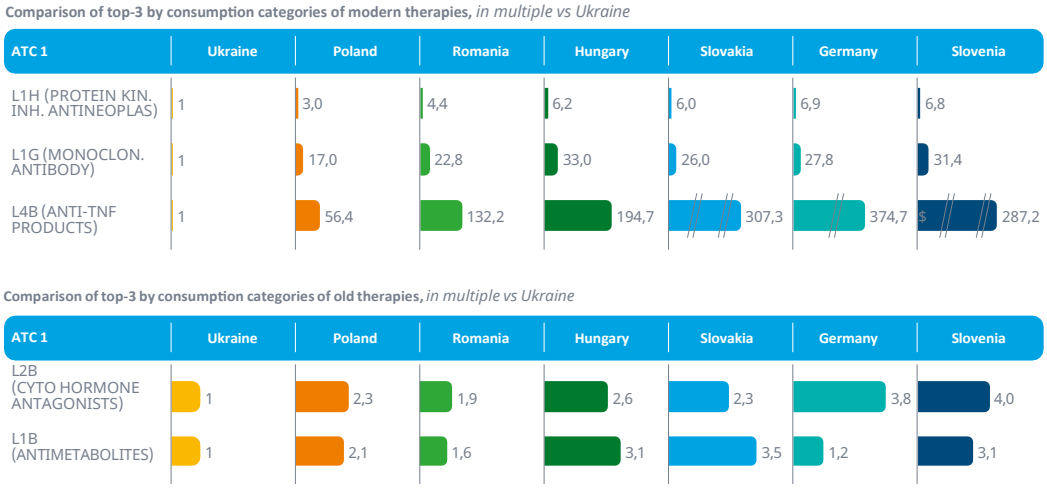
FIGURE 7: Spending on oncology drugs in Ukraine vs benchmarking countries by ATC 3 class (2021), in Euro (%)



Source: IQVIA MIDAS database; Proxima Research International.

highlight the industry's positive perception to patient enrollment, a trend mostly driven by a willing patient population and the low cost of doing business in the region. Analyses of clinical trial activity by study phase suggests that the clinical trial pipeline in Ukraine was heavily focused on late-stage, Phase III trials (~65%).

FIGURE 8: Ukraine consumes few modern anti-cancer medicines compared to neighbouring countries



Source: IQVIA MIDAS Database; Proxima Research International for Ukraine.

THE IMPACT OF THE WAR ON ONCOLOGY PATIENTS

Since Russia's invasion of Ukraine, damage to key healthcare infrastructures, power outages, and shortages of medicine and food supplies have represented major hurdles for patients requiring time-critical interventions. In particular, because hospitals and health services have had to recalibrate their focus to trauma emergencies, oncology services have experienced severe disruptions. Additionally, the war has started to shift some of Ukraine's cancer burden to neighbouring countries. Due to the unique challenges associated with cancer, new solutions are urgently required to manage the multiple dimensions of cancer care in Ukraine.

UKRAINIAN CANCER PATIENTS HAVE BEEN HEAVILY IMPACTED BY THE WAR. SOME OF THE CHALLENGES DISCUSSED IN THIS SECTION INCLUDE:

- Damage to key medical infrastructure
- Language barriers
- Limited availability of medical records
- Difficulties in adherence and pharmacovigiliance
- Cancer medicine shortages
- Limited oncology capacity in neighboring countries
- Insufficient psychological support
- Discrepancies in treatment regiments
- Limited patient access to surgery, radiotherapy and experimental medicines

TREATMENT CENTRES, HOSPITALS AND OTHER MEDICAL FACILITIES ARE CONTINUALLY DAMAGED BY ATTACKS

The most visible impact on healthcare and to patients in Ukraine is the damage to medical facilities. Data on the impact of the war on the Ukrainian health system is in constant evolution, so the full measure of the impact on health infrastructure remains difficult to quantify. Ukraine already had a lower availability of oncology treatment centres and physicians prior to the war, but according to the Ukrainian Minister of Health, Victor Liashko, in October 2022 there were "1000 damaged medical facilities, 120 were demolished, and 300 of these are being renovated but it's a partial renovation" due to Russian attacks.

At least one cancer center was damaged soon after the war began in Mykolaiv[23], while two additional oncology centres, one in Kharkiv and one Mariupol, were completely destroyed by Russian missile strikes and had to cease operations in May 2022.[24] Recent estimates suggest that more have been damaged.

The healthcare system has been subject to continued attacks since the outbreak of the war and is tracked by the WHO's Surveillance System for Attacks on Health (SSA). This reports over 550 attacks which are defined as "violence with heavy weapons requiring more than one person to use firearms, tanks, missiles, bombs, mortars", that impacted healthcare facilities, as well as attacks to transport, supplies, and warehouses.[25]

> Of additional concern is the recent, indiscriminate shelling of Ukraine's energy plants which threatens to disrupt energy supply to key oncology hubs in the country

Each attack has direct consequences for patients and citizens as well as weaking the system for future patients. Of additional concern is the recent, indiscriminate shelling of Ukraine's energy plants which threatens to disrupt energy supply to key oncology hubs in the country. Energy operators have responded to threat by imposing rolling blackouts to ease pressure on the grid. However, these measures can be expected to curtail treatments for the critically ill, causing a new wave of migration for those cancer patients that continued their treatment in Ukraine.

DISPLACEMENT OF PATIENTS TO NEIGHBOURING COUNTRIES THREATENS CONTINUITY OF CARE

The war has caused the displacement of a large number of Ukrainian citizens since February 2022. As of October 2022, almost 8 million Ukrainian refugees have been recorded across Europe and 4.3 million were registered for temporary protection.[26]

As disruptions to key healthcare services continue in Ukraine, some cancer patients have been transported to neighbouring countries to assure continuation of their treatments. However, several challenges remain in ensuring adequate continuity of care abroad.

Interviews with medical experts indicate that the most prominent challenge for these patients is language barriers. Clear and understandable communication is key to accurately diagnose patients and provide them with a sufficient level of information about their rights, condition and treatment methods. In the first few months after the war began, lack of proper communication and poor availability of interpreting services was reported to hinder medical history and physical examinations to determine eligibility for treatments. When available such support was mainly provided by volunteers or charity organizations.

Language barriers can also be expected to prevent patients from using prescription medicines adequately and safely. Previous work has highlighted how individuals that are not familiar with the language used in their dispensing labels are at higher risk of poor health outcomes and adverse events.[27]

This problem is compounded by limited access to patients' medical records and data on previous oncological treatments. Difficulties in obtaining medical records and information on previous oncological treatment has been reported to delay the restoration of treatment with a negative impact on patients' health outcomes.[28] For those patients where surgery is recommended, delayed diagnosis may postpone oncologic surgery and lead to cancer progression. This may in turn result in the tumor no longer being resectable, with the associated worse survival outcomes.

PATIENTS REQUIRE ADDITIONAL SUPPORT

Importantly, patients fleeing Ukraine have received varying level of psychological support since the beginning of the war. Support programs have been developed to support these patients, however, the basic help offered to most refugees may be insufficient

for cancer patients where the process of dealing with the war-related trauma may be augmented by their chronic condition and require specialized mental health support. Reported stressors for these patients are not limited to the dangers of war, but also include difficulties in obtaining previous hospital records in Ukraine, medical expenses and uncertainty regarding the patient's and their family's future.[28] However, available data suggest that psychological services in neighbouring countries are limited or missing. A 2016 survey found that Poland, the country that has taken in the most refugees from Ukraine, had just nine psychiatrists for every 100,000 people[29], making one of the countries in Europe with the lowest number of trained mental health professionals.

Another challenge is linked to discrepancies in treatment regimens between the Ukraine's health system and the patient's destination. Although alignment exists across most European countries in providing free health care for refugees, provision has varied according to the capacity of the available services, reimbursement models, and prevailing treatment guidelines.

IQVIA's and Proxima Research International's data indicates that the composition of oncology treatments in Ukraine differs significantly from neighbouring host countries involved in relief efforts. For instance, the implementation and use of innovative anti-cancer drugs in Ukraine lags behind most CEE countries. Germany was used as an example of a high-income, developed country with large availability of cutting-edge therapies. Comparing the most consumed therapies in Germany to Ukraine, it is possible to see how the adoption of these therapies is minimal in Ukraine, highlighting that patients arriving in host countries were likely subject to changes in therapeutic modality.

FIGURE 9: Ukraine has the lowest consumption of all top 10 oncology molecules used in Germany

Consumption in countries, *SU per 100K, 2021*

INN	Germany	Ukraine	Poland	Romania	Hungary	Slovakia	Slovenia
1. Azathioprine	69,595	973	34,272	19,977	79,617	71,225	28,530
2. Tamoxifen	58,380	10,150	36,321	36,353	34,329	30,542	68,821
3. Tacrolimus	55,193	5,609	34,981	33,547	39,114	33,690	56,646
4. Letrozole	49,332	107	39,004	22,495	51,781	42,779	72,003
5. Mycophenolate Mofetil	45,490	0	42,461	13,470	22,583	17,834	76,561
6. Ciclosporin	26,897	4,666	23,199	7,540	10,413	27,614	23,859
7. Anastrozole	25,902	1,409	12,796	17,959	28,045	16,353	20,779
8. Hydroxycarbamide	23,050	5,989	27,422	18,752	19,274	0	25,285
9. Leflunomide	22,947	0	13,039	22,627	12,744	8,402	23,861
10. Enzalutamide	18,464	4	7,164	5,282	5,731	8,693	17,587

Source: IQVIA MIDAS, Proxima Research International for Ukraine.

THE CANCER BURDEN IS EXPECTED TO RISE

Armed war in Ukraine is forecast to exacerbate the high cancer burden in the country by exposing vulnerable cancer patients to infections, while diverting resources away from cancer care. There is growing consensus that changes to the provision of care, including modification of treatment schedules and omissions, as well as delays in cancer diagnosis will increase cancer incidence and mortality in the long term.[30]

Damages to critical medical infrastructures will further impede basic cancer care delivery for those patients returning to their homeland. Patients receiving treatment in host countries may also face their own challenges. The unexpected flux of cancer patients from Ukraine may overwhelm oncology capacity in the long term, thereby limiting access to essential therapies. This is especially true for those countries that already offered limited oncology care capacity before the war began. Early data on Ukrainian patients treated at oncology centers in Poland since the start of the war suggest that the number of cases may be higher than reported by official data.

Additionally, low- to middle-income countries with weak healthcare systems may struggle to direct sufficient medical attention and resources to cancer patients. This may, in turn, negatively affect the health outcomes of Ukrainian patients with acute and enduring needs in the long term. Moldova, for instance, one of the key destinations for Ukrainian refugees, has a per capita gross domestic product of $4,547[31], which makes it one of Europe's least economically advanced countries.

MEDICINE SHORTAGES RISK WORSENING HEALTH OUTCOMES

A related issue concerns cancer medicine availability. According to a survey of pharmacists in 46 cancer centres and hospitals in most refugee-receiving countries conducted in May 2022, over a third of all hospitals in these countries faced severe shortages of medications used to treat cancer.[32] These shortages can turn into significant delays to therapeutic plans with profound consequences for the patients. Every 4-week delay in cancer surgeries has been reported to increase the risk of death by cancer by 8%. A 12-week delay in surgery for breast cancer has been linked to a 26% increase in mortality.[33]

“There is growing consensus that changes to the provision of care, including modification of treatment schedules and omissions, as well as delays in cancer diagnosis will increase cancer incidence and mortality in the long term.”

> Since the start of the war, 2 single-country studies were initiated in Ukraine, as well as 44 multi-country trials.

The risk of delaying cancer treatment was made evident during the COVID-19 pandemic. Analyses of excess mortality during the pandemic showed that in addition to deaths directly linked to respiratory infections, a large number of deaths could be attributed to delays in cancer diagnosis and treatment. For instance, compared to pre-pandemic figures, deaths due to breast cancer are estimated to increase up to 9.6% in the United Kingdom, up to 5 years after diagnosis.[34]

Finally, it has been reported that cancer patients show increased vulnerability to COVID-19. With more active cases of the disease in Europe and low vaccination rates in Ukraine, there is a risk that COVID-19 infections may further exacerbate the cancer burden in Ukraine.

PATIENTS SUFFERED LIMITED ACCESS TO RADIOTHERAPY AND EXPERIMENTAL MEDICINES

War-related disruptions affected certain types of cancer treatments more than others. Radiotherapy, for instance, has been one of the most impacted therapies by the ongoing war. Before the war, Ukraine had only a limited availability of external beam radiation therapy (EBRT) machines, which was estimated at 2.6 per 1 million people.[35]

However, significant steps had been taken to expand radiotherapy capacity in the country. At the beginning of 2022, 16 linear accelerators were installed, and the Ministry of Health of Ukraine planned to purchase 20 additional linear accelerators later on this year. However, the war stalled progress in this area by not only delaying plans to expand radiotherapy capacity but also halting therapies in territories closest to the hostilities. Power outages, vibrations due to shelling and an unreliable internet connection have compounded damage to critical infrastructure, making it impossible to deliver this type of therapy to patients, particularly in the Eastern part of Ukraine.[36]

Access to experimental and potentially life-saving therapies has also been curtailed. This is because clinical research in Ukraine has faced severe challenges since the war began. There are direct (logistics, medicine supply, safety) and indirect war-related effects on trial participants (interfered with the collection and analysis of research data, disrupting the conduct of clinical trials in the region), and between 1st January and 1st October 2022, the number of recruiting sites has fallen from 1,814 to 940 (48%) in Ukraine.[37] A geographical assessment of Ukraine's clinical trial activity before the war indicates that despite a large number of trial participants in Kharkov and Kyiv, two cities particularly affected by the war, the large majority of trial sites are located away from the current, active hostilities.

In addition, eligible patients were not able to receive innovative and potentially effective cancer treatments where hostilities threatened the integrity of the trials. Sponsors faced ethical questions regarding the safety risk of interrupting therapeutic treatments for patients already enrolled in the trials, while preserving optimal research methods to adequately monitor treatment effects. This prompted the EMA to issue guidance for sponsors of clinical trials on how to effectively manage methodological aspects of ongoing trials in Ukraine.[38] However, difficulties in the conduct and planning of clinical trials have recently started to ease. In August 2022, the Ukrainian Association for Clinical Research president Dr Ivan Vyshnyvetskyy announced that Ukraine's local activity is on the journey to recovery.[39]

Figures on new trials initiated in Ukraine provide reason for cautious optimism. Since the start of the war, 2 single-country studies were initiated in Ukraine, as well as 44 multi-country trials.[39]

Additionally, some studies have returned to recruiting locally. An example is 'Ok!Clinic+', a clinical research center based in the capital Kyiv, where fighting has been particularly severe since the start of the war.

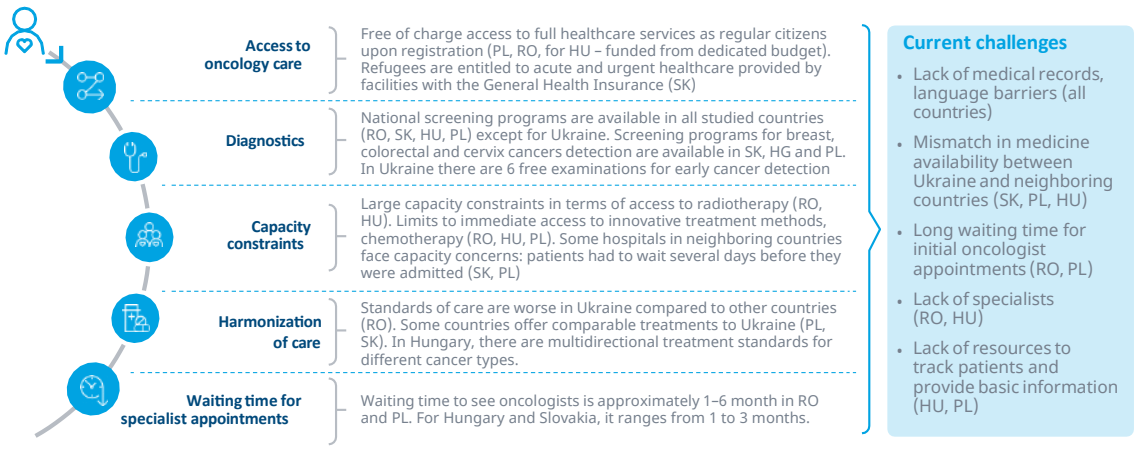
This clinic was still recruiting for patients, as of October 2022 with lung cancer being among the 10 therapeutic areas currently under investigation.[40] The clinic's research director Dr Olena Karpenko reports that since the war began, the clinic "did not stop its operations for more than a day", despite substantial changes to trial planning execution, including a careful monitoring of their medicine supply and an increased in the frequency of communication with sponsors.

THE WAR HALTED PROGRESS TOWARDS BETTER CANCER DETECTION PROGRAMS IN UKRAINE

While the human toll continues to grow, the collaborations to support Ukrainian patients and the healthcare system are unprecedented and continue to provide measurable support to Ukrainians throughout European countries. Interviews with medical experts indicated that most refugee-receiving countries are equipped with cancer screening capabilities for most forms of cancer, including breast, cervix and colorectal. Additional early detection programs are also planned for 2023-24 in Romania, Hungary and Poland, which are expected to further support Ukrainian cancer patients fleeing the war.

In contrast, Ukraine currently lacks a formal Strategic Cancer Plan. Existing programs for the early detection of oncological diseases (mammography, colonoscopy, hysteroscopy, gastroscopy, cystoscopy and bronchoscopy) lack a clear evidence base to support screening efficacy. As in many other countries, these programs were severely affected by the COVID-19 pandemic. This complicated the delivery of timely and accurate diagnoses of oncology patients by restricting access to healthcare facilities, forcing the postponement of planned interventions, and hampering preventive measures. As a result, there was a significant deterioration of existing services, with Ukrainian oncologists noting that in 2020 the proportion of cancers detected in the early stages was lower than before the pandemic.[41]

FIGURE 10: Status of cancer care in refugee-receiving countries and challenges ahead



Source: IQVIA EFPIA Oncology Platform: Assessment of the Oncology treatment and clinical trial landscape - Ukraine & 4 neighbouring countries. HU, Hungary; RO, Romania; PL, Poland; SK, Slovakia.

> The European Union is committed to overcoming key challenges associated with cancer treatment and diagnosis in Europe, as recently highlighted by the Commission's proposal for a revised Council Recommendation on Cancer Screening.

Ukrainian national health authorities have taken notable steps to solve these challenges. For instance, in 2020 Ukrainian officials launched an effective early screening program for breast cancer following consultations with the WHO and France.[42] Additionally, despite the lack of any pre-war formal cancer screening program in Ukraine, a healthcare reform was underway as directed by Parliament to strengthen primary care and improve earlier detection mechanisms.[43]

Despite these efforts, the war has led to a decline in the activity of cancer detection programs. As a result, any pre-war gain on cancer control will likely be lost until a new healthcare system can be rebuilt. In the upcoming years, Ukraine might face an increased number of undiagnosed patients in advanced stages of neoplasms, with significant downstream effects on civilian mortality and financial commitments. As the war continues, it remains unknown when structural reforms to the healthcare system can be expected to resume. The European Union is committed to overcoming key challenges associated with cancer treatment and diagnosis in Europe, as recently highlighted by the Commission's proposal for a revised Council Recommendation on Cancer Screening.[44]

Post-war cancer screening reforms in Ukraine should consider available frameworks in Europe to improve patients' chances of receiving treatment at the earliest possible opportunity.

ACTIONS TO SUPPORT PATIENTS NOW AND POST-WAR

The war in Ukraine will exacerbate the high cancer burden in the country by exposing vulnerable patients to infections, damaging critical medical infrastructures and impeding basic cancer care delivery to those who remain or return to the country. With an unknown duration for the war in Ukraine, this section discusses the immediate challenges that were raised by experts, as well as the strategic directions for post-war healthcare recovery. The focus is on the restoration of oncology services and patient care.

PRIORITY AREAS FOR UKRAINE

Ukraine's health authorities have started to respond to the most urgent needs of the population and health professionals. Based on what has been learned so far on the impact of the war on cancer patients, investments supporting the health system recovery in Ukraine should be focused around the following priorities:

- Collecting accurate data on the current and future cancer burden in Ukraine
- Removing organisational barriers to increase patients' access to therapeutic information (i.e. diagnosis, financing, radiotherapy, surgery, etc.)
- Rebuilding and expanding oncology capacity to meet rising demand
- Planning for the safe return of healthcare personnel
- Address critical psychological needs by expanding patient-centric services

FIGURE 11: Priority areas for Ukraine

PRIORITY AREAS	TIME TO IMPLEMENT	LOGISTICAL COMPLEXITY	COST
1. Collecting and analysing accurate data on the current and future cancer burden in Ukraine			
2. Removing organisational barriers to increase patients' access to therapeutic information (i.e., diagnosis, financing, radiotherapy, surgery, pathology)			
3. Planning for the safe return of healthcare personnel			
4. Address critical psychological needs by expanding patient-centric services			
5. Rebuilding and expanding oncology capacity and funding to meet the rising demand in treating both solid tumors and blood cancers			

1. COLLECTING ACCURATE DATA ON THE CURRENT AND FUTURE CANCER BURDEN IN UKRAINE

Adequate support requires a reliable estimate of the total number of cancer patients that are fleeing or have fled Ukraine. The United Nations (UN) noted that millions of Ukrainians have been displaced since the beginning of the war, but it remains unclear how many of them require cancer care.

Recent reports show that the refugee flux has slowed down. Data from the SAFER initiative, a humanitarian effort launched to support the safe passage of paediatric cancer patients out of Ukraine, indicates that 12 weeks after the war began, the volume of patients requesting evacuation decreased dramatically. As of September 2022, the team received one to two evacuation requests per week.[45] Changes in migratory patterns call for a reprioritisation of emergency responses and the implementation of tools to monitor the evolution of cancer care in Ukraine and neighbouring countries.

Despite widespread calls for them, the data captured by these tools remains incomplete.[46] Accurate data would allow governments and international organisations, including the WHO and charitable organizations, to secure appropriate financial protection mechanisms for patients returning to Ukraine.

2. REMOVING ORGANISATIONAL BARRIERS TO INCREASE PATIENTS' ACCESS TO THERAPEUTIC INFORMATION (I.E. DIAGNOSIS, TREATMENT, FINANCING)

Timely and appropriate health assistance for Ukrainian patients should consider pre-war public health shortcomings and devise strategies to overcome long-standing challenges in oncology care, including insufficient diagnostic capabilities and limited communication with patients. Problems linked to an underfunded health system are exacerbated by considerable organisational barriers which limit the amount of information available to cancer patients.

Before the war, hospitals or specialized cancer centers did not typically have websites or databases, making it impossible for physicians to provide timely and relevant information to patients on their treatment plans, costs or psychological services.[12] Although before the war, the Ukrainian government had made strides to modernise the health care system, COVID-19 and the ongoing war with Russia have significantly disrupted progress in this area.

Additional improvements should include launching pre-war agreed managed entry agreements (MEAs) and starting new ones to improve treatment access and outcomes.

3. PLANNING FOR THE SAFE RETURN OF HEALTHCARE PERSONNEL

Interviews with healthcare professionals by IQVIA revealed that no emergency plan was in place to ensure continuity of cancer care when the war broke out. As a consequence, the vast majority of healthcare professionals implemented improvised, organic approaches in the absence of central coordination.

Although oncology care in Ukraine is organised hierarchically, with the National Care Institute unifying diagnostics and treatment of oncology patients, the war forced oncologists to adapt to a rapidly changing environment. Physicians opened direct lines of communication with their patients via social media and private messaging channels to ensure a secure evacuation to neighbouring host countries and a safe and adequate transfer of care.[47] Hospital personnel was housed in hospitals to ensure safety and availability. Given the magnitude of the attacks on health infrastructures, the immediate priority should be to restore essential services, create a secure environment for healthcare professionals to return, expand tele-health capabilities and respond to new physical and mental health needs.

4. ADDRESS CRITICAL PSYCHOLOGICAL NEEDS BY EXPANDING PATIENT-CENTRIC SERVICES

Lack of family support, war-related psychological stress and financial losses represent additional problems that will require special consideration through the development of tailored, coordinated patient-support programs.

The number of mental health professionals available to patients in neighbouring countries is insufficient and linguistic barriers further undermine the successful delivery of psychological support services to those in need. Earlier this year, the European Commission recommended that member countries recognise the qualifications of Ukrainian professionals, allowing their rapid integration in their host country's health services.[48]

This measure has helped to deploy trained Ukrainian specialists among the refugee population to ease demand for mental health services. However, as the cancer burden shifts back to Ukraine in the aftermath of the war, meeting the psychological needs of patients returning to their homeland will require a fundamental restructuring of individual and public health services towards more patient- centric approaches. This implies, embedding disease-specific services with the development of tailored mental health and psychosocial support programs both at the national and local community level. These programs should be designed to satisfy the psychological needs of both individuals living with cancer and newly diagnosed patients, where the transition from a healthy individual to a cancer patient can cause additional stress.

5. REBUILDING AND EXPANDING ONCOLOGY CAPACITY AND FUNDING TO MEET THE RISING DEMAND IN TREATING BOTH SOLID TUMORS AND BLOOD CANCERS

In view of the projected rise in cancer diagnoses post-war, steps should be taken now to increase capacity and plan for enhanced provision of necessary medicines. Even before the war, healthcare expenditure in Ukraine was among the lowest in Europe. A rise in the level of hospital admissions, combined with attacks on key medical infrastructure and a fear of visiting the hospitals by the civilian population, will certainly contribute to the expanding backlog of patients, requiring a reprioritisation of healthcare in the country.

In anticipation of a reduction to humanitarian supplies, central procurement to cancer medicines should be expanded while new consideration should be given to medical supply lines and their resilience. Central to future recovery is enhancing screening and early cancer detection capabilities, monitoring health hazards and rebuilding specialized health services in liberated territories. Given the significant damage to medical infrastructure highlighted in this report, it will be of the utmost importance to restore cancer care services for Ukrainian patients returning to their homeland.

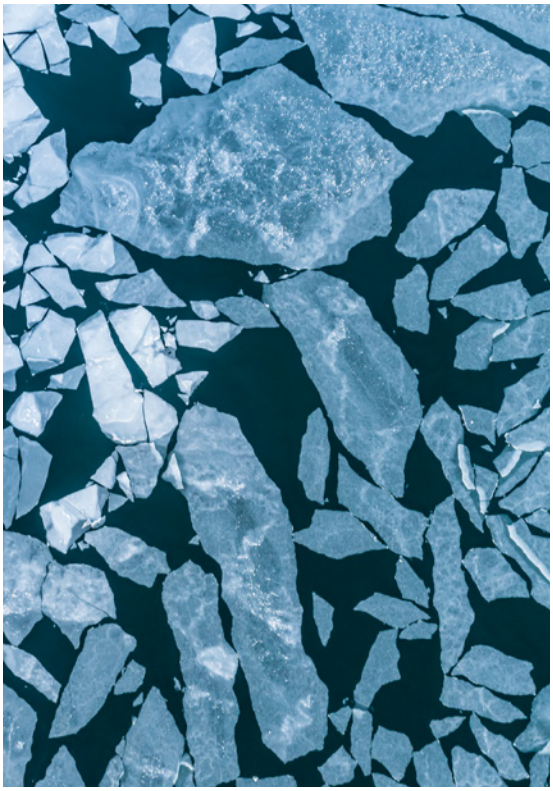
Central to this transition will be to systematically monitor and report attacks to key centres to ensure that disruptions to existing oncology networks are met with adequate financial commitments. This will also help to prepare for the return of health workers displaced by the war. Some of these priorities will require coordination with several countries and international agencies involved in relief efforts. The recent creation of a National Council for the

Restoration of Ukraine from the Consequences of the War (NCRUCW) represents a welcome initiative towards developing such coordinated approach. This approach should be aimed at aligning investments with the health reform that was already underway in Ukraine since 2017, as well as with future strategic ambitions, such as the European Union accession plan.

PRIORITY AREAS FOR EUROPE

Data on the impact of the war on the Ukrainian health system is in constant evolution, so the full measure of the impact on health infrastructure remains difficult to quantify. Given that the war is still ongoing, it remains unclear what shape the rebuilding phase will take and what level of assistance will be provided by organizations such as the WHO or the European Union. What is clear is that the healthcare system in Ukraine will need time to recover, especially in regions where oncology hospitals have been completely or partially destroyed. Priority areas for Europe include:

- Wider adoption of medicine conversion tools
- Targeted, community-level support to overcome language barriers for patients and HCPs
- Improving cross-border standardisation and availability of medical records to ensure continuity of care
- Introduction of oncology drugs to the EMA's Essential Main Therapy Group
- Accelerating transformation of the oncology sector via alignment with the EU's Beating Cancer plan



1. WIDER ADOPTION OF MEDICINE CONVERSION TOOLS

It is imperative that Ukrainian cancer patients currently treated abroad receive adequate care. Mismatches in drug availability between Ukraine and neighboring countries raise serious concerns about the ability of physicians to ensure continuity of care abroad. Language barriers further put patients at risk when they consume medicines. A potential solution to this involves leveraging new drug matching capabilities that have become available in response to the crisis. The Ukrainian Medicine conversion tool launched by IQVIA, in co-operation with Proxima Research International, helps to fill this gap by converting the name of medicines prescribed in Ukraine to equivalents in other European countries.[49] Wider adoption of this and similar tools, such as drug e-leaflets providing in-language information on Ukrainian medicines, can help to minimise delays to a patient's clinical pathway in the receiving country.

Earlier this year, EFPIA launched a tool allowing the Ukrainian patients displaced in the EU a rapid, direct, and free of charge access via their mobile phone to essential product information on prescription medicines, in their native language.[50] Efforts must be directed at raising awareness on these tools to ensure broad access to these services.

2. TARGETED, COMMUNITY-LEVEL SUPPORT TO OVERCOME LANGUAGE BARRIERS

Language barriers represent another key concern. Information about how to access medical care in another country is not always immediately available or readily translated in the native language. The EU should help to overcome this challenge by providing up-to-date, online resources with information on the actions needed to connect health services to the people who need them, creating ad-hoc e-learning resources for healthcare personnel receiving Ukrainian or other foreign patients, and expanding community-

level service delivery. Challenges may differ depending on each region: countries bordering Ukraine host the largest group of cancer patients and may need more targeted support in the form of welcome centers or wider participation of professional interpreters. Given the significant and pressing need for psychological support, wider availability of trained mental health professionals should also be given rapid attention.

European countries should employ and collaborate with oncologists who have left Ukraine to mitigate language barriers while ameliorating shortages of medical personnel in the most crowded centers.

3. IMPROVING CROSS-BORDER STANDARDIZATION AND AVAILABILITY OF MEDICAL RECORDS TO ENSURE CONTINUITY OF CARE

Technological barriers to the transfer of a patient's clinical records should be identified and removed to increase the speed with which cancer patients can receive treatment abroad. In 2019, Ukraine started to expand its technological capabilities in this area, when the country appointed its first Minster of Digital Transformation with the goal of providing all public services digitally by 2024.

Despite this, digitisation of medical records has been slow and mostly left to the private sector. In August 2022, Kyivstar, Ukraine's largest digital operator, announced plans to launch a new digital health service to enable the preparation of treatment plans, maintenance of patient medical records and data integration with pharmacy chains and laboratories.[51]

To foster interoperability of electronic medical records and ensure the continuity of healthcare for patients treated abroad, European countries should collaborate with Ukrainian health authorities in removing barriers to the secure transfer of patients' data in the full respect of the General Data Protection regulation (GDPR). Oncologists in receiving countries should communicate actively with their counterparts in Ukraine or other foreign counties to overcome gaps in information sharing and secure access to relevant patients' data.

Where digital records are available, efforts should be directed to allocate sufficient interpreting capabilities to ensure the rapid translation of sensitive data.

FIGURE 12: Priority areas for Europe

PRIORITY AREAS	TIME TO IMPLEMENT	LOGISTICAL COMPLEXITY	COST
1. Wider adoption of medicine conversion tools;			
2. Targeted, community-level support to overcome language barriers for patients and HCPs;			
3. Improving cross-border availability of medical records to ensure continuity of care;			
4. Introduction of oncology drugs to the EMA's Essential Main Therapy Group;			
5. Accelerating transformation of the Ukrainian oncology sector via alignment with the EU's Beating Cancer plan;			

4. INTRODUCTION OF ONCOLOGY DRUGS TO THE EMA'S ESSENTIAL MAIN THERAPY GROUP

Available intelligence from neighbouring countries suggest that most facilities involved in treating Ukrainian cancer patients face severe drug shortages. Given the alarming data on medicine supply shortages in neighbouring countries, immediate efforts must be made towards securing additional supplies of cancer medicines essential to standard care. In July 2022, the EMA adopted an Essential Main Therapy Group (MTG) list to ensure the preservation of critical medicine supply during emergency responses. However, the list makes no mention of oncology products. These products should be included in this list to expand the delivery of vital cancer medicines to Ukrainian patients and mitigate potential or actual shortages following major events, such as the ones unravelling in Ukraine at the time of writing. Close consideration should also be given to develop a framework for the rapid allocation of pan-European financial resources following major events or critical public health emergencies. This framework would strengthen the recommendations provided in the MTG list and enable their rapid implementation.

5. ACCELERATING TRANSFORMATION OF THE ONCOLOGY SECTOR VIA ALIGNMENT WITH THE EU'S BEATING CANCER PLAN

In recent years, Ukraine's health sector has been steadily deprioritized, compromising the country's ability to address pre-existing and future needs on its own. However, United24, an initiative launched by President Zelenskyy identifies health as one of the three areas to which charitable donations will be channeled. To accelerate the recovery of Ukraine's oncology network, donations should be aligned with the main directions of Ukraine's health reform, including the EU accession plan.

The EU accession process offers the opportunity to modernise and improve cancer care in Ukraine by aligning its tenets with the EU's Beating Cancer plan. Ukraine announced plans to improve the diagnosis and treatment of cancer in 2021, with the launch of the 'National Cancer Control Strategy until 2030'.

However, its adoption was suspended during the Conflict. Close collaboration with EU's health officials to facilitate the implementation of reforms that reflect the ambitious goals of this Strategy represent an opportunity to tackle structural caveats in cancer detection and care. Finally, plans to create a virtual European Cancer Patient Digital Centre (ECPDC) under the EU's Mission on Cancer could facilitate the exchange of patients and survivors' health data, with significant benefits for current and future displaced patients.[52]

OTHER PRIORITIES TO BE CONSIDERED

During the project other priorities were also raised, which require additional consideration:

1. Standardisation of emergency protocols among refugee-accepting countries while ensuring equivalent level of reimbursement
2. Increase access to professional support and bespoke intervention for HCPs and patients affected by post-traumatic stress disorder (PTSD)
3. Implementation of dedicated Patient Support Programs in Ukraine focusing on awareness campaigns, early screening and diagnostic, recovery programs
4. Enhancement of the European Health Emergency preparedness and Response Authority (HERA) initiative for Ukraine

DEFINITIONS AND METHODOLOGY

Collecting information during an ongoing war is complex and therefore multiple sources were used for this report, including observations from HCPs based in Ukraine. Specifically, the information included on the status of healthcare in Ukraine prior to the war was obtained through internal IQVIA databases, including MIDAS, and external sources including Proxima Research International.

The data refer to cancer epidemiology figures covering the period 2020-2021 in Ukraine. Comparable data for European countries is also available and was determined using additional sources indicated under References. Clinical research activity was determined by leveraging internal and external databases, including IQVIA MIDAS, Trialtrove and Global Patient Enrollment.

Information in relation to the impact of the war on Ukrainian oncology care was derived through a variety of methods, including dedicated workshops run by IQVIA in specified countries as well as expert interviews with KOLs and patient advocacy groups. In some cases, the information was provided in local languages and was then translated for this report. Medicine availability data describes the analysis of oncology treatments available in Ukraine and 6 other selected countries.

Data in connection to oncology screening programs, infrastructure damage, and recovery plans in Ukraine was collected by IQVIA. Additional information was added through publicly available sources referenced in the text.

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