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RAPID ANTIRETROVIRAL TREATMENT START SEEMS AS VITAL AND COST-EFFECTIVE STRATEGY IN CENTRAL AND EASTERN EUROPE

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ABSTRACT

BACKGROUND. It is essential to deliver specialist human immunodeficiency virus (HIV) care with maximum effectiveness, but also minimum time delay. Therefore, we aimed to determine whether rapid linkage to care defined as starting combined antiretroviral therapy (cART) on the day of the first visit at the HIV clinic is a cost-effective approach.
METHODS. In the analysis, Markov's lifetime model presented in our previous study was implemented. The inputs used in the model were updated in the terms of costs, life expectancy, and patient characteristics. For the analysis we used information from the previous model about the additional costs of treatment and quality-adjusted life years (QALYs) lost in the life horizon for people newly infected with HIV. The number of newly infected persons was estimated based on available data.
RESULTS. Input data was available for 344 men having sex with men (MSM) who registered in the HIV specialist care between 2016 and 2017. The estimated QALY loss due to lack of rapid treatment initiation, where the viral load is not (was) taken into account, equals 0·018 (0·022), 0·039 (0·047), 0·131 (0·158) respectively in low, medium and high risk transmission groups. Rapid cART initiation was dominant regardless of the chosen scenarios.
CONCLUSIONS. Cost-effectiveness analysis considering the HIV transmission indicates that the rapid initiation of HIV treatment is a cost-effective and potentially cost-saving approach to improve HIV care and reduce HIV transmission in Central and Eastern Europe.

Key words: *HIV, rapid treatment, antiretroviral therapy, transmission risk, Eastern Europe*

INTRODUCTION

The sustainability of already achieved progress in stopping human immunodeficiency virus (HIV), defined by 90-90-90 World Health Organization goal, was significantly endangered in times of SARS-CoV-2 epidemic (1-3). Thus, the rapid treatment initiation may be beneficial, as it limits the number of necessary visits and contacts. In addition, the rapid start of the treatment proved to be an effective method of linkage to care and is recommended by the IAS-USA, considering that there are many structural barriers that may prevent people from being immediately linked to care (4). In Central and Eastern Europe half of the physicians involved in HIV care were at the same time involved in the COVID-19 treatment (5). Taking into account that majority of newly registered cases in Poland occur through sexual contacts and mainly among men having sex with men (MSM) rapid initiation could contribute to decreasing infectivity of those patients who initiate treatment immediately.

Here we aimed to determine whether starting the combined antiretroviral therapy (rapid cART) on the first visit to the HIV clinic is a cost-effective approach for this region of Europe. In the analysis direct costs of cART therapy, most important comorbidities (AIDS-defining illness, non-AIDS-defining illness, and cardiovascular events), and cost of the treatment of new HIV infections from the public payer's perspective in 20-years horizon were included. Among incremental

outcomes number of sexual HIV transmissions, life years gained (LYGs) and quality-adjusted life years (QALYs) were calculated.

METHODS

Our analyses were performed to assess the potential benefits and costs in the population of men having sex with men (MSM) related to the treatment started immediately at the time of HIV diagnosis (0 day delay) compared to the standard treatment path. The treatment with cART in Poland was generally initiated approximately a month after HIV diagnosis (mean delay was 25,72 days based on data for 344 MSM patients).

For this study a new simple computational model in Microsoft Excel 365 was built to assess the cost-effectiveness of rapid cART treatment for newly diagnosed HIV-infected patients from the public payer's perspective. Considering the disease and compared treatment paths, it was decided that the effects and costs only in the period from diagnosis to cART start (possible benefits resulting from earlier treatment initiation in a long term perspective were omitted) will be taken into account. Because of the HIV treatment attributes and a short period of the treatment delay, the presented simplification should not cause any significant differences in the patient's state of health and precisely illustrates the incremental effect of compared paths of treatment (Figure 1). The above assumption considering that previously published papers suggested that delaying cART is associated with additional costs, could be considered as a conservative approach (6).

In our calculations we also used the lifetime Markov model built in Microsoft Excel 2013 with Visual Basic Application for the previous study (Kowalska 2017), which allowed us to perform cost-utility analysis and determine lost QALYs and additional costs for the payer for newly HIV infected patients (6).

The model has one-month cycles (from baseline patient's age of 33 up to a maximum of 100 years) and takes into account 33 events or illnesses divided into 18 health states and 8 additional events or diseases affecting estimated costs and the length of life. The baseline state of the model is an asymptomatic HIV, that is, the people with HIV who do not experience additional comorbidities. In each cycle of analysis, patients were distributed between health states with assigned corresponding probabilities. We made an assumption that after changing baseline health state it is not possible for a person to change their health state except for the case of death and that there is no possibility of the occurrence of the same event repeatedly and no possibility of having several diseases at the same time (Figure 2). Detailed information about used Markov model was described in the previous study Kowalska 2017 (6).

For the purposes of this analysis, the previously developed Markov model was also updated in terms of baseline characteristics of patients who registered in HIV specialist care between 1st January 2016 and 31st December 2017: mean CD4+ cells count, median HIV RNA, other features (Table 1), and costs. Thus, costs and lost benefits (QALYs, LYGs) in 20-years time horizon due to new HIV infection were taken from previously developed Markov model and used in new simple computational model. We chose to include data from real-life cohort collected in 2016 and 2017 as the most recent available data prior to COVID-19 pandemic, which significantly impacted reporting. At the same time no major change in the way HIV care was financed in Poland was noted, as well as no major changes in the HIV epidemic.

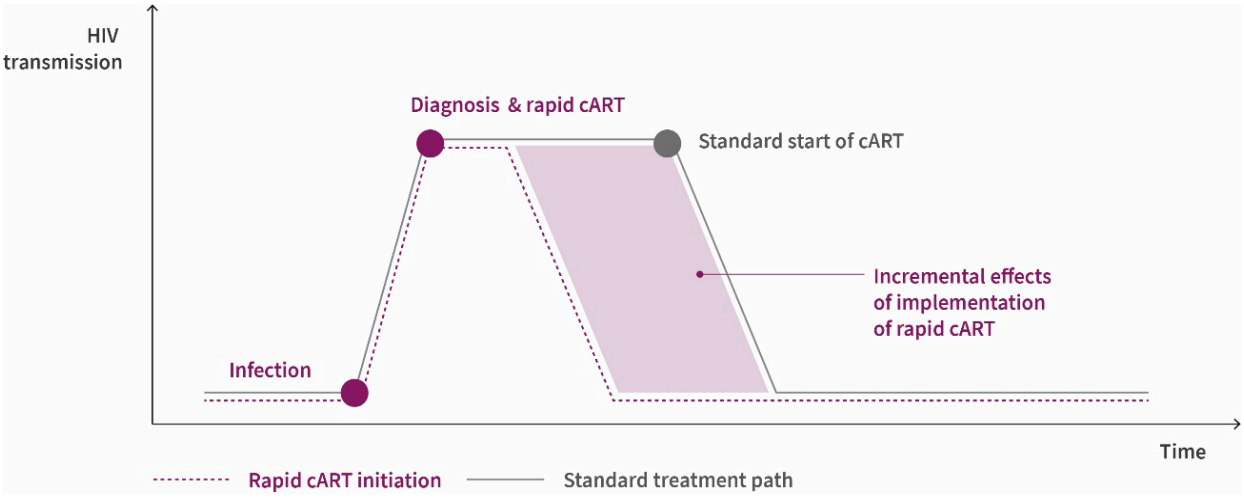

Figure 1. Simplified comparison of treatment pathways

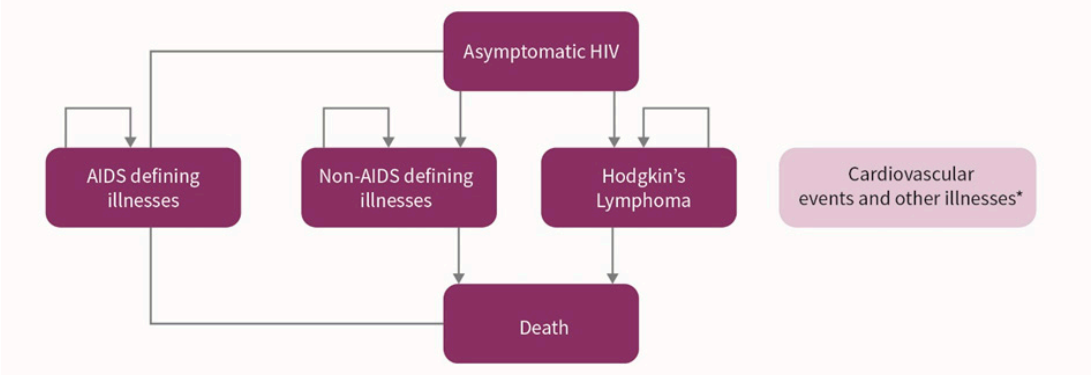

Figure 2. Markov model for HIV treatment
* They do not determine independent health states. Only additionally costs and deaths due to cardiovascular events and other illnesses were charged, regardless of the state of health in each cycle of analysis.

Table 1. Baseline characteristic of newly registered patients in routine medical care 2016-2017

Parameters	Value
CD4+ count	391 (209·6)
Patients with 1·70 – 3·54 log10 HIV RNA copies/ml (50 – 3 499 HIV RNA copies/ml)	32 (9·3%)[a]
Patients with 3·54– 4·00 log10 HIV RNA copies/ml (3 500 - 9999 HIV RNA copies/ml)	33 (9·6%)[a]
Patients with 4·00 – 4·70 log10 HIV RNA copies/ml (10 000 – 49 999 HIV RNA copies/ml)	99 (28·8 %)[a]
Patients with >4·70 log10 HIV RNA copies/ml (50 000+ HIV RNA copies/ml)	180 (52·3%)[a]
HIV RNA	4·72 (4·22 - 5·24)[b]
Age	33 (8·24)
Males pct.	100%[c]
MSM pct.	100%[c]

Mean and SD are presented for continuous variable
a) N and (n/N%), b) median (IQR), c) n/N %

Risk of HIV transmission per sexual act

At the first stage, the number of potentially avoided new HIV infections due to the rapid treatment implementation was estimated based on the literature review. To find necessary data on the risk of HIV transmission associated with sexual acts among MSM, a search in the Medline medical database (via Pubmed) was performed. During the search, attempts were made to identify only the most reliable studies, i.e., published meta-analyses for the population consistent with our analysis – MSM patients not yet treated with cART. Three publications were finally included in the analysis, Lasry 2014 (7), Patel 2014 (8) and Baggaley 2018 (9), in which the risk of transmission per sexual act (different for insertive and receptive anal sex) was found (Table 2). Due to the fact that the Baggaley 2018 study was published quite recently, in 2018, and that its significant part is included also in other reviews, we decided to use this data in the base case scenario of analysis. In addition, the results from the remaining reviews were included in a sensitivity analysis.

Time from diagnosis to cART start

Based on the data collected for MSM who registered in HIV specialist care, such as time of conducting the HIV-test, time of HIV diagnosis, and the start of cART treatment, the average and median time of a delay in access to the therapy were determined. The statistical analysis of survival curves for the time to the treatment start was conducted. In the final calculations, curves based on the generalized gamma distribution (main scenario) and Weibull distribution (sensitivity analysis) were selected as the best fit according to the AIC and BIC criteria (Figure 3).

Viral load and risk transmission

Identified studies clearly show that plasma viral load is directly associated with the risk of sexual transmission of HIV. Hence, the new simple computational model built for this analysis allows performing calculations for two different variants: 1. Excluding the impact of the viral load on the risk of HIV transmission and 2. Including the level of viremia.

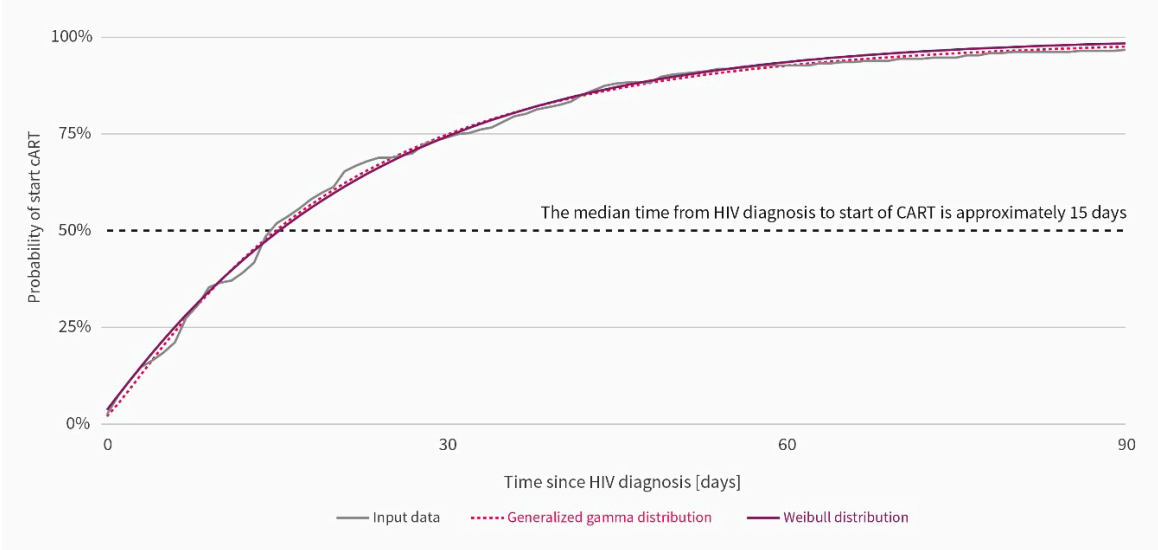

Figure 3. Time from diagnosis to cART treatment start

The baseline risk of HIV transmission adopted from the review was adjusted for HIV RNA viral load according to the Quinn 2000 (10) study. According to the estimation presented in this paper, each log increase in the viral load is associated with an increase of the transmission risk by a factor of 2·45.

At the first stage, the data for the cohort was stratified into five risk groups depending on the viral load (1·70 to 2·60, 2·60 to 3·54, 3·54 to 4·00, 4·00 to 4·70 and over 4.70 $\log_{10}$ HIV RNA copies/ml), as in the Quinn 2000 (10) publication. Based on this data, the average HIV RNA viral load in each of the five groups was also determined. In the end, due to the small size of the group with the viral load between 1·70 and 2·60 $\log_{10}$ HIV RNA copies/ mL (only 11 patients out of 344 patients in the cohort, 3%) it was decided to include them into the group of patients under 3·54 $\log_{10}$ copies HIV RNA copies. Then, the probability of HIV transmission was determined for each group based on the difference between the mean viral load in each group compared to the mean HIV viral load in the whole cohort and the data from the Quinn 2000 study. For example, in the group of patients with 1·70-3·54 $\log_{10}$ HIV RNA copies/mL, the average level of viremia was 2·77 $\log_{10}$ copies which was about 1·86 $\log_{10}$ copies/mL lower than the average viral load in the entire cohort. According to the data in the Quinn study, this difference is associated with more than 5-fold reduction of the risk of sexual transmission to 19% of the baseline risk from Baggaley 2018 (9) and others.

Ultimately, when the impact of the viral load on the risk of HIV transmission was included in our assessment, the probability of HIV transmission per insertive sexual act for patients with less than 3·54 $\log_{10}$ HIV RNA copies/mL was established at the

Table 2. Risk of HIV transmission when viral load is included

Baseline risk of HIV transmission per act		1·70 – 3·54 $\log_{10}$ copies/mL [2·27 $\log_{10}$ copies/mL 19% basic risk]	3·54 – 4·00 $\log_{10}$ copies/mL [mean 3·76 $\log_{10}$ copies/mL 46% basic risk]	4·00 – 4·70 $\log_{10}$ copies/mL [mean 4·40 $\log_{10}$ copies/mL 81% basic risk]	>4·70 $\log_{10}$ copies/mL [mean 5·25 $\log_{10}$ copies/mL 174% basic risk]
Insertive anal sex					
Lasry 2014[7]	0·62%	0·12%	0·28%	0·50%	1·08%
Patel 2014[8]	0·11%	0·02%	0·05%	0·09%	0·19%
Baggaley 2018[9]	0·17%	0·01%	0·03%	0·05%	0·10%
Receptive anal sex					
Lasry 2014[7]	1·40%	0·26%	0·64%	1·14%	2·44%
Patel 2014[8]	1·38%	0·26%	0·63%	1·12%	2·40%
Baggaley 2018[9]	1·25%	0·26%	0·64%	1·14%	2·44%

level of 0·01% compared to 0·17% reported in the Baggaley 2018 (9) study. Detailed information about the probabilities of new HIV infections per sexual act (different for insertive and receptive anal sex) for all stratified groups is presented in Table 2.

Sexual risk profiles

In our analysis HIV transmission was assumed to occur only through sexual contacts. The probability of infection was based on data found in published meta-analyses. Our calculation also takes into account the impact of condom use on the final risk of transmission.

Due to the methodology of the analysis and shown incremental effect of the immediate treatment start, the estimated number of new HIV infections relates to the period in which the patient is not receiving cART. Profiles of the risk of transmission were adopted in a similar way as in the previous study Kowalska 2017 (6), i.e, based on the average number of sexual partners, number of sexual acts, % frequency of condom use per act.

Additionally, we assumed that each patient from the analysed cohort had the same number of intercourses and had the same number of intercourses with each sexual partner. For the medium risk scenario, which was considered a baseline model, the rate of transmission was estimated assuming that an average HIV-positive person has 10 partners per year, 10 monthly sex acts, and 50% frequency of condom use per act. For the low and high risk scenarios, we assumed a person to have 3 and 50 partners per year, 10 and 20 sex acts per month, and 90% and 0% coverage with condom use, respectively.

In the analysis we also assumed that 28% of MSM patients have HIV+partners (this assumption reduces the total number of new potential infections) (6).

Costs and other data

For the purposes of this analysis, previously built Markov model was updated in terms of each health state representing different AIDS and Non-AIDS defining illness and the costs of cART treatment. The costs of cART treatment were adopted from the National Program of cART Treatment and expert opinion, and was EUR 482 per month (461 EUR drugs and 22 EUR monitoring treatment), while the cost of treating health states were adjusted based on the inflation rate between 2015 and 2019 published by the Central Statistical Office (11). The costs of HIV diagnosis were not included in the calculations. Additionally, data about patient mortality used in Markov model, i.e., life expectancy tables, was updated.

Additional costs related to the implementation of rapid cART were not included due to the flat-fee financing of Centers of HIV Treatment in Poland. In Polish conditions, HIV treatment Centers receive funds from a public payer as a lump sum (for treatment management) without information on the detailed distribution of these funds. Rapid initiation of HIV treatment could take place in Centers of HIV Treatment and from a payer's perspective would not be generate additional costs. Accordingly, the simplification approach should not have a significant impact on the results and conclusions.

RESULTS

Base Case scenario (scenario A1: Transmission risk with no adjustment for viral load level

In the base case scenario (scenario A1), which includes data from Baggaley 2018 (9), estimated avoided sexual HIV transmission rate within the rapid cART therapy ranged from 0·011 to 0·076 compared to receiving cART immediately later. A lower transmission rate due to rapid cART leads to an additional gain of QALYs and savings due to lower costs of the treatment associated with avoiding new infections. Estimated additional QALYs gained due to avoiding new HIV infections was from 0·018 to 0·131 depending on the risk profile (low, medium, and high). The additional treatment costs savings associated with the lack of new infections ranged from EUR 745 for the low risk profile to EUR 5 351 for the high risk profile.

Despite the additional costs of the treatment since a day of HIV diagnosis related to the implementation of rapid cART, this path was associated with savings for the public payer in the amount from EUR 331 to EUR 4 937 in a 20-year time horizon per 1 included patient.

Rapid cART therapy was found to be dominant (more effective and cost-saving) than the standard treatment path regardless of the risk profile (Table 3).

Scenario A2: transmission risk adjusted for the viral load level

Next, we carried out the analysis with the risk of MSM sexual HIV transmission adjusted for the level of HIV RNA viral load (scenario A2). In this case scenario (data from Baggaley 2018 (9) was used), the estimated averted sexual HIV transmission rate for rapid cART therapy was from 0·013 to 0·092 compared to receiving cART immediately later. A lower transmission rate due to rapid cART leads to additional gain of QALYs and savings due to lower costs of the treatment associated with avoiding new infections. Estimated additional QALYs gained due to avoiding new HIV infections was from 0·022 to 0·158 depending on the risk profile (low, medium, and high). The additional savings of the treatment costs associated with the lack of new infections ranged from

Table 3. Results of analysis

Analysis	Scenario	Risk profile	Fixed cost of rapid treatment [EUR]	Cost of cART treatment since day of diagnosis [EUR]	Cost of treatment new infections [EUR]	Total costs [EUR]	Sexual HIV transmission	LYG	QALY	ICER [EUR]
Incremental results / base case scenario	A1	Medium risk (Low risk / High Risk)	0 (0 / 0)	414 (414 / 414)	-1 601 (-745 / -5 351)	-1 188 (-331 / -4 937)	-0·023 (-0·011 / -0·076)	0·017 (0·008 / 0·056)	0·039 (0·018 / 0·131)	Rapid c-s (Rapid c-s / Rapid c-s)
	A2		0 (0 / 0)	414 (414 / 414)	-1 929 (-896 / -6 454)	-1 515 (-482 / -6 041)	-0·028 (-0·013 / -0·092)	0·020 (0·009 / 0·068)	0·047 (0·022 / 0·158)	Rapid c-s (Rapid c-s / Rapid c-s)
	A3		0 (0 / 0)	414 (414 / 414)	-303 (-141 / -1 011)	110 (272 / -597)	-0·004 (-0·002 / -0·014)	0·003 (0·001 / 0·011)	0·007 (0·003 / 0·025)	14 853 (78 490 / Rapid c-s)
Incremental results / sensitive analysis	S1		0 (0 / 0)	414 (414 / 414)	-1 623 (-755 / -5 423)	-1 209 (-341 / -5 009)	-0·023 (-0·011 / -0·077)	0·017 (0·008 / 0·057)	0·040 (0·019 / 0·133)	Rapid c-s (Rapid c-s / Rapid c-s)
	S2		0 (0 / 0)	414 (414 / 414)	-2 199 (-1 022 / -7 356)	-1 786 (-609 / -6 943)	-0·031 (-0·015 / -0·105)	0·023 (0·011 / 0·077)	0·054 (0·025 / 0·180)	Rapid c-s (Rapid c-s / Rapid c-s)
	S3		0 (0 / 0)	414 (414 / 414)	-1 863 (-866 / -6 234)	-1 450 (-452 / -5 820)	-0·028 (-0·013 / -0·093)	0.020 (0.010 / 0.069)	0·048 (0·022 / 0·160)	Rapid c-s (Rapid c-s / Rapid c-s)

Rapid c-s = Rapid cost-savings

Scenarios description: (1. Data for HIV transmission per act / 2. Population (HIV viral load) / 3. Distribution for curve of time from diagnosis to start cART / 4. Adjusting risk transmission for HIV viral load

Scenario A1: 1. Baggaley 2018 / 2. All patients / 3. Generalized gamma distribution / 4. No adjusted

Scenario A2: 1. Baggaley 2018 / 2. All patients / 3. Generalized gamma distribution / 4. Adjusted

Scenario A3: 1. Baggaley 2018 / 2. Patients with 1·70 – 3·54 log10 copies/ mL / 3. Generalized gamma distribution / Adjusted

Scenario S1: 1. Patel 2014 / 2. All patients / 3. Weibull distribution / 4. No adjusted

Scenario S2: 1. Lasry 2014 / 2. All patients / 3. Weibull distribution / 4. No adjusted

EUR 896 for the low risk profile to EUR 6 454 for the high risk profile.

Despite the additional costs of cART since a day of HIV diagnosis related to the implementation of rapid cART, this path was associated with savings for the public payer in the amount from EUR 482 to EUR 6 041 in a 20-year time horizon per 1 included patient. In case the transmission risk was adjusted for the viral load, estimated savings for the national payer were even higher than in the scenario when the viral load was not included.

Rapid cART therapy was found to be dominant (more effective and cost-savings) than the standard treatment path regardless of the risk profile (Table 3).

Scenario A3: patients with low level of viral load (1·70 - 3·54 $\log_{10}$ copies/mL)

In addition, within this analysis, calculations for a group of patients with a low level of viral load (50-3 499 copies) were conducted (scenario A3). The estimated avoided sexual HIV transmission rate within the rapid cART therapy was from 0·002 to 0·014 compared to receiving cART immediately later. A lower transmission rate due to rapid cART leads to an additional gain of QALYs and savings due to lower costs of the treatment associated with avoiding new infections. Estimated additional QALYs gained due to avoiding new HIV infections was from 0·003 to 0·025 depending on the risk profile (low, medium, and high). The additional treatment cost savings associated with the lack of new infections ranged from EUR 141 for the low risk profile to EUR 1 011 for the high risk profile.

The calculated total treatment costs of implementation of rapid cART for public payer were EUR 272 and EUR 110 for the low and medium risk profiles, respectively. This means that for a group of patients with both low viral load and low risk profile, rapid cART is not a cost-effective treatment path (ICER = 78 490 EUR while the actual cost-effectiveness threshold in Polish settings was set to about EUR 29 312). In the case of the medium risk profile, rapid cART is a cost-effective treatment path (ICER = 14 853 EUR), but not cost-saving as for high risk profile of patients (597 EUR savings for public payer per 1 included patient) (Table 3).

Sensitivity analyses

To test whether the model is solid and the inference is sensitive we have run the calculation with three additional scenarios using different data sources (Patel 2014 (8) and Lasry 2014 (7) for scenario S1 and scenario S2 respectively) and Weibull distribution (scenario S3). Regardless of the analysed scenario, the obtained results were similar to those presented in the base case scenario. When data for the risk of HIV transmission from the Patel 2014 (8) or Lasry 2014 (7) was used and a curve of time from a diagnosis to cART start was fitted to the Weibull distribution, rapid therapy was also found to be dominant (more effective and cost-saving) than the standard treatment path. The estimated savings for the public payer were from EUR 341 to EUR 5 009 and EUR 609 to EUR 6 943 in a 20-year time horizon per 1 included patient for Patel 2014 (8) and Lasry 2014 (7) data, respectively. If additionally, the effect of viral load was taken into account in the calculations (scenario S3), the savings for the public payer ranged from EUR 452 to EUR 5 820 (Table 3).

DISCUSSION

Rapid cART is a concept of starting treatment as soon as it is possible, preferably on the day of diagnosis, even if most of the laboratory tests results are not available (12). This approach is based on three main achievements of modern cART: developing antiretroviral medicine with minimal toxicity, proving their effectiveness irrespective of CD4 count or HIV viral load, and confirming that viral suppression protects HIV-negative sexual partners from acquiring (13-16). The most important effect of rapid cART is improved treatment uptake and greater viral suppression, as well as improved retention in care (17, 18). However this was well proven only for low and middle income countries, whereas adequate studies for high income countries with more complex healthcare systems are lacking (17). This is relevant in particular for Central and Eastern Europe, where most countries have more developed healthcare systems and are considered to be high income. At the same time linkage to care in this region remains unsatisfactory and an important obstacle in adapting WHO strategy, namely providing cART to 90% of those with diagnosed HIV infection (19-22). WHO has already recommended rapid cART start strategy in 2017 (23). Governments and scientific societies in Europe seem to be more reluctant in adapting bold strategies due to lack of proper evidence based on local population (24).

Here we present that implementation of rapid cART on a national scale generates health benefits, reduces the number of HIV infections, and is associated with additional savings for the payer in a 20-year time horizon. In addition, because of falling prices of cART drugs, related to the expiration of patent protection for some drugs, the initial cost of implementation of such a solution is increasingly lower. This should facilitate decision-making by the public payer.

Regarding the subgroup analyses, for most of them the introduction of rapid cART is a cost-effective or even a dominant intervention (cheaper and more

effective). Only in the population of people with low HIV viral load and low risk sexual behaviors, rapid cART may not be a cost-effective intervention from the public payer's point of view. To our best knowledge there is no other work from the region to compare to. The Rapid Initiation of Treatment (RapIT) randomized controlled trial evaluated an intervention that allowed patients in public sector clinics in Johannesburg, South Africa to have ARV medications dispensed on the day of their first HIV-related clinic visit. Comparison was to standard of care ART initiation, which typically required 3-5 additional clinic visits. The cost-effectiveness outcomes measures were: average cost per patient enrolled and per patient achieving the primary outcome of initiated ≤90 days and suppressed ≤10 months, and production cost per patient achieving primary outcome (=all costs/primary outcome patients). Costs were estimated from the provider perspective over the 10-month study period taking into account cost of all resources for care and treatment. Resources captured included drugs, laboratory tests, clinical staff time, buildings, equipment, general supplies, and other shared services, such as non-clinical staff. Same-day treatment initiation was more effective than standard initiation, more expensive per patient enrolled, and less expensive to produce a patient achieving the primary outcome (25).

There is a number of limitations that need to be considered while interpreting our data. Firstly, the results obtained in the group of patients with a very low viral load and low risk sexual behaviors, rapid cART probably may not be cost-effective. However, considering the data about the profile of HIV patients, the size of this group is very small and should not affect the results of the analysis. Moreover, rapid cART seems to be especially beneficial to those at the highest risk of acquiring HIV through sexual contact, namely MSM population, which due to changing trends in the HIV epidemic in Central and Eastern European region seems to be a key factor for HIV prevention (26).
It should be noted, that including the impact of HIV viral load on the final transmission risk was not the primary aim of this study. Our assumptions and calculations in this area are burdened by some uncertainties and limitations, thus, there is an additional area for exploration in the future. Regardless of whether rapid cART is a profitable intervention in the population with the lowest risk of HIV transmission, it should be noted that people with low HIV viremia at diagnosis accounts for less than 5-8% of those diagnosed with HIV and at least half of newly diagnosed people are presenting high risk behaviours (27).

The analysis included only the costs of additional cART treatment and the total costs of treating newly infected persons. We did not include other costs associated with adapting HIV treatment centers to implementation a new path of treatment or additional workload of medical staff due to the characteristics of the healthcare system in Poland. In Polish settings, other non-drug related costs in HIV treatment centers in Poland are financed on a flat-rate and it should not significantly affect the results of the analysis.

In summary, rapid cART is a cost-effective strategy for Poland, which could be also suitable for other countries from the Central and Eastern European region. In addition, in the time of the current COVID-19 pandemic, it provides a safer option by reducing the number of necessary personal visits in the clinic and improving linkage to care.

Declarations:

Ethics approval and consent to participate.: This study obtained ethical approval from the Bioethical Committee of the Medical University of Warsaw and a waiver for informed consent was granted (AKBE/99/16).

Consent for publication: All authors read and approved the final manuscript. All authors consent for publishing this work.

Availability of data and materials: The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests: All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript.

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