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COMPARISON OF ECONOMIC AND HEALTH IMPLICATIONS FROM EARLIER DETECTION OF HIV INFECTION IN THE UNITED KINGDOM AND POLAND

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ABSTRACT

PURPOSE. To model the financial and survival impact of early HIV infection detection versus late and compare results between the UK and Polish setting among the newly detected patients.
PATIENTS AND METHODS. A Microsoft Excel decision model (SUNRISE) was designed to generate a set of outcomes for a defined population. Survival was modelled on the COHERE study extrapolated to a 5-year horizon as a constant hazard. Hazard rates were specific to age, sex and whether detection was early or late. The primary outcomes for each year up to 5 years were: annual costs, numbers of infected cases, hospital admissions and surviving cases. Total population was observed in UK and Poland. ISPOR Budget Impact Model - Principles of Good Practice were utilised in SUNRISE development.
RESULTS. The projected cumulative cost-savings over 5 years in Poland and UK were 5,823,479 PLN (£1,109,234) and £21,608,562 respectfully. When including the value of life-years saved projected cumulative cost-savings in Poland and UK amounted to 8,374,018 PLN (£1,595,051) and £29,834,679 respectively. Savings were insensitive to transmission rates, but were sensitive in direct proportion to the percentage shift from late to early detection. In UK, savings were in higher proportion to Poland, due to much higher overall cost of HIV treatment (whether early or late HIV detected patient).
CONCLUSION. Estimated cost savings that could be translated into identification of appropriate programmes (providing wider coverage of HIV testing, awareness building) that would lead towards higher proportion of early HIV detected patients are very sensitive to the cost of HIV test and overall HIV treatment cost.

Keywords: HIV, testing, costs, savings, model, late detection

INTRODUCTION

In 2008, it was estimated that 30,000 people in Poland were infected with HIV (human immunodeficiency virus), with approximately 30.5% unaware of their condition.(1) In 2014, as many as 1,085 people were newly infected in Poland.(2) The estimated prevalence of HIV in Poland and UK (United Kingdom) was 0.8 and 1.5 per 1000 population (all age), with a greater proportion of infected males (1.3 and 3.7 per 1000) than females (0.3 and 1.9 per 1000) respectively (3,4).In 2013, it was estimated that 107,800 people in the United Kingdom (UK) were infected with HIV, with unchanged number of approximately 24% unaware of their condition (3).

A late diagnosis of HIV is the most important predictor of morbidity and short-term mortality in HIV infected individuals. A late HIV diagnosis is defined as a CD4 count <350 cells//µl within three months of an HIV diagnosis (3). It has been estimated that the difference in predicted life expectancy between early diagnosis (CD4 count 432 cells/µl) and late diagnosis (CD4 count 140 cells/µl) is 3.5 years (5). Other studies have confirmed that early detection and high CD4 counts can result in life expectancies similar to those of the general population (6,7). A direct benefit of early detection is that infected individuals can immediately start antiretroviral treatment (ART) if they meet the treatment initiation criterion, which in Poland is a CD4 cell count below 500 cells/µl and UK for primary infection was a CD4 cell count below 350 cells/µl and in case of co-infection over 500 cells/µl (8,9). Individuals diagnosed late with HIV are six times more likely to die of AIDS than those diagnosed earlier (10). Not only does early detection increase life expectancy, it also decreases

the annual cost of healthcare (11-13). There has been an overall trend in the UK towards earlier detection; in 2004 it was estimated that 57% of individuals were diagnosed late within three months of their diagnosis (CD4 cell count < 350 cells/μl), which had improved to only 42% by 2013 (3).

Both Polish and UK national guidelines on HIV testing reflect the need for earlier detection and intervention (9,14). Universal screening is recommended in genitourinary and sexual health clinics, antenatal services, termination of pregnancy services, drug dependency programmes and healthcare services for individuals diagnosed with tuberculosis, hepatitis B and C and lymphoma. In addition, the Polskie Towarzystwo Naukowe (PTN) and British HIV Association (BHIVA) guidelines state that where the HIV prevalence in the local population exceeds 2 per 1000 there should be screening for all persons registering in general practice and all general medical admissions, and that the test should be offered to all high risk groups (9,14).

Much of the evidence for the cost-effectiveness of screening comes from modelling studies in the United States (US), where the incremental cost-effectiveness ratio (ICER) for routine HIV testing in an inpatient setting was estimated at $38,600 per Quality-adjusted Life Year (QALY) gained, whilst testing every five years for high-risk patients in the outpatient setting cost $50,000-$57,000 per QALY gained (15,16). When other variables remained constant, estimated ICERs fell (i.e. became more favorable) as the prevalence of HIV infection increased. This provides an economic rationale for expanding universal screening programmes to all geographic areas where the prevalence exceeds a given threshold.

The economics of screening become even more favorable when indirect effects are taken into account (15). Early detection of HIV-positive status may reduce the rate of onward viral transmission, reducing the numbers of infected individuals and the consequent cost burden within the population at risk.

This decision model (SUNRISE) predicts the impact of implementing expanded testing on healthcare system costs and population survival over a 5-year time period. It illustrates these outcomes at the country level for Poland and UK.

MATERIAL AND METHODS

The model framework

SUNRISE is a Microsoft Windows-compatible computer program with a user-friendly, graphical interface. It was designed to estimate the potential budget and survival impact of implementing interventions to increase the uptake of HIV testing and achieving an increase in the proportion of cases that are detected early in a given population.

Other user input requirements are; population size split by age (< 50 years, ≥ 50 years), sex, the incidence of newly-detected HIV cases per annum and the proportion of early- and late-diagnosed patients receiving ART. Other input parameters are set at default values, though they may be altered by users to allow sensitivity analyses. These parameters include epidemiological assumptions to model survival and transmission; and the annual costs of HIV care contingent on disease status.

SUNRISE generates a set of outcomes for the defined population under the current and future scenarios. The primary outcomes are annual costs, numbers of newly HIV infected cases, hospital admissions and surviving cases, for each year to a maximum 5-year horizon. From these primary data, differential outcomes between scenarios are calculated: cost savings, infected cases avoided and deaths avoided.

Optionally, the model also allows users to input additional costs to support a fuller Polish NHF (National Health Fund) and UK NHS (National Health Service) payer perspective. This feature may be used to include assumptions about the costs of interventions that are expected to bring about the user-defined shift in late to early diagnosis. These investment costs are deducted from the savings in the overall cost impact calculation. The calculation of cost impact can optionally include a monetary valuation of survival; for example, £20,000 per life-year gained in UK and £7,000 in Poland (17). By monetising the flows of survival for each scenario, the net present value (NPV) of the intervention can be calculated; where NPV > 0, the decision rule would be to implement the intervention. The model does not explicitly allow for utility adjustment of survival. Alternatively, omitting a valuation of survival corresponds to a budget impact analysis. All flows of costs and survival are discounted to present values at 3.5% per annum (18-20).

Epidemiological assumptions and data

In 2013, percentage of 50+ age group of newly-detected patients was 7.7% and 16.3% in Poland and UK respectively.

Survival was modelled based upon the COHERE study(6) and extrapolated to a 5-year time horizon as a constant hazard. HIV detected population was divided into 8 categories: >200, 200-350, 350-500, >500 per μL, further by male or female for each early and late detected group, to derive average hazard rate per annum in each newly-diagnosed HIV early and late detected group, for male (M) or female (F), resulting in Poland with 0.45% (M), 0.29% (F) and 2.75% (M), 1.99% (F) and UK with 0.40% (M), 0.25% (F) and 2.52% (M), 1.83% (F) respectively.

SUNRISE observed population detected early or late, with CD4 cell count > 350/µl or < 350/µl, respectively.

Hazard rates were specific to age, sex and early or late detection, defined as at a CD4 cell count of > 350/µl or < 350/µl respectively. The constant per annum risk of death is r, with the expected survival after one year in a population of HIV newly-infected patients being:

$$S(t+1) = (1-r)S(t)$$

When expressed more generally, for a population of N patients infected with HIV, survival over time was represented by the hazard function:

$$S(t) = N(1-r)^t$$

Survival in years 1 to 5 is evaluated at the beginning of each year. Therefore, the specific structure of the equation becomes:

$$S(t) = N(1-r)^{t-1}$$

Accounting for gender differences in survival rates, the survival function becomes:

$$S(t) = N[\rho(1-r_M)^{t-1} + (1-\rho)(1-r_F)^{t-1}]$$

where subscripts M and F denote male and female respectively, t denotes time.

This framework allows modelling of the survival benefits associated with a given shift in the proportion of late and early diagnoses. The number of life-years gained over t years from a percentage point shift in the distribution is derived using the hazard rates associated with late and early HIV detection, respectively.

Based on literature review, it was assumed that older adults (≥ 50 years) diagnosed late have a 2.4 times greater risk of dying within a year of diagnosis than those diagnosed early, and that those diagnosed late were 14 times more likely to die within a year of diagnosis than those diagnosed early (21).

The assumptions that 7.7 and 16.3 % of all newly-diagnosed HIV infections occur in individuals aged over 50 years, and that 80% and 64% of these are in males in Poland and UK, respectively, were further considered in order to generate the survival probabilities in Table 1 (Panel A - Poland and Panel B - UK) (1,21,22).

Calculation results were validated against the study of life expectancy data from a cohort of recently diagnosed individuals in the Netherlands (7).

The assumed number of onward transmissions avoided per year per positive patient was 0.02773 (23). This value was the default for the transmission multiplier scalar, which represent rate of infection avoided if patient was early detected. It is utilized to account for new patients that were infected in a previous year.

Cost impact calculations

The annual cost is the sum of all categories of HIV clinical care from a payer perspective and includes inpatient, outpatient and day patient care, test procedures,

Tab I. Survival data by stage of presentation

A- Poland

	Age group: 15-49		Age group: 50+	
Year	S(t) Early	S(t) Late	S(t) Early	S(t) Late
1	100.00%	100.00%	100.00%	100.00%
2	99.61%	97.53%	99.17%	94.07%
3	99.21%	95.12%	98.36%	88.28%
4	98.82%	92.77%	97.57%	82.64%
5	98.43%	90.48%	96.80%	77.15%

B - UK

	Age group: 15-49		Age group: 50+	
Year	S(t) Early	S(t) Late	S(t) Early	S(t) Late
1	100.00%	100.00%	100.00%	100.00%
2	99.65%	97.73%	99.24%	94.55%
3	99.31%	95.51%	98.49%	89.22%
4	98.97%	93.34%	97.76%	84.02%
5	98.62%	91.22%	97.05%	78.94%

Table II Annual costs by category according to early versus late HIV diagnosis (Poland, 2013)

A Treatment costs in year 1 by diagnosis category

Cost category	Early detection	Late detection	Difference
Mean inpatient care	276.05 zl	2,484.41 zl.	2,208.36 zl
Mean outpatient care	2,701.28 zl	3,177.98 zl.	476.70 zl
Mean day patient costs*	0.00 zl	0.00 zl	0.00 zl
Average annual ART costs	1,050.00 zl	3,496.50 zl.	2,446.50 zl
Other drug costs	631.05 zl	1,786.05 zl.	1,155.00 zl
Tests & procedures	66.62 zl.	95.24 zl	28.61 zl
Total	4,725.00 z	11,040.17 zl	6,315.17 zl

* Polish system encompasses dayward clinics (day patient cost) under the outpatient care.cART ART ics (day patient cost) under the

B Treatment costs from year 2 onwards by diagnosis category

Cost category	Early detection	Late detection	Difference
Mean inpatient care	1,380.23 zl	2,760.45 zl	1,380.23 zl
Mean outpatient care	3,177.98 zl	3,177.98 zl	0.00 zl
Mean day patient costs*	0.00 zl	0.00 zl	0.00 zl
Average annual cART costs	2,625.00 zl	3,496.50 zl	871.50 zl
Other drug costs	948.68 zl	1,918.61 zl	969.94 zl
Tests & procedures	78.49 zl	99.23 zl	20.74 zl
Total	8,210.37 zl	11,452.77 zl	3,242.40 zl

* Polish system encompasses dayward clinics (day patient cost) under the outpatient care. cART – Combination Antiretroviral Therapy

costs of ART (based upon current NHF Poland and BHIVA guidelines) (8,24) and other drugs. Costs for these resource categories were taken from data collected by NHF Poland, MoH Poland and the National Prospective Monitoring System from 1996-2006 (11,12,24,25). In Poland, the average annual NHF cost of HIV patient included: ART treatment reimbursement cap per capita 3,500 PLN (£666), hospitalisation 13,802 PLN (£2,629), outpatient (ambulatory) care reimbursement cap per capita 3,178 PLN (£605), other drug cost ranging 948-1,918 PLN (£180-365), tests and procedures 63-95 PLN (£12-18) (Table 2A) (20,24,25). Therefore, the higher treatment costs reported with late stage detection are not the result of factors correlating with the timing of the HIV diagnosis, but rather reflect the independent effect of an early vs. late diagnosis after controlling for other confounding factors. ISPOR Budget Impact Model - Principles of Good Practice were followed during SUNRISE decision model development (26).

Settings and assumptions for analyses

There were 1098 HIV, 102 newly-detected AIDS cases and 61 deaths registered in 2013 in Poland. This equates to an estimated new HIV diagnosis rate of 0.29 per 10,000 population (27).

There were 6,000 HIV, 320 newly-detected AIDS cases and 530 deaths registered in 2013 in the UK. This equates to an estimated new HIV diagnosis rate of 1.0 per 10,000 population (2).

RESULTS

Figures 1 and 2 illustrate graphically the cumulative financial impact of achieving shifts to early diagnosis and its breakdown for Poland and UK, respectively. In each figure, the total savings under the future scenario (30% shift from late to early diagnosis, 2.773% transmission rate) is displayed. Figure 3 represents the impact in terms of number of avoided HIV individuals due to a 30% relative shift from late to early detection.

Poland

With 30% relative shift in HIV detection from 46% to 32.2% late detected HIV patients, over 5 years, would result in estimated direct NHF £1,438,050 (7,549,768 PLN), £1,326 (6,960 PLN) savings per infected person, 61 life years gained and 36 HIV infections avoided. If a broader societal perspective is used, monetizing life years saved, total savings would be £1,923,867 (10,100,303 PLN).

UK

In the UK, with 30% relative shift in HIV detection from 42% to 29.4% late detected HIV patients, over 5 years, would result in estimated direct NHS £21,608,562 savings, £3,471 savings per infected person, 411 life years gained and 212 HIV infections avoided. If a broader societal perspective is used, monetizing life years saved, total savings would be £29,834,679.

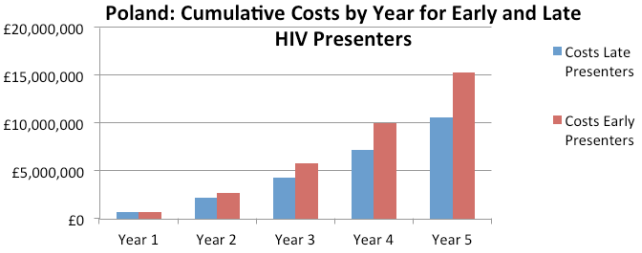
In both, Polish and UK setting, the direct savings were insensitive to the transmission rate within the 5-year analytic horizon, but were sensitive in direct proportion to the percentage shift from late to early diagnosis, such that savings would be more than tripled (333%), if a complete (100%) shift to early diagnosis were achieved.

DISCUSSION

Savings that could be achieved from earlier detection of HIV infection in different countries were estimated. The estimates critically depend on whether the assumed shifts in late to early detection actually occur. For the purposes of the analyses, we have assumed a 30% relative shift, reducing the national proportion of late diagnoses from approximately 42% to 29.4% in UK and 46% to 32.2% in Poland. This figure was chosen because 30% success might be viewed as the minimum plausible outcome for expanded testing programme to be considered. As the scenarios show, the main driver of cost savings is the shift actually achieved from late to early diagnosis: a 100% shift whereby all cases were diagnosed early would more than triple the savings.

The cost per test in three different Polish settings ranged £5,71-6.28 (30-33 PLN). These costs must be considered indicative only and it is conceivable that, once implemented, they could be reduced by economies of scale, scope and learning effects. Evidence is lacking

Panel A - Poland



Panel B – UK

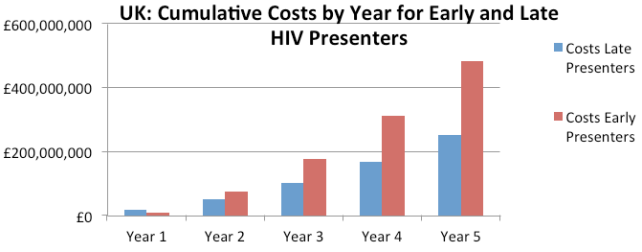


Fig I. Financial impact of future versus current scenario for Poland and UK

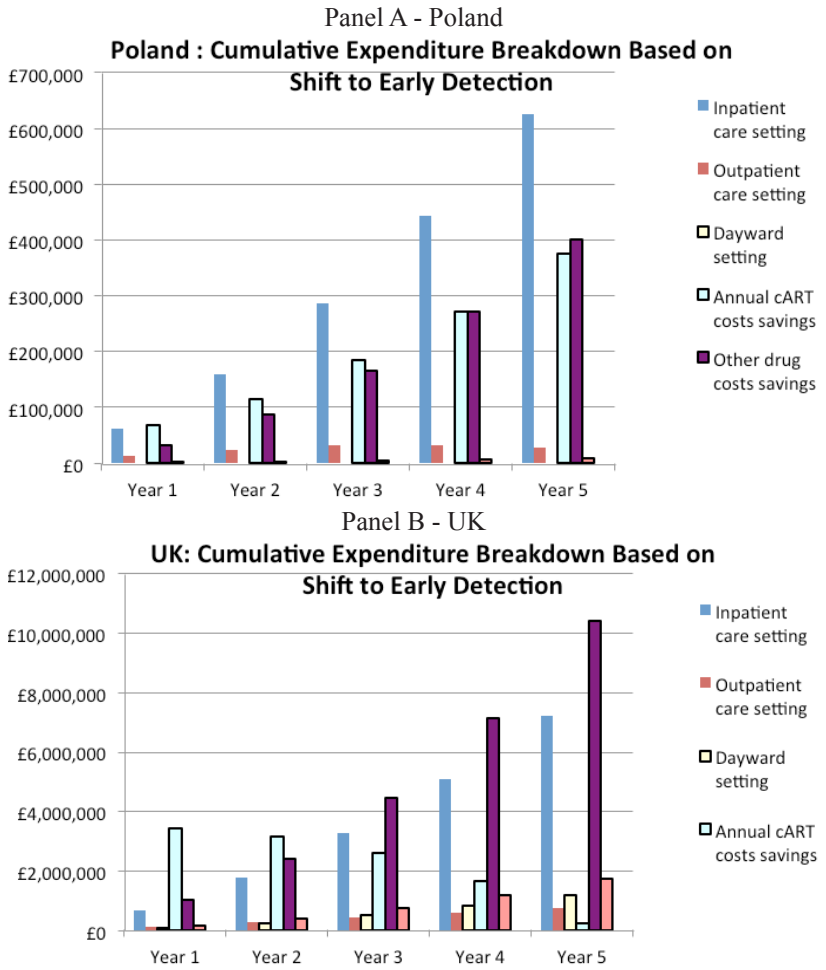


Fig II. Cumulative expenditure breakdown for Poland and UK

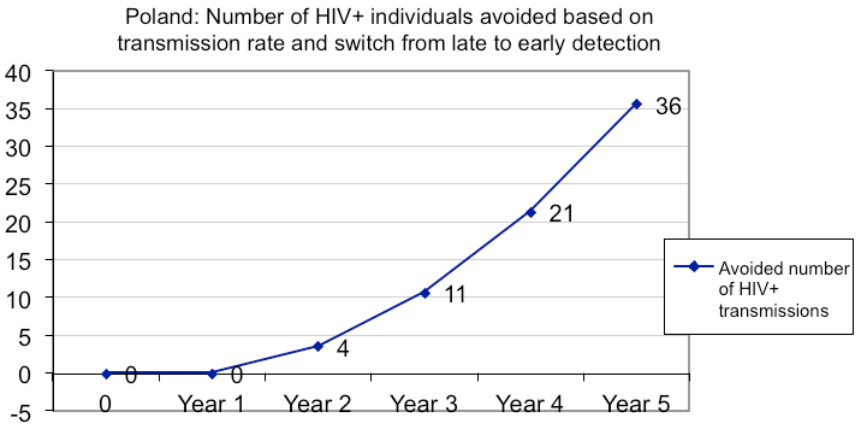
on the quantitative relationship linking the number of tests likely to be performed following a policy decision and the resulting shift to early detection. In Poland, 1,574,320 screening tests were performed nationally in 2013 with 0.6 HIV positive cases per 1,000, whereas excluding blood donors resulted in 2.7 per 1,000 (4). In the London and Leicester pilots, 7-11 cases were found per 1,000 tests administered, while in Brighton the pilots found fewer than 2 new cases per 1,000 tests, which seems surprisingly low for such a high-prevalence locality.

30% relative HIV detection shift to early-detection in Poland (from 54% to 67.8% early detected patients) resulted in instant 150 per year or 750 early-detected patients over the five-year span. If the NHF projected cost savings of £1,438,050 (7,549,764 PLN) are deployed to capture this 750 early-detected patients, this would require a detection of at least 1,630 all new HIV infected individuals, based on the premise that late-detected patients represent 46% of all newly-detected individuals; assuming a detection rate of 2 per 1,000, after 815,000 completed tests, with the required maximum cost per test of £1.76 (9.26 PLN), cost savings would be neutral. If we assume a detection rate of 3 per 1,000, the cost per test could rise to a maximum of £2.64 (13.89 PLN) for cost savings to remain neutral. With the value of life years saved, cost of the test could rise to a maximum of £2.36 (12.39 PLN) and £3.54 (18.59 PLN), respectively. The cost per test in three different Polish settings ranged £5.71-6.28 (30-33 PLN), thus additional investment would be needed for potential improvement in early HIV detection rate (28-30). However, in Poland with a current fixed annual reimbursement policy per capita for ambulatory care and HIV antiretroviral therapy, there are considerable patient out of pocket expenses which were not captured in this study, as only direct cost impact to NHF was considered.

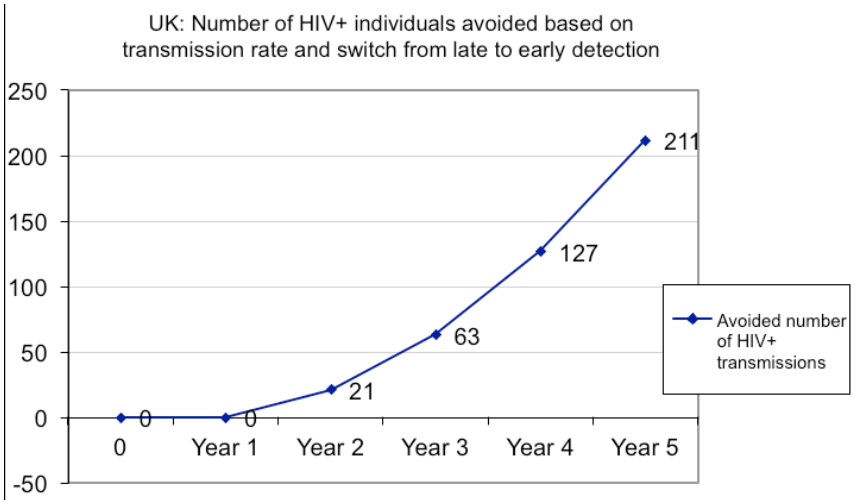
30% relative HIV detection shift to early-detection in the UK (from 58% to 70.6% early detected patients) resulted in instant 785 per year or 3923 early-detected patients over the five-year span. If the NHS projected cost savings of £21,608,562 are deployed to capture this 3923 early-detected patients, it would meant that it would require a detection of at least 9,350 new HIV infected individuals, based on the premise that late detected patients represent 42% of all newly-detected individuals; assuming a detection rate of 2 per 1,000, after 4,672,500 completed tests, with the required maximum cost per test of £4.62, cost savings would be neutral. If we assume a detection rate of 3 per 1,000,

Fig. III. Difference between future (30% shift towards early detection) versus current scenario for Poland and UK

Panel A - Poland



Panel B – UK



the cost per test could rise to a maximum of £6.93 for cost savings to remain neutral. With the value of life years saved, cost of the test could rise to a maximum of £6.20 and £9.29, respectively. Increase in number of HIV tests performed would probably lower the cost of actual HIV test, which would in return further add value towards cost neutral HIV testing in low and middle-prevalence settings.

The range of costs and benefits that are included in the economic calculation depend on the perspectives and attitudes of the decision-maker. For economic evaluations submitted to NICE and Polish HTA Agency, a formal cost-utility analysis is required. We did not formally utility-adjust survival in this study in the interests of avoiding complexity, but £7,000 in Poland and £20,000 in UK per life-year saved can be taken as a reasonable proxy for both Polish HTA Agency cost-utility threshold of £6,000 - £12,000 and NICE's stated cost-utility threshold of £20,000-£30,000 per QALY gained (31). If the utility of a year spent in asymptomatic HIV+ infection with CD4+ cell count between 200 and 500 cells/μL is 0.933 (32), a valuation of £20,000 per LY gained corresponds to £20,000/0.933, or approximately £21,350 per QALY gained. Economic evaluations submitted to NICE should consider all relevant NHS costs, measured over the full period of time that they accrue. The horizon of this study was limited to 5 years because any investment to hasten HIV detection is likely to have to be self-financing within a short timescale, as "new" money may not be available. Even though relatively few deaths occur in the 5-year timescale, the impact of valuing life-years saved at £20,000 per annum becomes substantial by year 5. In contrast, avoidance of onward HIV transmission has a smaller impact on costs over the 5-year timescale of this analysis, but this effect does compound to become more significant in a lifetime analysis.

This study has a number of limitations. The CD4 level of 350 cells/μL within 3 months of diagnosis as a threshold between early and late detected patients was utlised in both Poland and UK scenario. Even though, new guidelines have raised the threshold, the impact would probably be similar, as higher the CD4 level, the greater the proportion of late detected patients (e.g. <500 cells/μL), but at the same time smaller the gap in savings between late and early detected patient. The cost inputs were derived from the most comprehensive source available in the UK: the National Prospective

Table III. Annual costs by category according to early versus late HIV diagnosis (UK, 2013)

A Treatment costs in year 1 by diagnosis category

Cost category	Early detection	Late detection	Difference
Mean inpatient care	£156.89	£1,056.66	£899.77
Mean outpatient care	£470.28	£629.07	£158.79
Mean day patient costs	£126.75	£238.13	£111.38
Average annual cART costs	£200.00	£4,491.74	£4,291.74
Other drug costs	£968.29	£2,299.04	£1,330.74
Tests & procedures	£345.23	£575.14	£229.90
Total	£2,267.44	£9,289.78	£7,022.34

cART – Combination Antiretroviral Therapy

B Treatment costs from year 2 onwards by diagnosis category

Cost category	Early detection	Late detection	Difference
Mean inpatient care	£528.33	£1,125.60	£597.27
Mean outpatient care	£538.35	£595.74	£57.39
Mean day patient costs	£253.49	£380.24	£126.75
Average annual cART costs	£4,617.55	£4,491.74	-£125.81
Other drug costs	£1,476.03	£2,406.88	£930.85
Tests & procedures	£432.85	£593.86	£161.00
Total	£7,846.60	£9,594.06	£1,747.46

cART – Combination Antiretroviral Therapy

Monitoring System, which has been recording the care provided to HIV patients at 15 participating hospitals since 1996. The most recent UK data are from 2008, which were adjusted for inflation to 2013 costs. In the absence of costing based on late or early detection in Poland, ratio based on UK resource use between the two groups was further applied on the average 2013 cost of treatment components (inpatient, outpatient cost) in Poland to derive total cost of late or early detection in treatment-naive or treatment-experienced patient (25). Further cost adjustment was made due to Polish NHF annual reimbursement cap per capita for ambulatory care and antiretroviral drugs which are purchased using tender process. We used 2013 average PLN / £ (GBP) currency exchange rate of 5.25, however currency exchange rate is subject to fluctuation that may impact the results. As such, GBP currency was calculated based on actual PLN cost. In the absence of detection rate by CD4 cell count in Poland, UK rate was adjusted based on the percentage difference of newly-detected AIDS cases (Poland 9.3% vs UK 5.3%), which is a very conservative estimate of 46% vs 42% reported as late-detected HIV patients in Poland vs. UK, respectively. The rate of onward HIV transmission per HIV positive individual of 2.773% is a UK national average (23), which was assumed for Poland, as there was a small difference between two countries when comparing the ratio of newly detected patients to existing HIV patients (2,4). The actual figure is likely to vary between countries areas according to prevalence. In the absence of data, we performed sensitivity analyses around feasible ranges for this parameter. There was total of 36 and 211 new HIV infections avoided in Poland and UK over the five-year span, respectively (Figure 3). If the study horizon expanded from 5 to 10 or 15 years, there would be a great impact of onward transmissions, however payers are very hesitant to observe study results that expand beyond 5-year horizon.

CONCLUSIONS

Results of this study indicate that in the case of two financially different healthcare systems, shift from late to early HIV detection will create budgetary savings that could be re-directed towards HIV testing. However, re-directed funds on their own will not be enough, as the current cost per HIV test is above the estimated required cost for a breakeven point. Thus, either a cost drop per HIV test due to greater consumption or further additional investment will be required to achieve budget neutrality.

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Disclosure
The authors VZ and MT report no conflicts of interest in this work.

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