Integrating Hepatitis B Care and Treatment with Existing HIV Services is Possible: A Cost Minimization Analysis from a Low Resource Setting.

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Abstract

Background: In recent years there has been growing interest in exploring methods by which the care pathways for people with comorbid physical and health problems may be integrated. The success of such an integration however would depend on several factors including feasibility, acceptability and costs involved. Therefore, this report presents estimated provider costs associated with managing an integrated HBV and HIV clinical pathway for patients on life-long treatment in low resource setting in Uganda.

Methods: A cost minimisation analysis from the providers perspective was done by considering financial costs as a measure of the amount of money spent on resources used in the clinical pathways. The annual cost per patient was simulated based on total amount of resources spent for all the patient visits to the facility for HBV or HIV care per year.

Results: Findings showed that drugs and laboratory tests were the main drivers of costs in the pathways. A high-volume facility (Arua regional referral hospital- ARRH) had a higher cost per patient in both clinics than did the low volume facility (Koboko District Hospital- KDH). Variations occurred due to differences in the carders of health workers, the infrastructure, the amounts of consumables used in the facilities. Cost per HBV patient was $163.59 in ARRH and $145.76 in K DH while the cost per HIV patient was $176.52 in ARRH and $173.23 in KDH. The integration resulted into total saving of $36.73 per patient per year in Arua RRH and $17.5 in Koboko DH. The cost saving accrued from savings from personnel, fixed costs, consumables and utilities incurred in running the standalone Hepatitis B clinic and the reduction in per HIV patient costs from sharing of resources in the integrated pathway.

Conclusion: This analysis showed that the application of the integrated Pathway in HIV and HBV patient management could improve hospital cost efficiency compared to operating stand-alone clinics. This could further improve adherence to treatment by Hepatitis B patients and improve patient outcomes as HBV patients get access to counselling services.

1. Background

Hepatitis B virus (HBV) infection remains a major endemic public health problem with global burden of 257 million persons infected with 60 million of this in sub-Saharan Africa and causing 900,000 deaths annually (1). This is in contrasts with a global HIV burden of 38 million infected people with 690,000 deaths annually (2). According to the Uganda Population based HIV impact assessment survey approximately 4.1% of the population are estimated to have chronic infection (defined as presence of hepatitis B surface antigen), but there is significant regional variation, with a much higher prevalence of infection in the mid North of 4.6%, lowest in South Western region of 0.8%. (3)

In Uganda and likely other low resource settings standalone clinics for care and treatment of HIV and HBV have been established. The standard HIV care delivery structures serve broad, heterogeneous populations with easy to adopt, uniform procedures. The cost of standard HIV care delivery in Uganda has been declining over the years with the advent of less expensive ART medications and improved clinical operations (4) However, for HBV there are limited data on the costs of available healthcare delivery models partly because

the HBV clinics are poorly served with very limited local government funding compared to the relatively well funded HIV clinics, with funds from donor community. Despite the availability of now comprehensive guidelines on HBV testing, care and management for low-income settings from World Health Organization (WHO)(5) and from Ministry of Health (MOH) (6), there remains many challenges in implementation (7). A major impediment to effective implementation is that there are few examples or models of how to optimally deliver a simplified clinical care pathway (8), and how best to leverage existing health services and infrastructure (9). There is growing interest in exploring methods by which the care pathways for people with related comorbid health problems may be integrated, and in assessing the impact that any resulting changes have on both patient outcomes and costs to the healthcare system (10). When implemented in several common treatment clinics, integrated pathways have been reported to reduce costs and resource utilization(11).

The 2for1 study is a pilot project aimed at establishing a demonstration integrated HIV and HBV clinical care pathway in the West Nile region of Uganda. This study was conducted in Arua Regional Referral Hospital (ARRH), a high-volume facility and Koboko District Hospital (KDH), a low-volume facility. This pilot developed a model for a simplified care pathway across the entire continuum of HBV care (linkage to care, counselling, treatment assessment, treatment initiation, adherence support, monitoring and follow up) through integration with HIV care services. However, there is little resource implication evidence to support the use of an HIV and HBV integrated treatment pathway. Therefore to inform current resource allocation policies on accelerating and scaling up Hepatitis B care, we sought in this analysis to estimate provider costs incurred per patient per year in an integrated HBV and HIV clinical pathway for patients on life-long care and treatment.

2. Methods

A cost minimization analysis technique adopting the healthcare providers' point of view as at the time of data collection was conducted. This was done to illustrate the cost variations from the standalone pathways to the integrated clinical pathway. A model was developed to calculate total direct costs associated with managing patients in the standalone HBV and HIV clinics compared to the costs when the two clinics were merged and both HBV-mono-infected and HIV infected patients were seen through one clinical pathway.

2.1 Data collection

Data and relevant information was collected in two phases prospectively from the standalone and integrated pathways. In both facilities, we sought expert opinions from key staff who were purposively selected to provide information about the respective costing elements. These included: Medical superintendents, Hospital administrators, Nurses, Clinicians, Laboratory technicians and Accountants. This was done to ascertain types and, in some cases, amounts of on-site resources (e.g. clinic staff, staff salaries and benefits, medications recurring consumables and administrative costs). Costs for off-site resources (e.g. linkage officers, community out reaches, transportation costs) which were not directly linked to the pathway were not determined. In addition, we reviewed administrative records such as delivery notes, invoices, payment vouchers and budgets to ascertain staff salaries and allowances for support staff, costs of medications and laboratory tests, costs of consumables and utilities, costs of transportation and equipment. Finally, we

conducted time use surveys in each section of the pathway in both clinics before and during the integration to establish the proportion of total work time clinic staff spent providing care.

2.2 Description of the Clinical Pathways.

In both hospitals, we surveyed the standalone and the integrated clinics to determine patient flow in the clinical pathway. We mapped patient flow in the standard standalone clinics for both HBV and HIV clinics in both hospitals and then designed a standard integrated pathway incorporating HBV patients into HIV clinical pathway in each of the hospitals in accordance with the guidelines for HIV and HBV treatment.

2.3 Costing methodology

2.3.1 Costing Inputs.

The study captured only financial costs to measure the amount of money spent on a resource used in the running of the standalone and the integrated clinical pathway. These were inputs used in the delivery of services along the pathway that could be directly assigned to patients. We considered case-specific direct costs that were collected based on the services received by the patient along the pathway before and during the integration. For example, an HBV infected patient on treatment required services of the pharmacy whereas the one on monitoring did not. These inputs included: physical infrastructure used for client care; medical equipment; medical consumables and supplies used; laboratory testing; drugs; and staff time in caring for clients. Labor costs of administrative staff; overhead expenses (such as office supplies, communication, etc.), biosafety requirements and data management systems. There were no user fees involved. Patient costs on treatment in rural health centers, private transportation and indirect cost (such as cost of food, accompanying family members, lost labor time etc.) were not considered. Drug costs within the hospital were only considered when directly associated with HBV or HIV treatment regimen.

2.3.2 Cost data sources

Cost estimates were obtained from clinic inputs and procurement invoices. Additional information was obtained from budgetary documentation reviews, procurement guides, and publicly available product information. Expert opinion was sought from suppliers, implementing partners, local distributer and health workers. Previous costing studies within and outside Uganda were reviewed to validate some of the estimates (4). More cost data was obtained from the hospital administration and accounts department, implementing partners, available literature, expert opinion, National medical stores price catalogue and health facility records such as delivery notes, budgets and invoices among others.

2.3.3 Costing Approach

This study predominantly used activity based (bottom-up) approach except for some overheads where a top-down analysis was used (12). This costing approach was based on the concept that activities consume resources to produce an output. It measures the cost and performance of activities, resources and cost objects. Resources are assigned to activities, then activities are assigned to cost objects based on their use (13). In this study, the entire treatment process was divided into several activities at different sections of the pathway. We modelled the total annual costs per patient as a sum of the five cost categories: personnel, medications, laboratory testing, other recurrent costs (Utilities and consumables) and fixed costs along the clinical pathway.

2.3.4 Quantification and valuation of inputs.

Model inputs involved only health facility inputs. Project inputs from implementing partners such additional staff and top-up allowances provided to staff were excluded from the analysis in both facilities. Resources associated with the standalone and integrated pathways were measured through observation of standard operating procedures as health workers and supporting staff performed their duties in their respective sections within the pathway. Staff salary for example was allocated based on the time spent on the reference case as a proportion of monthly worktime. The useful life span of medical equipment used was considered according to the manufactures' instructions where possible or an estimated time period from expert opinion. Building space occupied was given an assumed expected lifetime of 30 years. All costs were estimated as of mid-year prices of 2020 and converted to US dollars using published Bank of Uganda exchange rates. The time horizon for cost analysis was one year and thus discounting for future costs was not done. A unit cost per patient per year was calculated by summing up the unit costs determined from each cost center in the pathway. We estimated per person per year (pppy) costs obtained as a sum total of the costs incurred for all clinic visits in one year. The model did not include long-term effects of missed appointments or unintentional delays in pathway. Sensitivity analysis done was majorly centered on the varying patients' numbers per month, the number of refill of visits per year and the frequency of monitoring laboratory tests done annually. These varied by patient condition as determined by the medical team from time to time. We also varied the costs of consumables because their values were majorly obtained from expert opinion and fluctuating market prices.

2.4 Costing assumptions

We assumed an average number of four visits per year for both HBV and HIV stable regular patients since the frequency of appointments varied based on patients' level of adherence, rate of missing appointments, viral load levels and distance to the facility among others. We assumed a male HBV/HIV mono-infected patient on first line treatment as a reference case in assigning the costs. In the cost minimisation analysis, we assumed equivalence in patient health outcomes for the standalone and the integrated pathways since the medications received by the patients was the same in both pathways. The study also assumed that all the overhead costs of infrastructure, laboratory tests, drug prescriptions, sample collection requirements and bio-safety requirements were equal for the standalone and integrated pathways in both facilities.

The useful life of the medical equipment was assumed to vary between 2 to 5 years and 20% of that use was allocated to HBV patients in the standalone clinics since the clinic used to operate one day a week (five working days) in both facilities. The useful life of the furniture in the clinics was assumed to vary between 5-10 years depending on the type and 100% of that use was allocated to patient use. We also assumed that the standalone clinics were independent of each other and that all patients from the HBV clinics were integrated into the existing HIV clinic structures.

3. Results

In the standalone pathways, an average of 1982 and 480 HIV clients were seen at Arua and Koboko ART clinics respectively. This number moved up to 2300 and 578 clients in Arua RRH and Koboko DH respectively during the integration period of 6 months due to the new cases enrolled on care. Similarly, HBV infected patients increased from 144 to 163 in Arua RRH and from 72 to 80 in Koboko DH, before and during the integration respectively.

3.1 Average Per Patient Per Year Costs (USD)

Table 1
Per patient per year costs in Arua RRH

	HBV patient cost (USD)			HIV patient cost (USD)		
Cost centre	**Standalone Pathway**	**Integrated Pathway**	**Change costs (%)**	**Standalone Pathway**	**Integrated Pathway**	**Change in costs (%)**
Personnel	28.40	13.76	-51.5	15.71	13.76	-12.4
Fixed costs	1.93	3.02	57.1	3.86	3.02	-21.7
Consumables and utilities	2.93	4.82	64.8	5.92	4.82	-18.6
Drugs	64.12	64.12	0.0	82.10	82.10	0.0
Lab tests	66.22	66.22	0.0	68.92	68.92	0.0
Total	163.59	151.95	-7.1	176.52	172.63	-2.2
Exchange rate 1USD=3700UGX						

The total cost per patient per year in a standalone Hepatitis B clinic and HIV clinic was $163.59 and $176.52 respectively. When integrated, the total cost per patient lowered to $151.95 and $172.63 per year for HBV and HIV patient respectively. Drugs, Laboratory tests and personnel costs were the main drivers of costs in both the standalone and integrated pathways.

There was an overall cost reduction of 7.1% per HBV patient shifting from the standalone ($163.59) to the integrated pathway ($151.95). The major cost variation occurred in personnel costs, fixed costs and consumables and utilities. There were no changes in costs of drugs and Laboratory tests before and during the integration. Personnel costs per patient reduced by 50.5% ($28.40 in the standalone to $13.76 in the

integrated pathway). This was because patients were being seen by lower cadre health workers such as clinical officers and nurses, contrary to the standalone pathway where all patient were seen directly by the physician

Similarly, the costs for consumables and utilities for HBV patients increased by 64.8% when integrated. This increase in costs is explained by an increase in amount of resources utilised in the integrated pathway, for example HBV patients were able to access services at the triage, health education at the waiting area and counselling. On the other hand, the overall cost per HIV patient reduced by 2.2% ($176.52 in the standalone to $172.63 in the integrated pathway. There were cost reductions in all the cost centres except for drugs and Lab tests that remained unchanged. Personnel costs reduced by 12.4%, Fixed costs by 21.7% and consumables and utilities by 18.6%. Cost reductions noticed in this analysis were due to sharing of resources in the integrated pathway by both HIV and HBV patients.

Table 2
Per patient per year costs in Koboko hospital

	HBV patient cost (USD)			HIV patient cost (USD)		
Cost Centre	**Standalone Pathway**	**Integrated Pathway**	**Change in cost (%)**	**Standalone Pathway**	**Integrated Pathway**	**Change in cost (%)**
Personnel	12.70	15.95	25.6	17.53	15.95	-9.0
Fixed costs	1.76	2.95	67.6	3.19	2.95	-7.3
Consumables and utilities	0.96	1.16	21.1	1.48	1.16	-21.9
Drugs	64.12	64.12	0.0	82.10	82.10	0.0
Lab tests	66.22	66.22	0.0	68.92	68.92	0.0
Total	145.76	150.40	3.2	173.23	171.09	-1.2
Exchange rate 1USD=3700UGX						

In Koboko hospital, the total cost per HBV patient per year in a standalone HBV and HIV clinical pathways was $145.76 and $173.23 respectively. Just like in Arua Hospital; drugs, laboratory tests and personnel costs were the main drivers of costs in both pathways. For an HBV patient, drugs accounted for 44% (standalone) and 42.6% (integrated); Lab tests contributed 45.4% (standalone) and 44% (integrated) while personnel costs accounted for 8.7% in the standalone and 10.6% in the integrated pathway. For a HIV patient, ARV costs accounted for 47.4% (standalone) and 48% (Integrated); Lab tests: 39.8% (standalone) and 40.3% (integrated); Personnel; 10.1% (standalone) and 9.3% (integrated). There was an overall cost increase of 3.2% per HBV patient shifting from the standalone ($145.76) to the integrated pathway ($150.4) due to increased number of services and resources used by patients in the integrated pathway. The main cost variations occurred in the personnel, fixed and costs for consumables and utilities. Personnel costs per patient increased by 25.6% and Fixed costs by 67.6% and the costs for consumables and utilities increased by 21.1%

following integration. On the other hand, overall cost per HIV patient reduced by 1.2% due to resource sharing among HBV and HIV patients in integrated pathway. There were cost reductions in all the cost centres except for the drugs and Lab tests that remained unchanged. Personnel costs reduced by 9%, Fixed costs by 7.3% and consumables and utilities by 21.9%.

3.2 HBV and HIV pathway Integration cost efficiency

The integration process the transfer of only patients from the Hepatitis B clinic to the HIV clinic. Therefore, initial cost savings were realised from Personnel costs, fixed costs and Consumables and utilities that were consumed in running the standalone clinic. Additional savings were appreciated in the integrated pathway primarily due to the sharing of resources.

Table 3
Annual Cost saving per patient following integration

Hospital	Patient	Standalone (USD)	Integrated (USD)	Savings (USD)
Arua RRH	HBV patient	32.84	0.00	32.84
	HIV patient	25.50	21.61	3.89
	Total cost saving			36.73
Koboko DH	HBV patient	15.36	0.00	15.36
	HIV patient	22.20	20.06	2.14
	Total cost saving			17.50

Results indicate that Arua RRH would register a cost saving of $32.84 from Personnel, fixed costs, consumables and utilities used to run the standalone HBV clinic. After integration of HBV patients into the HIV clinic, the cost per HIV patient reduced by $3.89. Thus, the integration resulted into total saving of $36.73 per patient per year. However, there was an overall increase in cost per HBV patient in Koboko that resulted from increase in service packages received by HBV patients in the integrated pathway. Koboko DH would have a total cost saving of $17.5 per patient per year accruing from savings from Personnel, fixed costs, consumables and utilities ($15.36 incurred in running the standalone HBV clinic, plus $2.14 from reduction in the cost per HIV patient).

3.3 Cost variation.

The major contributor to variation in per patient per year costs was number of scheduled appointments for refill visits for patients on treatment and review visits for HBV patients on monitoring. Clinic visits for HBV stable patients ranged from once a year to 6 times a year, while HIV stable patients had clinic visits ranging from twice to 6 times a year. Sensitivity analysis was done to determine the influence of refill visits on overall cost per patient per year.

Table 4
Annual Cost variation per patient.

		Arua RRH (USD)			Koboko DH (USD)		
Patient	**Pathway**	**Base value**	**Minimum Value**	**Maximum Value**	**Base value**	**Minimum Value**	**Maximum Value**
HBV patient	Standalone	163.59	74.53	246.44	145.76	68.98	219.28
	Integrated	151.95	71.75	228.43	150.40	71.16	226.25
HIV patient	Standalone	176.52	164.12	257.62	173.23	162.13	251.97
	Integrated	172.63	162.19	251.82	171.09	161.17	249.63

Table 4 shows that the major cost per patient variation was among HBV patients whose costs varied from $74.53 to $246.44 and $68.98-219.28 in Arua and Koboko hospitals respectively. Integration resulted in reduction of this variation by 15 units and 5 units per patient in Arua and Koboko hospitals respectively. Integration did not have any significant variation in the cost per HIV patient.

4. Discussion

The study found that the high-volume facility (Arua RRH) had a higher cost per patient in both clinics than did the lower volume facility (Koboko DH). Cost per HBV patient was $163.59 (Arua RRH) and $145.76 (Koboko DH) while the cost per HIV patient was $176.52 (Arua RRH) and $173.23 (Koboko Hospital). The total cost per patient estimates in this study fell within the ranges of per patient costs estimated in previous HIV studies(14) and slightly below other studies that used the societal perspective (4) (15) . Drug costs and laboratory tests were major contributors to patient care costs in the pathways (15).

The study found that integration of the HBV and HIV clinics resulted into cost reduction in cost per HBV patient in low volume facility and slight increase in the low volume facility. In Arua RRH, the total annual cost per HBV patient reduced by 7.1% ($11.66) and resulted in 2.2% ($3.89) reduction in total cost per HIV patient. In Koboko DH, cost per HBV patient increased by 3.2% ($4.64) and lowered by 1.2% ($2.14) per HIV patient. The lowering of costs demonstrates the evidence that integrated clinical pathways have the potential of achieving lesser costs while improving patient health outcomes(16)(17). Sharing of services (personnel, infrastructure, utilities, consumables and other services) in the integrated pathway resulted into the lowering of costs for HIV patients in both facilities. Variable costs changed proportionally with service units (the number of patients) while fixed costs did not change (18); For example the cost for equipment are fixed and do not increase if more patients are enrolled on care. Consequently, the average fixed cost per patient will decrease with a growing number as costs are distributed among more patients.

Since there was no integration of resources, findings indicate that integration was cost-efficient in both facilities. It resulted in total savings of $36.73 per patient per year in Arua RRH and $17.5 per patient per year in Koboko DH. Savings accrued from Personnel, fixed costs, consumables and utilities incurred in running the standalone HBV clinic and sharing of resources in the integrated HIV clinic. In the context of these facilities with fewer unstable patients for both HBV and HIV, and where most clients are stable on treatment, long term

costs of care will go down and the integrated model will, in the long run become more cost-efficient. This is possible since stable HBV clients return for review only once a year, with reduced need for frequent monitoring lab tests and health worker-time. In addition, the Ugandan health care system has both larger and smaller facilities, so our findings fit well into this context. This is particularly important as HIV service model has many years of experience and integration will further streamline processes for patient flow, and increase both the efficiency of health worker time and quality of services.

Given that we performed a cost-minimization analysis primarily, we did not explicitly quantify benefits. However, our analysis from the social perspective portrays positive gains from the integration to both HBV and HIV patients. From the patient perspective, HBV infected patients received HIV testing without additional costs and without additional blood draws or waiting time for results. They received health education on HIV risk reduction thus increasing their awareness about HIV prevention; their records were properly managed; there was quicker linkage to care and prompt follow up through the HIV established structures. HBV infected patients now have access to counselling services from experienced HIV counsellors. This will, in a long run improve adherence, reduce stigma and minimise loss to follow up as it has been reported among HIV infected patients (19). This explains why there was an increase in HBV per patient costs personnel, fixed costs, consumables and utilities with exception of Arua RRH where personnel costs reduced because stable HBV patients were no longer being seen by the physician. On the other hand, HIV infected patients benefited from the integration as they gained awareness about HBV and its prevention, minimized fear and reduced myths about HBV. The synergy brought by the integrated model will result in an overall improved community awareness and engagement for prevention of HBV. All these indicate that the integration resulted in improvement in quality of services received by both HBV and HIV patients.

These findings are however, limited by data perspective used in this study; the providers' perspective does not provide a holistic view of costs as would, the societal perspective (20) (21). In addition, the assumptions used in this study are only applicable as at the time of the study as costs and patient needs are constantly changing. Therefore, these findings should be interpreted based on the assumptions made relative to the time of the study.

Conclusion

The HIV and HBV integrated clinical pathway provides a streamlined standard of care for patients and ensures cost savings (22). This rigorous analysis has shown that the application of integrated Pathway in HIV and HBV patient management could improve hospital cost efficiency compared to operating separate clinics. This could further improve adherence to treatment by hepatitis B patients and improve patient outcomes (23). Given that the integration of HBV and HIV treatment into one pathway demonstrates a cost efficiency in both lower and higher-level facilities with functional structured HIV clinics, this model has significant potential for scalability to other facilities. The Ministry of Health and implementing partners could consider adopting this model based on its cost efficiency and additional social benefits that HBV patients access from the well-structured HIV clinical pathways.

Abbreviations

RRH: Regional Referral Hospital; ART: Antiretroviral Therapy; HBV: Hepatitis B virus; HIV:Human Immunodeficiency Viruses; DH: District Hospital; LFTS;Liver Function; RFTS: Renal Function Tests PPPY: Per Person Per Year; UNCST: Uganda National Council for Science and Technology; UNHLS: Uganda National Health Laboratory Services; SOMREC: School of Medicine Research Ethics committee.

Declarations

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DLE and JNM collected the data, performed the analysis and drafted the manuscript together with CW. ES, AJ, AK, PE, AM, BR, KM and PO extensively reviewed the manuscript and approved the final version.

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The authors declare that they have no competing interests.

Ethics statement:

The 2for1 Study was approved by School of Medicine Research Ethics committee (SOMREC) of Makerere University College of Health Sciences (approval code is REC REF 2018-185) and was also registered with Uganda National Council for Science and Technology-UNCST (approval code is Ref SS 4986). Study participants signed a written informed consent to participate

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