

# Out-of-pocket payments of End-stage Renal Disease Patients on Regular Hemodialysis: Cost of illness analysis, Experience from Sudan

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## Research article

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# Abstract

**Background** In Sudan, the number of End Stage Renal Disease (ESRD) patients receiving hemodialysis is growing. Patients and their families incur a high out of pocket expenditure provided that hemodialysis treatment is expensive. There is limited data about out of pocket spending on hemodialysis in the country. This study aims to explore patients' out-of-pocket expense on direct medical and non-medical goods and services and to which extent they can be predicted from socio-demographic characteristics, health insurance status, comorbidity, and accommodation change. **Methods** This is a cross-sectional descriptive study conducted in Ibn Sina Hospital. One hundred and thirty patients undergo regular two hemodialysis sessions were randomly selected. **Results** Among the study participants the median of the overall total out-of-pocket (direct medical and direct non- medical) spending per patient per year was found to be US\$ 3859.1 (Inter quartile Range(IQR): 2298.1- 6261.1). As for the medians out-of-pocket expenditure on direct medical and non-medical costs, they were found to be US\$2327.6 (IQR 1421.5-3804.8) and US\$ 1096 (IQR 715.2-2345.2), respectively. The direct medical expenditure (355586US\$) accounted for (60%) of the overall total expenses. Medications and investigations were the primary drivers of direct medical spending. Higher out-of-pocket expenditure rates were found among those with one or more of these merits; uninsured patients, Patient with comorbidity, female gender, and over 40 years age. The multivariate analysis showed that the significant predictors of direct medical expenditure were health insurance, comorbid conditions, while the predictors for direct non-medical expenditure were accommodation change and gender. **Conclusion** Results of this study provide a better understanding of out-of-pocket spending on direct medical and non-medial spending among hemodialysis patients within the context of Sudan. Furthermore, it provides descriptive information on patients' characteristics that are found to be associated with increased out of pocket expenditure among hemodialysis population. Further research needed in this area.

## Background

End Stage Renal Disease (ESRD) is a serious disease that has adverse health and economic burden (1-4). The treatment of ESRD is expensive, and the high cost of treatment has a substantial effect on patients, their families as well as the healthcare system (5-7). Patients with ESRD require Renal Replacement Therapy (RRT) to stay alive(8). The RRT involves two modalities, Dialysis; whether peritoneal dialysis (PD) or hemodialysis (HD) and Renal Transplantation(9). With RRT, HD is the preferred modality as compared to PD, particularly in African countries(10, 11).

Globally the number of patients with ESRD who receive HD is increasing. In 2004 a study revealed that the number of patients on dialysis is growing annually by 7% (7). In the same study, the global prevalence of patients treated by dialysis was estimated to be 190 patients per million population (PMP). In Africa, the prevalence was 65 PMP. Based on these statistics, the dialysis population was expected to exceed three million patients by the end of the year 2016. Glomerular diseases, hypertension, and diabetes mellitus are driving factors of ESRD cases (2, 12). In Sudan, hypertension is the leading cause of ESRD, followed by glomerular diseases and diabetes mellitus(13, 14). Variation exists between countries in the number of patients who treated with HD; for instance, in 2007 the numbers of HD patients in Sudan, Egypt, and South Africa were 2,750, 33,000, and 2,450 respectively(10). With rising numbers of HD patients, more patients and families need to spend out of their pockets. With a population of approximately 39 million distributed across Sudan's 18 states

(15)ESRD is a common health problem(10, 11, 13, 14, 16); however the true prevalence of ESRD is unknown. In total, there are 51 HD centers in Sudan, 21 being located in Khartoum state, including Ibn Sina Hospital Dialysis center that was established in 1985(11). ESRD patients on an average undergo two sessions of HD per week (16). Data from Sudan indicated that prevalence of ESRD patients increased from 90 PMP in 2009 (16)to 205 PMP in 2013 (Sudan National Center for Kidney Diseases and Surgery database).

In Sudan, HD related expenditures shared between the government, the patients, and patients' families (16). The government through the National Center for Kidney Diseases and Surgery is responsible for funding the HD centers' development and operational aspects such as staff salaries, and consumables (i.e., dialyzers, solution, and dialysis' lines). Out-of-pocket (OOP) expenditure has direct consequences for patients, their families, and the government, as they need to mobilize more resources; however, it has been shown to improve accessibility and availability of treatment (5, 6). In comparison to PD, the cost of HD is relatively less (10, 17). The OOP HD spending incurred by the patients and their families includes direct medical and direct non-medical expenditure, and they include payment made on consultations, lab tests, hospitalization, medication, transport, food, and accommodation change (18, 19). The indirect cost includes loss of working days, and in tangible cost such as pain, among others.

Furthermore, in Sudan, OOP HD spending may be difficult for patients and families to meet for numerous reasons. First, there is a high rate of unemployment among HD patients (13, 20). Secondly, HD treatment is usually long-term due to low renal transplantation rates (16). Thirdly the ESRD is generally associated with comorbid conditions (21) and that patients with comorbidities have higher expenses rates compared to their counterparts(22).In India, where governmental funds for dialysis are limited, patients incur high burdened with the cost of treatment and studies have shown that some patients discontinued treatment because they could not afford it(18, 23, 24).

A large proportion of the population of Sudan (46%) lives below the poverty line(25). Hence OOP HD expenditure accentuates the economic burden and financial hardships of patients and households. In 2013, the Gross Domestic Product (GDP) per capita was found to be US\$3,265 (25) in Sudan, and the OOP HD expenditure on health was estimated to be 78.9%(15) which is significantly high compared to other countries. In such a context, HD spending has many consequences ranging from the discontinuation of and non-compliance with HD treatment to the impoverishment of patients and households(23, 26). The majority of ESRD patients who undergo HD are enrolled in the Social health insurance scheme. However, patients need to pay or to share payments for some services. A study from China showed that insurance might not prevent patients from being impoverished (27). Available studies in Sudan have not explored OOP HD spending from patients' perspective, apart from a study that investigated the overall cost of HD(14). Therefore, this study aims to explore the OOP spending of HD patients on direct medical and non-medical expenditure and to predict OOP expenditure from their socio-demographic characteristics, comorbidity, insurance status, and accommodation change. The results of this study may reflect the suffering of the Patients and their families to be put into consideration and policy maker to set economics and non-economic mitigation polices.

## Methods

### Study design and setting

This study is across-sectional descriptive study conducted in Ibn Sina Hospital Dialysis Center. The Ibn Sinna is a tertiary Hospital in Khartoum State which is one of the renal transplantation centers. The dialysis center was established in the hospital in 1985(11). It receives ESRD patients from Khartoum State and other country states. The center had four HD shifts per day. Ibn Sina Dialysis Center provides HD treatment for more than two hundred and forty patients with different socio-demographic and health-related characteristics.

### **Study population**

The population of the study was the patients receiving HD treatment in Ibn Sinna Dialysis Center aged 18 years or more and who received two HD sessions per week during the study period (from October 2016 to April 2017). Patients receiving three HD sessions per week were excluded from this study.

### **Sample size and sampling technique**

The study sample was calculated using the single proportion formula. The proportion of 80%, which was the prevalence of HD among treated ESRD patients in Sudan in 2013(Sudan National Center for Kidney Diseases and Surgery database), was used in the calculation with an acceptable margin of error of 7% and a 95% confidence interval. The sample size obtained was 126 patients 3% was added to cater for the defaulters, giving a total sample size of 130 patients. A systematic sampling technique was used to reach the estimated sample size. After listing all the participants who received two HD sessions per week in Ibn Sina Dialysis Center, the first patient was chosen randomly then every second patient was selected and interviewed. Any patient who refused to participate in the study was substituted by the immediate next patient until the sample was completed.

### **Study tools**

A structured questionnaire was applied to collect the data from the study participants. The questionnaire was translated into Arabic because it is the mother tongue for all patients attending Ibn Sina Dialysis Center. Participants were asked about their socio-demographic characteristics such as age, gender, marital status, schooling, residence, working status, comorbidity, health insurance status and accommodation change. The participants were also questioned about OOP spending on direct medical (medication, investigation, vascular access and doctor visits) and direct non-medical (accommodation change, transportation, and meals) expenses. The investigations included laboratory tests and radiology tests expenditure. Prior to data collection, a pilot study was conducted to test the structured questionnaire, which was revised accordingly.

### **Statistical analysis**

Data one hundred and thirty participants were included in the final analysis. Version 21 of Statistical Package for the Social Sciences (SPSS) was used to analyze the data. Descriptive statistics (frequencies and proportions) were calculated. The median and interquartile range (Q1-Q3) was used to describe skewed variables. The explanatory variables included were socio-demographic characteristics, comorbidity conditions, and health insurance status, and accommodation change. These variables were dichotomized and coded as One and Zero. The outcome variables of this study were direct medical and direct non-medical HD expenditure over a period of one year. The direct medical and non-medical expenditure was computed and analyzed. For comparison, Sudanese currency (SDG) was converted to US dollars at the exchange rate of one US\$ equals 6.98S DGs(Central Bank of Sudan indicative exchange rate April 2017)

Normality of the outcome variables was assessed with the Shapiro-Wilk test, and it was found that data was not normally distributed ( $P \leq 0.001$ ) with skewing to the right. The Mann Whitney U test was used as a non-parametric test to explore whether there was a difference in direct medical and non-medical spending within each group of explanatory variables with an  $\alpha$ -value  $\leq 0.05$  level of significance. The effect size was computed for the difference between the groups.

Two hierarchical multiple regression models were conducted to predict the adjusted outcome from the explanatory variables, for the following model:

Due to technical limitations, Equation 1 has been placed in the Supplementary Files section.

Y : Is symbol use for dependent variable (expenses).

$\beta_1, \beta_2, \dots$  etc are co-efficient for independent variables.

$x_1, x_2, \dots$  etc are symbol use dependent variable (predictors of expenses).

$\epsilon$ : Error term.

A 95% confidence interval that did not include one and a value  $\leq 0.05$  were considered statistically significant.

## Results

Of the two hundred fifty-one patients receiving regular HD sessions in Ibn Sinna Dialysis Center, 130 patients were recruited for the study. The response rate was high (97%). Socio-demographic characteristics of the participants showed that more than two-thirds of the patients were aged 40 years or more and 88 (68%) were married. Of the participants, 79 (61%) were males and 86 (66%) lived in Khartoum State. A total of 31 respondents (24%) had experienced accommodation change, and 74 (57%) received schooling for more than eight years. Among the patients, 77 (59%) reported comorbidity conditions, and 87 (67%) had health insurance (Table 1).

Table 1 also shows the results of Mann Whitney U test for the difference in direct medical and non-medical expenditure in each of the two groups of age, gender, marital status, working status, residence, schooling, and comorbidity, health insurance status and accommodation change variables. The Mann Whitney test showed that spending in direct medical expenditure was greater for patients over the age of 40 years (Median = \$2507.7) than for patients aged 40 years or less (Median = \$1755.4),  $p = .032$ . Also the test showed a significant difference between female patients (Median = \$3529.7) and male patients (Median = \$1634.8),  $p = 0.001$ . OOP direct medical spending for health insured patients (Median = \$1634.7) was less than for those who did not have insurance (Median = \$4272.4),  $p = 0.001$ . Results also revealed that direct medical spending was significantly higher in the group of patients with comorbidity (Median = \$3157.9) in comparison to their counterparts (Median = \$1356);  $p = 0.001$ . No significant difference was found between groups of residence, schooling, and work status before and after HD.

The results showed a significant difference in OOP direct non-medical expenditure between the group of patients who reported the accommodation change (Median = \$3900.9) and the group who did not (Median =

\$854.5);  $p = 0.001$ . Also, the test revealed significantly higher spending among females (Median = \$2433.4) compared to males (Median = \$817.3);  $p = 0.001$ . The patients who did not work before dialysis (Median = \$2424.1) had higher spending than those who worked before (Median = \$2294.4),  $P = 0.03$ . Regarding OOP direct non-medical expenditure, there were no statistically significant findings for age groups, marital status, residence, schooling, and working status after starting the dialysis:

Table 2 shows the analysis of the annual direct medical and non-medical expenditure subset. OOP medication expenses accounted for 41% of total direct medical spending with a median per patient per year of US\$924.5 (574.3-1416.3). The median for investigations, doctor's visits, and vascular access were US\$743 (372-1400.3), US\$464 (248 - 743) and US\$232 (155 - 356), respectively. The direct non-medical expenditure spending accounts for 40% of the overall patients' OOP expenditure. The median for accommodation change per patient per year was found to be US\$3010.1 (IQR, 1598.3 -4664.4) and for transportation, it was US\$494.8 (IQR, 340.5-835.9). The home change expense represented 41% of the total direct non-medical expenditure.

Table 3 shows the results of the hierarchical multiple regression analysis for the direct medical expenditure. In the first step, age, gender, marital status, schooling, work status and residence were entered, and they explained 24% of the variance in the direct medical spending. Addition of the comorbidity and health insurance in the second step increased the explained variance by 37 percentage points ( $R^2 = 0.61$ ). The predicted direct medical spending, US\$3064.785, decreased by US\$ 1999.9 if there was Health insurance, increased by US\$ 808.9 with comorbidity, and was US\$ 517.1 less for males. All three variables were statistically significant predictors.

For direct non-medical, the socio-demographic variables mentioned before were entered in the first block, and they accounted for 27% of the variance. Adding accommodation change in the second block increased the explained variance in spending by 29 percentage points (Table 4). A significant regression model was found ( $F(6,123) = 25.6, p < .001$ ) with  $R^2$  of 0.57. The predicted direct non-medical expenditure was US\$ 1438.5, which increased by US\$2730.9 with a change of accommodation and was less by US\$567.5 for men. Both accommodation change and gender were significant predictors. Medical insurance was the most important contributor to direct medical costs (-54%), and home change was the most important in non-medical costs (+64%).

## Discussion

The analysis of OOP of HD spending showed that the annual direct medical and non-medical expenditure for the 130 patients was US\$ 594119.2 with a median of US\$ 3859.1 (2298.1-6261.1) per patient. The OOP direct medical spending per patient per year is much higher than direct non-medical expenditure. This finding is consistent with several other studies (5, 18, 19, 28). The median OOP expenditure on medication per patient per year was found to be US\$ 924.5 while the median for investigation was US\$ 743. A study from Brazil reported medication cost per patient per year at US\$ 9092 (19). OOP spending on investigation per patient in this study was much higher than that reported by a study conducted in Sudan in 2010 (29). The reason for this variation was the inclusion of radiological test-related expenses within the investigation expense. This spending may be hard for some patients to cover, partly because of the high unemployment rate among HD patients in Sudan

(13). Difficulty in covering the medication-related spending may push patients to non-adherence to their medication (26).

The results showed that the median of OOP direct medical expense was significantly higher in the female group of patients as compared to the male group. This finding is different from a previous study result conducted in India among HD patients where they found OOP expenditure to be higher among males than females (30). Furthermore, the study showed that the median OOP expenditure is significantly lower among insured patients (US\$1634.7) compared to those who are not covered by insurance (US\$4272.4). This variation is plausible due to the financial support and reimbursements health insurance schemes provide for investigations and medications related expenses, as compared to an uninsured patient who covers all fees and costs. Due to the cost uninsured patients are more likely to have unmet health needs(31). However, in Sudan, health insurance benefits are limited and so even insured patients turn to OOP payment schemes to cover the high cost of treatment.

With regards to comorbidities, results revealed that the median expenditure was significantly higher in the group of patients with comorbidities (US\$3157.9) in comparison to the group with no comorbidities (US\$ 1356). This result is consistent with a previous case-control study conducted in the United States that revealed patients in stage four chronic kidney disease who had comorbidity required more treatment and had higher costs than patients with no comorbidity (22). The patients with ESRD on dialysis usually have comorbidity(21), so they are more prone to hospitalization and have more medication than their counterparts.

Additionally, results showed that the OOP direct non-medical spending was 40% of total patients' spending. A study conducted by Suja A. et al., found that direct non-medical costs represented 19.6% of the total hemodialysis treatment cost including indirect costs (18).

Although 24% of the patients reported an accommodation change, their spending made up 41% of the total direct non-medical expenditure. Change in residency is often experienced by ESRD patients who reside in other states or live far from the dialysis center. The median out of pocket expenditure of those who reported accommodation change was US\$ 3901.0 compared to US\$ 854.5 as a median for those who did not move.

Our multivariate analysis findings identified health insurance status as a significant predictor of the direct medical cost. The OOP payments were lowest for those insured. A previous study has also documented that OOP medical spending is reduced with health insurance (32). Therefore it is essential to increase health insurance services coverage in Sudan to minimize patients' OOP medical spending. Also the results of the study indicate that there is a positive relationship between the OOP direct medical spending and comorbidity conditions. These findings agree with results from a past study that showed that the existence of comorbidity is a significant predictor of dialysis cost by adding additional costs (33). Hospitalization rates increase among dialysis patients with comorbid conditions (34).

Another predictor of OOP medical expense was gender. The OOP was lower for males compared to females. This result agreed with a study from other countries that showed that mean annual OOP spending with chronic conditions for a female was more than for a male (35).

Also, our multivariate analysis results identified changing accommodation and gender as significant predictors of OOP direct non-medical spending after controlling for other sociodemographic variables. The direct non-

medical spending increased with altering residence, presumably because changing accommodation adds more cost to the OOP spending. However, no study was found to reflect on that.

One possible limitation of this study is that estimates of OOP HD expenses made by patients may be subject to recall bias, although data collectors were trained to minimize the expected recall biases. Also, the study sample included only patients from Ibn Sinna Dialysis Center. It is probable that study findings may be different if a sample of diverse patients was taken from more than one dialysis center. Finally, there is assumption that inflation rate in Sudan may have influenced the results. We used the official currency exchange rate while in reality, the market value of the US\$ may be over three folds of the Central bank's official rate.

## Conclusions

We conclude that patients on regular HD have a high OOP HD spending compared to the GDP per capita in Sudan. The main OOP expenditure drivers were found to be medications, investigations and accommodation change. Gender, health insurance, and comorbidity were identified as significant predictors of direct medical expenses while accommodation change and gender are the significant predictors of the direct non-medical spending. Improving health insurance coverage of ESRD patients and expanding its benefits would help in reducing OOP HD spending. Furthermore, we recommend implementing an advocacy program among civic organizations to support HD patients. However, other factors may influence OOP HD spending in Sudan and so research to identify them is required.

## Abbreviations

ESRD	End Stage Renal Disease
GDP	Gross Domestic Product
HD	Hemodialysis
IQR	Interquartile range
OOP	Out-of-pocket
OOP HD	Out-of-pocket on Hemodialysis
PD	Peritoneal dialysis
PMP	Per Million Population
RRT	Renal Replacement Therapy
SDG	Sudanese currency
SPSS	Statistical Package for the Social Sciences (SPSS)
UNDP	United Nation Development Population
US\$	United Satate of America dollar
WHO	World Health Organization

## Declarations

- **Ethics approval and consent to participate**

Ethical clearance was obtained from Ibn Sina Research Unit and permission was received from the Dialysis Center Managerial department to interview the patients the informed consent was obtained from each participant after the purpose and information related to the study were explained.

- **Consent for publication**

Not applicable

- **Availability of data and material**

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

- **Competing interests**

We declare no competing interests for this study.

- **Funding**

This study did not received any fund from public, commercial and none profit bodies."

- **Authors contribution:**

Dr. Aisha contributed to topic conception, reviewed the literature, conducted the study, analyzed data, interpreted the results, and drafted the manuscript. Dr. Mousnad contributed to supervising and reviewing the study process and revised the manuscript. Dr. Almutaz contributed to the statistical analysis, result interpretations, writing the final paper. Dr. Elsamani revised the statistical analysis and finalized the final manuscript. The final manuscript was approved by all authors.

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## Tables

**Table 1 Mann Whitney U test comparing the difference of Direct Medical and None Medical spending in USD Dollar across socio-demographic characteristics, co-morbidity, and health insurance status (N=130)**

Variables		N (%)	Direct Medical expenditure			Direct None Medical expenditure		
			Median	U	Effect Size (r)	Median	U	Effect Size (r)
Age group	≤ 40 y	39 (30%)	1755.4	1351.5*	0.19	965.9	1642	0.06
	≥ 40 y	91(70%)	2507.7			1207.4		
Gender	Male	79 (61%)	1634.8	895**	0.47	817.4	720**	0.54
	Female	51(39%)	2322.9			2433.4		
Marital Status	Yes	88 (68%)	2498.5	1410*	0.19	975.2	1744	0.05
	No	42(32%)	1791			1198.1		
Residence	out Khartoum	44 (34%)	2294.4	1885.5	0.002	1133.1	1862	0.01
	In Khartoum	86 (66%)	2413			1086.7		
Schooling	≤ 8 y	56 (43%)	2322.9	1874	0.08	1058.8	1990	0.03
	≥ 8 y	74 (57%)	2380.8			1151.7		
Work before HD	Yes	68 (52%)	2294.4	1987.5	0.05	984.5	1646*	0.19
	No	62 (48%)	2424.1			1235.3		
Work After HD	Yes	16 (12%)	1772.1	742	0.11	1216.7	874	0.02
	No	114 (88%)	2339			1068.1		
Comorbidity	Yes	77 (59%)	3157.9	618.5**	0.59			
	No	53(41%)	1356					
Health Insurance	Yes	87 (67%)	1634.7	249**	0.70			
	No	43 (33%)	4272.4					
Home change	Yes	31(24%)				3901	184.5**	0.65
	No	99 (76%)				854.5		

\* P value > .05, \*\* P value > .001

<b>Expenditure</b>	<b># of patients</b>	<b>Median (IQR)</b>	<b>Sum</b>	<b>% of subtotal</b>	<b>% of overall total</b>
<b>Direct Medical spending</b>					
Medication	130	924.5 ( 574.3 - 1416.3)	146090.1	41%	25%
Investigation	130	743 (372 -1400.3)	127176.8	36%	21%
Doctor visit	130	464 (248 -743)	69216.1	19%	12%
Vascular access <sup>B</sup>	50	232 (155 - 356)	13103.3	4%	2%
Subtotal	130	2327.6 (1421.5-3804.8)	355586	100%	60%
<b>Direct Non-Medical spending</b>					
Transport	130	494.8 (340.5-835.9)	84661.8	36%	14%
Home Change	31	3010.1 (1598.3 -4664.4)	98555.6	41%	17%
Meal	130	371.2 (294.7 -554.3)	55315.2	23%	9%
Subtotal	130	1096(715.2-2345.2)	238533	100%	40%
Overall expenditure	130	3859.1(2298.1-6261.1)	594119.2		100%

<sup>B</sup>= Arteriovenous Fistula and catheter

IQR= Interquartile range

<b>Entered Variables</b>	<b>R<sup>2</sup></b>	<b>R<sup>2</sup> Change</b>	<b>F-change</b>	<b>B</b>	<b>SE</b>	<b>β</b>	<b>T estimate</b>	<b>P Value</b>	<b>95% CI for B</b>	
Socio demographic variables <sup>a</sup>	0.24	0.24	5.54					□ .001		
Health insurance and Comorbidity	0.61	0.37	56.80					□ .001		
Constant				3064.785	502.940		6.094	□ .001	2068.998	4060.572
Health insurance (Insured =1)				-1999.091	244.290	-0.54	-8.183	□ .001	-1515.415	-2482.768
Comorbidity (having Comorbidity=1)				807.913	227.878	0.23	3.545	□ .01	356.730	1259.096
Gender (Male =1)				-517.141	235.123	-0.15	-2.199	0.030	-982.668	-51.614

**a** = Marital status, age group, Residence, work status, schooling

**B** = Unstandardized Coefficients

**SE** = Std. Error

**β** = Standardized Coefficients

Table 4: Hierarchical Regression analysis for Direct None-Medical expenditure as the dependent variable and Socio-demographic characteristics, and home change as the independent variables

Entered Variables	R <sup>2</sup>	R <sup>2</sup> Change	F-change	B	SE	β	T estimate	P Value	95% CI for B	
Socio demographic variables <sup>a</sup>	0.27	0.27	9.01					0.001		
Home change (Yes =1)	0.57	0.29	97.80					0.001		
Constant				1438.485	332.127		4.331	0.001	781.061	2095.910
Home change (Yes =1)				2730.878	305.710	0.64	8.932	0.001	2125.110	3336.031
Gender (Male =1)				-567.470	282.306	-0.15	-2.010	0.050	-8.662	-1126.278

**a** = Marital status, age group, Residence, work status, schooling

**B** = Unstandardized Coefficients

**SE** = Std. Error

**β** = Standardized Coefficient

## Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [Equation1.png](#)