Background: A growing number of studies suggest that informal (illicit) fees for healthcare are prevalent in low and middle income countries. These fees are regressive and deeply embedded, often proving impervious to policy interventions.
Methods: The author conducted a critical interpretive synthesis of peer reviewed literature, grey literature, global standards, and donor funding related to informal fees in order to assess their prevalence, critically interrogate the paradigms that are applied to understanding them, assess to what extent fees are addressed in global policy and funding, and propose future areas for policy and research. In contrast to a systematic review, critical interpretive synthesis fosters cross-disciplinary research that encompasses quantitative, qualitative, and conceptual work. As such, it can open new avenues of discussion on persistent public health problems whose roots reach into the political, social, and cultural realms. Pursuant to established methods for critical interpretive synthesis, key terms were searched in databases and selected journals. Resources were added through an iterative process of developing new lines of enquiry from the initial papers identified, and obtaining resources identified in paper citations.
Findings: Patients and providers perceive informal fees on a continuum from gift giving to forced payment. The often disrespectful and coercive nature of fee requests undermines trust and future utilization, and perpetuates helplessness and disempowerment. Health system "hardware" drivers, such as low salaries, scarcity of health workers, and poor infrastructure are widely explored in the literature. "Software" drivers, such as values and norms, are less explored, except in a few qualitative investigations. Policy literature is dominated by rational choice approaches. While the prevalence of fees is well documented, maternal health strategies and donor policies acknowledge the relevance of all out of pocket fees (both formal and informal) with little — if any — attention to informal fees as such.
Interpretation: The empirical literature about informal fees is limited by the paradigms applied. Rational choice approaches ignore cultural and practical meanings. International standards and strategies reflect this limitation, presumably exacerbated by reluctance to describe illicit practices. Two trends in international health and development offer opportunities. First, the emerging quality agenda in global health could include informal fees. Second, the governance field is evolving to focus on addressing the function of informal practice, rather than resorting solely to regulation and incentives to end it. Critical interpretive synthesis insights on the function of informal fees — from expression of consumer power to resistance of the health system — illuminates possible interventions beyond simple prohibition or incentives. This study is notable for its examination of both public health literature and policy. However, all data regarding informal fees were secondary, the key limitation of this study.
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Abstract #: *01GMHE010*

Collection and use of human biological specimens in research: Is there adequate ethics governance in Africa?

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Background: Innovations in biotechnology and advances in the potential of research to produce life-saving discoveries have led to rapid escalation in genetic and genome-based studies in developing countries. This is particularly true in Sub-Saharan Africa (SSA), where many research protocols call for the collection, use, and storage of human biological specimens (HBS) and where major efforts to establish biorepositories are underway. International codes of ethics and regulatory guidance require that these initiatives be reviewed by ethics review committees in both the researchers' own institutions as well as local host countries. This study is part of a multi-phase study examining the extent to which regulatory frameworks at the national level in SSA exist to guide local ethics review of HBS-related protocols.
Methods: Two systematic reviews were undertaken in this study. The first involved a literature and web-based review of publicly accessible laws, codes, and procedures in each SSA country relating to its ethical governance of HBS-related research and biobanking. The second review identified active clinical trials in SSA calling for HBS collection and use. Data from these two sources were compared to determine if countries with high-volume HBS-related activity had ethics governance structures in place.
Findings: Of the 46 countries in SSA, 31 (67%) had publicly available ethics regulations, of which only 12 (38%) had regulations with language specific to HBS. Of these, guidance was provided on informed consent (11/92%), collection (8/67%), ownership (2/25%), reuse (8/67%), storage (10/83%), disposal (7/58%), and export (10/83%). As of September 2014, 314 of the 1529 registered clinical trials active in SSA involved HBS collection. Of the seven SSA countries that currently host the majority of HBS-related research, all had regulations on HBS, yet, of these, only 4 (57%) had regulations on reuse and only one contained guidance on ownership.
Interpretation: Viewed at a regional level, SSA does not yet possess capacity to take full advantage of HBS-related research while ensuring adequate protection for research subjects. With only 12 of 46 countries possessing publicly accessible guidance on the ethical conduct of HBS-related research and biobanking, the region as a whole still lacks the governance systems it needs to review and facilitate ethical, high-quality research of potential benefit to its populations. Findings from this study suggest that those countries in which the largest volume of HBS-related research is currently situated include those with adequate regulatory guidance in place to support local ethics review. Before research efforts can expand beyond these locations to other countries within SSA, however, ethics capacity-building to improve national governance of HBS-related research and biobanking is needed.
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Quality improvement of ward medicines management at a public sector hospital in the Southern Africa region

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Background: Equitable access to essential medical products, vaccines and technologies of assured quality, safety, efficacy and cost-effectiveness is one of the World Health Organisation's building blocks of a well-functioning health system. Pharmacists are trained as the custodians of medicines, to manage medicines selection, procurement, distribution and use, aimed at quality care and minimisation of waste. In most public sector hospitals in Southern Africa, pharmacists are primarily stationed in the pharmacy, with restricted medicines management involvement in the wards, limiting quality assurance of medicines used by in-patients. The study aimed to determine the role and impact of the active involvement of a pharmacist in the management of medicines at ward level in a public sector hospital in Southern Africa.
Methods: A 3-phased, operational, intervention study was implemented. A baseline assessment of medicines management practices in

two general paediatric wards and two general medical wards of an academic hospital was conducted using a 30-item practice indicator checklist, based on standards set by regulatory bodies (Phase 1). The checklist contained six focus areas, namely physical storage conditions, inventory management, medicines security, quality management, temperature monitoring and control, and record keeping. Shortcomings in medicines management practices were identified, a quality improvement plan (QIP) was developed and implemented as interventions in one paediatric and one general ward (experimental group) (Phase 2). A post-intervention assessment was conducted in Phase 3. Pre- and post-intervention scores for observed practice indicators were converted to percentage and compared for the experimental and control wards (Fisher's Exact test). Ethical clearance for the study was obtained from the University of Limpopo, Medunsa Campus Research and Ethics Committee and permission granted by hospital management prior to commencement.

Findings: Positive indicator scores at baseline (pre-intervention) ranged from 20% (6; n=30) to 40.0% (12; n=30) amongst the four wards. Phase 2 interventions included ward visits, introduction of ward-specific standard operating procedures, cycle counts and targeted formal and informal training for ward staff. Post-intervention scores amongst the four wards ranged from 20% (6; n=30) to 76.7% (23; n=30). Indicator scores for the two experimental wards improved from 36.7% and 26.7% at baseline, to 76.7% and 73.3% respectively in Phase 3. The change observed in the experimental wards (43.3%) and in the control wards (6.7%) post-intervention, was statistically significant ($p < 0.001$; Fisher's Exact test).

Interpretation: Shortcomings in the management of medicines at ward level were identified and addressed with subsequent improvement in medicines' management practices. Future, continuous involvement of a pharmacist in ward medicines management practices will be required to sustain the impact of the intervention and will benefit quality assurance in public sector hospitals.

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Cost effectiveness analysis of couples voluntary counseling and testing (CVCT), long acting reversible contraceptives (LARC) and couples family planning and counseling (CFPC) programs in Zambia

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Program/Project Purpose: Zambia Emory HIV Research Program (ZEHRP) has spent the last 20 years in Zambia building CVCT capacity by offering these services and conducting trainings for counselors. To address Zambia's high total fertility rate and high HIV infection rate, ZEHRP has integrated CVCT with LARC provision and CFPC. The aim of this analysis was to show net cost savings of the integrated programs in Zambia and to ultimately encourage government to create policies that would fund CVCT and LARC in Zambia universally. The project was conducted over ten weeks between May 2014 and July 2014 and data analysis completed in Atlanta, Georgia at the parent site Rwanda Zambia HIV Research Group (RZHRG).

Structure/Method/Design: Costs were determined using a mixed methods approach. Interviews were conducted with 25 program and administrative staff to understand procurement of resources and staff perceptions of value for money. Historical cost data from ACCPAC was assigned to different aspects of the program using a micro-costing approach. Data was analyzed using a sensitivity analysis in excel to understand where there was greatest uncertainty. Cost data was then compared to staff interviews to determine recommendations for the organization. Recommendations specified reducing cost through behavior change within the organization and strategic planning of trainings to maintain sustainability.

Outcomes & Evaluation: A major cost driver was months with rural LARC trainings overlapping with CVCT trainings straining the organization's resources. It was recommended that procurement officers at each site take active part in early training planning to ensure best procurement practices (competitive bidding, accurate budgeting etc.) and to focus on building demand for LARC and CVCT services to reduce fuel and transport costs during trainings. We developed 8 value for money indicators to track program outcomes and costs.

Going Forward: Historical cost data is currently being analyzed using TreeAge software to determine the Incremental Cost Effectiveness Ratio by building a decision tree model. Currently, developing a decision tree model where two outcomes (HIV infections averted, unwanted pregnancies averted) are assessed using a single program is a challenge. Year three budgets will be based on this modeling and reported to the grantee. This program will be used as a model for other combined CVCT, LARC and CFPC programs in Sub-Saharan Africa.

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