A CASE CONTROL STUDY OF FACTORS INFLUENCING CARE SEEKING FOR MALARIA IN CHEMICAL SHOPS INVOLVED IN THE DANGME WEST CLUSTER RANDOMIZED TRIAL OFVRAPID DIAGNOSTIC TESTS FOR MALARIA (Dangme CommRDT Study)

Background

Malaria remains a significant and leading cause of outpatient visits and health facility-associated deaths in Ghana. The main strategy for malaria control in Ghana is prompt delivery of effective treatment for every case of uncomplicated malaria.

In many African countries, self-treatment with drugs from shops and chemical sellers is reported widely and ranges from 4-87% of cases[i] [ii] [iii]. It is well recognized that the majority of children and pregnant women with malaria do not access formal health care[iv].

Many studies have acknowledged the important role drug retailers at community level and as such have developed interventions to improve the delivery of appropriate malaria treatments through these retailers[v] [vi]**.** In addition, some studies have shown that making even partially efficacious malaria treatments available closer to home has been associated with measurable reductions in severe malaria morbidity and overall child mortality[vii] [viii]. As malaria-endemic countries in Africa begin to adopt new treatment policies based on artemisinin-containing antimalarial drugs, defining clearly, the role for private sector drug retailers has become even more imperative[ix].

Rationale

Even though a number of studies have documented the role that drug stores can play in care-seeking behaviour[x] [xi] [xii], relatively little is known about the factors that influence care seeking from these drug retail outlets. Very few studies have provided information on the determinants of utilization of the private sector as against formal care. Where these have been carried out, they have been conducted in areas where rapid diagnostic tests for malaria were unavailable in the chemical shops.

The on-going cluster randomized trial is looking at the role of malaria rapid diagnostic tests (mRDTs) for targeting of ACTs at community level. There is however no information about those who choose to use the services of these chemical sellers instead of the existing public sector

facilities. This nested case-control study aims to identify the factors that are associated with care seeking at community level in the context of AMFm and testing in chemical shops. This information is important for explaining the findings from the cluster-randomized trial.

Objectives

The overall aim of this nested case-control study will be to identify factors associated with care seeking for fever in chemical shops in the context of AMFm a rural area. The study will answer the question "what makes people/parents with fever go to private rather than public health providers". Issues around malaria as an important and common cause of fever will be explored.

Specific Objectives

- To identify the factors associated with care seeking for fever in chemical shops in in the context of AMFm
- To identify the factors associated with care seeking for fever at a primary care public facility in the same area context of AMFm
- To identify the factors associated with care seeking for fever at a primary care public facility in the same area in the context of AMFm
- To determine what proportion of the fever cases seeking care in the three facilities are malaria

Methods and Materials

Study Area

The study will be carried out in the Dangme West District of Ghana, a rural and deprived district with an estimated 2012 population of 130,570 based on the 2010 census. The population lives in scattered small communities of less than 2000 people. Vehicular transport is unavailable in many parts of the district and people have to walk long distances (approx. 2-6hrs) to reach the nearest main road making access to formal care difficult. The district is typical of poor disadvantaged rural districts across the country. Poverty is widespread.

There are 4 health centres, 6 community clinics and five private facilities. 52 chemical sellers and 2 pharmacies also sell pharmaceutical products. Earlier studies carried out in the district showed that for presumed "malaria" in the household, the first action taken in order of the

most common are home treatment, chemical seller, health centre, hospital, drug peddler, and traditional healer in that order. Recent Demographic surveillance data from the district indicates that about 67% of all deaths take place at home[xiii].

Study Design and Subjects

This will be a frequency-matched nested case-control study with two arms. Cases for the first arm will consist of clients who present to any of the two randomly selected primary care facilities with a complaint of fever or a history of fever. Cases for the second arm will also consist of clients who present to the district hospital with a complaint of fever or a history of fever. Controls for both arms will be selected from any of the chemical shops participating in the trial. The controls for each of the cases of both arms will be matched by community only.

Fever is what patients normally complain of. To be able to look at the issue of malarial fever as one of the commonest and important causes of fever, all cases will have additionally expert malaria microscopy to determine the level of parasitaemia. Malaria will be defined as fever or history of fever with parasitaemia > 2,500 parasites/µl. Just as with the cases, a blood slide will be taken from controls for expert microscopy. The definition of malaria will be the same as for the cases. Study teams will visit the participating chemical shops to on sequential days to recruit controls matched for community corresponding to cases recruited within the previous 5 days.

A comprehensive questionnaire will be used to ascertain factors that influence care seeking behavior of patients with uncomplicated malaria at community level.

Sampling and Sample Size

The study is powered to detect a difference of 20-40% difference between arms. Assuming 15% extra to account for possible clustering would therefore require a total sample size of 250 cases and 250 controls.

Data Management

This will involve double entry of the data into Stata version 8 for validation of data entry. Prior to this, data will be checked for quality, internal consistencies and validity of response as well as count for each variable. Blank records will coded as "missing" and given a category during the analysis.

Odds ratios (ORs) and exact confidence intervals (CIs) will be calculated using StataSE (version 8). Adjusted ORs will be calculated by putting into the model pre-defined potential confounding factors.

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