A. Cover Page:

1. Improving Dyslipidaemia Awareness and Management in Oman and the Gulf Cooperative Council (GCC) Countries. IAS – Pfizer Grant 11540163

2. Abstract:

The main objective of this Collaborative Action is to improve dyslipidaemia awareness and management mainly in Oman. We will also include the other Gulf Cooperative Council (GCC) countries in this initiative in order to decrease the high cardiovascular disease (CVD) burden in the region. This collaborative action will mainly target subjects with dyslipidaemia associated with metabolic syndrome, diabetes and CVD as well as clinicians, nurses, health educators and societies who have an interest in managing dyslipidaemia. In addition to the general public, media and government sectors like the Ministry of Health (MOH) and The Research Council (TRC) in Oman will be involved. The interventions will include the implementation of strategies to raise awareness of dyslipidaemia among clinical specialties in Oman and other GCC countries and the identification and implementation of strategies to raise public awareness of dyslipidaemia, not only in large cities but also in rural areas. Questionnaires and assessment forms will evaluate participants in this collaborative action in terms of satisfaction with the programs especially with educational activities (e.g. outreach programs and scientific meetings). Laboratory measurements will be funded from sources other than the IAS-Pfizer grant. The proposed action plan can be scaled down should less funding from the grant be awarded.

B. Table of contents:

C. Main Section of the proposal

1. Overall Goal & Objectives:

Overall Goal:

The main objective of this Collaborative Action is to improve dyslipidaemia awareness and management mainly in Oman. We will also include the other Gulf Cooperative Council (GCC) countries. We hope that this initiative will decrease the high cardiovascular disease (CVD) burden in the region.

Objectives:

a) Identification and implementation of strategies to raise awareness of dyslipidaemia among clinical specialties in Oman and involve other GCC clinical specialities in this program like the Emirates Cardiac Society (ECS).

   I. Implement international guidelines, which are simplified and adapted for national use.

   II. Outreach programs (symposia, workshops) to Increase the knowledge of physicians on cardiometabolic risk in children and adolescents and patients with familial hypercholesterolemia (FH), their risk factors, diagnosis, methods of management based on the experience of European countries (UK, Greece, Poland, Italy), and European and National guidelines. Numerically, the main high risk groups in Oman and GCC countries are those with Diabetes (DM), Metabolic Syndrome (MetS) and Cardiovascular Disease (CVD).

   III. Creating a network of lipid specialist and lipid clinics in Oman and the GCC countries. Together with our collaborators and the International Atherosclerosis Society (IAS) we aim to create a group of lipid experts (via continuous education, training and certification) in Oman and the GCC countries to allow physicians to refer difficult cases with lipid disorders. We plan to initiate the development of a GCC Lipid and Atherosclerosis Society, GCC Lipid Guidelines, a FH forum and to improve the communication and networking with the IAS and other international societies for scientific meetings, education and research in the field.

b) Identification and implementation of strategies to raise public awareness of dyslipidaemia, not only in large cities but also in rural areas.

   I. Organizing “the Oman and GCC Dyslipidaemia Awareness Day” with the largest media partners. Organizing public awareness campaign in different cities (parks, malls), with a mobile unit to measure cholesterol, glucose, blood pressure, body mass index (BMI) and waist circumference. Cholesterol and glucose measurements cost will be covered by internal budget from Oman Society of Lipid and Atherosclerosis

II. Providing educational material (Arabic and English) about the relevance, causes and management of dyslipidaemia.

III. Involve the media (e.g. TV, radio, mobile phone companies) to educate the public about dyslipidaemia.

2. Technical Approach:

CVD is the most common cause of death in the Arabian Gulf Countries, accounting for up to 45% of all deaths in these predominantly young populations [1]. The INTERHEART study, found that the mean age of the first presentation of acute myocardial infarction (AMI) was 10 years younger in the Middle East countries compared with other regions of the world [2]. These findings were attributed to the early onset of CVD risk factors of which the most prevalent were smoking, dyslipidaemia and diabetes (DM).

In Oman and the GCC states there is very limited data or registries about the prevalence of dyslipidaemia in the region. In addition, there are no national reference values for lipids and lipoproteins in Oman and the GCC states for different sex and age groups. One of our objectives in this proposal is to set the scene for establishing national reference values for lipids and lipoproteins and the prevalence of dyslipidaemia in Oman and the GCC states.

The Centralized pan-Middle East Survey on the under treatment of hypercholesterolaemia (CEPHEUS) Survey evaluated the attainment of low density lipoproteins-cholesterol (LDL-C) goals among patients on lipid-lowering drugs (LLDs) according to the updated National Cholesterol Education Program (NCEP) Adult Treatment Panel (ATP III) guideline in 6 Middle Eastern countries (Bahrain, Oman, Qatar, the United Arab Emirates, the Kingdom of Saudi Arabia (KSA) and Kuwait) [3]. The study found that 48% of the patients on LLDs in these 6 Middle-Eastern countries did not attain their LDL-C targets. The presence of multiple risk factors like DM, hypertension, and obesity may influence the rate of LDL-C target attainment. In this study 53% of the investigators failed to identify the guidelines that they follow. In addition poor patient knowledge about the consequences of treatment failure may influence adherence to treatment.

Overall, the prevalence of the MetS in the GCC states is some 10-15% higher than in most developed countries, with generally higher prevalence rates for women [4]. In Oman, the prevalence of MetS among patients with acute coronary syndrome (ACS) was around 66% and was associated with higher in-hospital heart failure and mortality [5].

The prevalence rates for type 2 DM (T2DM) and CVD in the GCC are between 25% and 35% for the adult population, while evidence of the MetS is emerging in children and adolescents [4]. A recent International Diabetes Federation (IDF) summary

suggests that countries in the Gulf region have some of the highest rates of T2DM in the world [6].

The prevalence of FH in the GCC region is not well known. There are few studies mainly from Oman [7-9] and Bahrain [10] that look at the genetic characterization of FH. In Oman at Sultan Qaboos University Hospital (SQUH) there is a specialized LDL-Apheresis unit, which is considered to be the only unit in the GCC region since 2008. In addition, the Oman Society of Lipid & Atherosclerosis (OSLA) and SQUH are planning to conduct cascade screening for FH in Oman and build up a GCC/Middle East and North Africa (MENA) network and forum for FH.

To our knowledge there are 3 certified lipidologist by the National Lipid Association in the GCC region. There are high need to certify more physicians and other health providers (nurses and dieticians interested in the field of lipid and lipoprotein disorders) in the GCC region.

In this collaborative project we will need to

a) To set the scene for establishing the prevalence of dyslipidaemia in Oman to help in accurately estimating the magnitude of the problem and introduce plans for managing it. This can be achieved by the following strategy:

    In Oman the 2008 National health Survey for the 10 Omani regions had surveyed around 3000 subjects and data were made available for total cholesterol (TC), LDL-C, high density lipoprotein cholesterol (HDL-C) and triglycerides (TG) [11]. However, this data are inconclusive in terms of age and sex distribution. In addition other parameters like apolipoprotein (apo) B and apo AI, blood glucose, height, weight, waist circumferences are not available.

    Based on the experience of our partners mainly from the Hellenic Atherosclerosis Society (HAS) and Polish Lipid Association (PoLA) (e.g. Greece ATTICA study (>100 publications), Polish NATPOL and POLSENIOR surveys) we need to establish national reference values by sampling the 10 regions in Oman including good distribution of age and sex. Also, blood sampling for blood glucose and lipid profile including the Apo B and A1. Weight, height waist circumference will be included in the measurements. The testing can be either done at a centralized laboratory or a mobile unit with point of care testing equipment. This Oman cohort study will allow us to standardize the method and gain enough experience in order to perform the same analysis in other GCC countries.
    The funds for establishing national reference ranges for lipid and lipoproteins and establish the prevalence of dyslipidaemia in Oman will come from applying separate grant to The Research Council (TRC) in Oman and not IAS-Pfizer grant

In addition serum levels of proprotein convertase subtilisin/kexin type 9 (PCSK9) will be measured to correlate with LDL-C levels in the same cohort. (This will be for research purposes – again funds will be applied through the TRC in Oman and not form the IAS-Pfizer grant)

Similarly, plasma levels of atherogenic lipoproteins, including small dense LDL particles, and subfractions of HDL-C will be measured for research purposes (National Scientific Agencies, EU Horizon 2020 grants, governmental bilateral/international financial support.) These lipoprotein measurements will be performed in the laboratory of Prof. M Rizzo, Euro-Mediterranean Institute of Science and Technology (IEMEST), Italy) and Prof. M Banach, Medical University of Lodz, Poland/Polish Lipid Association (PoLA).

In order to efficiently conduct this epidemiological study we need to learn from the experience of our partners in conducting such studies both (HAS, PoLA), has the expertise to organise in co-operation with the GCC Countries a great scale epidemiological study with no cost and this will be done with physicians-volunteers to investigate the extend of dyslipidaemia and related metabolic CVD risk factors in Oman and other Gulf Region.

b) To identify the treatment gap for achievement of lipid target goals among various risk groups in Oman (e.g. DM, MetS, CVD)

Although the Gulf CEPHEUS study [3] had partially addressed this question, the cohort of patients who were included was limited to few treatment centers. For example, in Oman all the patients were recruited from the University Hospital, which is a tertiary referral hospital specialized in lipid treatment. Other regions were not involved which will not accurately represent the treatment gap of lipid goals for the whole country.

In this project and with the support of our international partners (HAS, PoLA, IEMEST, UK), regional partner (ECS) and local partner Oman Diabetes Association (ODA) we will need to estimate the treatment gap with good representation from the 10 regions. In Oman all of the regions have primary health centers, we can use these centers (the existing patient information databases in each centres) to identify patients with DM, MetS, and CVD on lipid lowering treatment, analyse their risk and estimate the gap in LDL-C goal achievement. We also plan to educate the staff of these primary health centers (outreach program and scientific programs) concerning the lipid targets and the ways of obtaining them in different patients' populations. This experience will allow making the similar analyses in other GCC countries.

The funds for estimating the LDL-C treatment gap in Oman will come from applying separate grant to TRC in Oman and not IAS-Pfizer grant

c) Identification and implementation of strategies to raise awareness of dyslipidaemia among clinician and health providers (nurses and dieticians) in various specialties. In Oman there is no national guidelines for cardiovascular prevention, dyslipidaemia management in primary, secondary prevention and the high-risk groups. There is very limited data available to reflect and evaluate the existing practice in dyslipidaemia management across the different specialties in the country. To improve this gap, the following strategy can be implemented:

   I. Work closely with other active societies in the country like OSLA and the ODA, as well as similar societies in the GCC region (ECS) to set up a task force to address the prevalence of dyslipidaemia, existing management practices and gap in treatments. Then there will be a need come up with guidelines that can be easily implemented for the different specialties. The screening experience of our collaborators (Royal Free Hospital, University College London, HAS, PoLA, IEMEST) will help us achieve these goals.

   II. Conducting outreach programs (symposia, workshops) in the various regions in Oman and the GCC to educate health providers in dyslipidaemia management and introduce appropriate guidelines. We plan to involve speakers from the GCC region (ECS) as well as our collaborators from Europe. The experience of our collaborators (HAS, PoLA, IEMEST and Royal Free Hospital, University College London) will help us achieve these goals.

   III. Creating a network of lipid specialist and lipid clinics in Oman and the GCC countries. Together with our collaborators and IAS we aim to create a program to build up a group of lipid experts (via continuous education, training and certification) in Oman and GCC countries (geographically distributed) in order to allow physicians to refer the most difficult patients with lipid disorders, to develop a GCC Lipid and Atherosclerosis Society, develop GCC Lipid Guidelines, develop a FH forum and to improve the communication and networking with IAS and other international societies for scientific meetings, education and research in the field. This group will be chosen from Oman and other GCC countries who have high interest in lipid management and research, the training will be done in Oman or in one of our collaborator countries and we will aim to graduate between 30 lipid specialists in 2 years

d) Identification and implementation of strategies to raise awareness of dyslipidaemia in the public, not only in large cities but also in rural areas.

Conducting public awareness about dyslipidaemia causes and management in general is very important in reducing the magnitude of the problem and its consequences. In addition, poor patient knowledge about the consequences of treatment failure may influence poor adherence to treatment. To improve the public awareness

i. We will organize "the Oman and the GCC dyslipidaemia Awareness day" with the largest media partners (TV, radio, newspapers and mobile phone companies). Include organization of public awareness campaigns in different Oman and GCC cities utilizing the parks/malls, with a mobile unit for cholesterol, glucose, blood pressure, BMI, waist circumference measurements. Cholesterol and glucose measurements cost will be covered by internal budget from Oman Society of Lipid and Atherosclerosis

ii. In addition to providing educational materials (Arabic and English) about the relevance, causes and management of dyslipidaemia.

iii. Involve the media (e.g. TV, radio, mobile phone companies) to educate the public about dyslipidaemia.

e) Target groups:

This project would aim at the following targets:

I. Patients with dyslipidemia, MetS, DM and CVD.
II. Clinicians, nurses, health educators who have interest in managing subjects with dyslipidaemia.
III. Societies who have interest in managing dyslipidaemia.
IV. General Public
V. Media
VI. Government Ministry of Health (MOH) and TRC in Oman

f) Outcome Measurements:

i. We aim to improve LDL-C target achievement from baseline by 20%. Two measurements will be taken, one at base line at the start of the study and the second one at 12 months. Also targets for Apo B, non-HDL-C will be included as a secondary goal with similar 20% improvements in achieving target goals.
ii. For the clinicians and other health providers, assessment about the knowledge of dyslipidaemia management guidelines (national or international), can be evaluated at the initial visit of the outreach programs and at a later stage (6-

12 months). This assessment can be done in the form of distributing multiple choice questions (MCQ) based on written material and lectures.

iii. For the public questionnaires can be distributed during the public awareness campaign to assess their knowledge about lipid parameters, causes of dyslipidaemia, management of dyslipidaemia and their satisfaction about the amount and the quality of information disseminated by the media and the educational materials about dyslipidaemia. Patients can also be assessed by a questionnaires at initial visit and at 6-12 months about their knowledge about dyslipidaemia and its management. Expected improvement in knowledge from baseline by 40% will be the target.

iv. Patients-oriented outcomes – to increase the knowledge on dyslipidaemia and its complications in the population of Oman and GCC countries in order to increase the awareness and therapy adherence and in the consequence therapy compliance.

3. Detailed Work-plan and Deliverables Schedule

To achieve the goals of this project a total duration of 2 years will be needed.
Two teams will be assigned to achieve objectives A and B.

I. Team A consists of 1 clinician, 1 statistician and epidemiologist scientist, 2 nurses and 1 technician. This team will be responsible for planning the population size needed to calculate the reference values for the lipid profile and other parameters. Meanwhile, ethical approval needs to be obtained from the Ministry of Health, which will take between 1-2 months. A team of 3 nurses for sample collections and completing the appropriate consent form, questionnaire about medical health history and anthropometric measurements, 1 technical staff for processing the samples and 1 clinicians to explain about the important of data collection. This should take 12-18 months to cover the main 7 regions. The funds for establishing national reference ranges for lipid and lipoproteins and establish the prevalence of dyslipidaemia in Oman will come from applying separate grant to The Research Council (TRC) in Oman and not IAS-Pfizer grant

II. Team B consists of 2 nurses and 2 clinicians. Representatives of the Health Centers will be chosen. Two visits will be scheduled; the first visit will consist of obtaining information about reasons for lipid lowering prescription (Primary prevention, secondary prevention, DM, MetS, CVD), assessment of physician knowledge about lipid guidelines and patient compliance. Blood will be obtained for lipid profile, Apo A1 and B, glucose and anthropometric measurements. The second visit to the same centers will be scheduled in 6 and 12 months after the first visit and similar information and blood tests will be obtained. The funds for estimating the LDL-C treatment gap in Oman will come from applying separate grant to TRC in Oman and not IAS-Pfizer grant

III. Together with our collaborators and International Atherosclerosis Society we aim to create a program to build up a group of lipid experts (via continuous education, training and certification) in Oman and GCC countries. For the lipid clinic program we can develop one or use an existing certified program suggested by the IAS or our collaborators in the project. This group will be chosen from Oman and other GCC countries who have high interest in lipid management and research. The training will be done in Oman and we will aim to graduate between 20-30 lipid specialists in 2 years.

IV. A team of specialists such as a lipidologist, endocrinologist, cardiologist, and dieticians will be formed to plan the outreach educational program for the management of dyslipidaemia. This program will be planned to cover Oman and the GCC countries with a contribution from our collaborators to educate health care providers (physicians and nurses) and researchers in Oman and the GCC region who have an interest in dyslipidaemia.

V. Task force consists of specialist in the field of lipid and lipoprotein disorders will be formulated to come up with national guidelines for dyslipidaemia management and put framework for implementing these guidelines. There will also and input from our major associations like OSLA, ODA, ECS and support from our international collaborators.

VI. One scientific meeting will be organized with the help of our collaborators in this project. Two days conference and a workshop on October 2015, in Muscat, Oman (suggested topics management of dyslipidaemia in DM, MetS, CVD, lipid guidelines, update about HDL-C therapy, FH management, statin intolerance, combination pharmacotherapy and emerging therapies, lipid management in special cases and two workshops on cardiometabolic risk reduction programs and nutrition and lifestyle counselling workshop)

VII. Organizing “the Oman and the GCC dyslipidaemia Awareness day” with the largest media partners (TV, radio, newspapers and mobile phone companies). Include organization of public awareness campaigns in different Oman and GCC cities utilizing the parks/malls, with a mobile unit for cholesterol, glucose, blood pressure, BMI, waist circumference measurements. In addition to providing educational materials (Arabic and English) about the relevance, causes and management of dyslipidaemia; 2 campaigns in 2014 in Muscat, Oman and in 2015 in Dubai, UAE. Cholesterol and glucose measurements cost will be covered by internal budget from Oman Society of Lipid and Atherosclerosis

Timetable for plan of action

Deliverable	Time	Funds provider
Establishing national reference values for lipids	24 months	TRC in Oman
Estimating Lipid achievement Goals	Visit 1 at baseline Visit 2 at 12 months	TRC in Oman
Lipid Clinic Program	To be hold once in Muscat, Oman in 2014 or 2015	IAS-Pfizer grant
Outreaching educational program	In Oman and through the GCC countries (6 meetings)	IAS-Pfizer grant
National lipid guidelines meeting (formulation and implementation)	2 meetings during the 24 months	IAS-Pfizer grant (This meetings can be conducted through the outreaching educational program with no extra funds
Scientific meetings	1 meetings in 2014 in Muscat, Oman	IAS-Pfizer grant
The Oman and GCC Dyslipidemia Awareness Day	1-2 campaigns depend on fund availability 2014 in Muscat, Oman 2015 in Dubai, UAE	IAS-Pfizer grant

TRC; The Research Council
IAS; International Atherosclerosis society
GCC; Gulf Cooperative Council
UAE; United Arab Emirates

F. Required Documentation:

OSLA would sign a contract with an agency organizing meetings and Congresses, which will handle all the expenses during this program, if the proposal is accepted for funding.
OSLA will not require signing W-9 form.

I. Appendices:

References:

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