Introduction

Studies examining the link between research evidence and clinical practice have consistently shown gaps between the evidence and current practice. Some studies in the United States suggest that 30%–40% of patients do not receive evidence-based care, while in 20% of patients care may be not needed or potentially harmful. However, relatively little information exists about how to apply evidence in clinical practice, and the available data on the effect of evidence-based guidelines on knowledge uptake, process of care or patient outcomes is limited.

In recent years, specific clinical guidelines have been developed to optimize the quality of anemia management secondary to chronic kidney diseases (CKD).As a result, the National Kidney Foundation Kidney Disease Outcome Quality Initiative (K\DOQI) guidelines and the Renal-European Dialysis and Transplantation Association best practice guidelines have been published in USA & Europe. Therefore; clinical practice guidance help individual physician and physicians; to improve their clinical performance and thus raise the standard of patient care towards optimum levels. They may also help to insure that all institutions provide an equally good base line standard of care. **(Cameron, 1999)**

Guidelines practiced on anemia and actual practices are much different with different places and patients according to treatment. Moreover, in individual countries and individual units within countries local circumstances relating to economic conditions, organization of health care delivery or even legal constraints may render the immediate implementation of best practice guidelines difficult or impossible. Nevertheless, they provide a goal against which progress can be measured. **(Locatelli et al., 2004)**

Dialysis Outcomes and Practice Patterns Study (DOPPS) has observed a large variation in anemia management among different countries. The main hemoglobin concentration in hemodialysis patients varied widely across the studied countries ranging between 8g/dl to 11g/dl. The percentage of prevalent hemodialysis patients receiving erythropoietin stimulating agent 'ESA' has increased from 75% to 83%. The percentage of HD patients receiving iron varies greatly among DOPPS countries range from 38% to 89%. **(Locatelli et al., 2004)**

There are challenges in implanting clinical guidelines in medical practice. Overall DOPPS data which show that, despite the availability of practice guidelines for treatment of renal anemia, wider variation in anemia management exists as gap between what is recommended by the guidelines and is accomplished in every day clinical

practice. Compliance with clinical guidelines is an importance indicator of quality and efficacy of patient care at the same time their adaptation in clinical practice may be initiated by numerous factors including; clinical experts, patient performance, constrains of public health policies, community standard, budgetary limitation and methods of feeding back information concerning current practice. **(Cameron, 1999)**

Aim of the Work

To study the pattern of current clinical practice in hemodialysis prescription in regular hemodialysis patients in Egypt, Giza Governorate (Sector F), and to compare this pattern with standard international guidelines in hemodialysis prescription (K/DIGO), stressing on anemia, bone disease management and adequacy of dialysis.

Chapter I:

DOPPS

What is DOPPS?

The Dialysis Outcomes and Practice Patterns Study (DOPPS); is a prospective cohort study of hemodialysis practices based on the collection of observational longitudinal data for a random sample of patients from a representative and random sample of dialysis units. **(Young et al., 2000)**

The Dialysis Outcomes and Practice Patterns Study (DOPPS) is a leading source of up-to-date, representative, and comprehensive data on hemodialysis practice and patient outcomes worldwide. **(Robinson et al., 2012)**

The study is carried out in more than twenty countries (Australia, Bahrain, Belgium, Canada, China, France, Germany, Italy, Japan, Kuwait, New Zealand, Oman, Qatar, Russia, Saudi Arabia, Spain, Sweden, Turkey, the United Arab Emirates, the United Kingdom, and the United States), based on patient- and facility-level data reported from nationally representative samples of facilities within each country.

Practice Patterns; refer to the general range of treatment options faced by hemodialysis centers. Examples of practice patterns that may be related to outcomes include: staffing ratios and composition, size of unit, vascular access creation and salvage policies, dialyser reuse and methods of delivering dialysis.

Outcomes; refer to a variety of patient events that are associated with human and economic consequences. Important outcomes assessed in DOPPS include: mortality, hospital admission, vascular access failure, quality of life, and development of new medical conditions.

The Goal of DOPPS

The goals of this large international study of hemodialysis (HD) patients can be summarized as *"live longer, live better,"* which emphasizes its clinical focus. **(Young et al., 2000)**

DOPPS research goals are centered on the hypothesis that measurable differences in dialysis facility practices influence patient longevity, morbidity, and health-related quality of life (HR-QOL). Identifying opportunities for improvement is a primary motivation and guides research priorities. **(Goodkin et al., 2001)**

The Dialysis Outcomes and Practice Patterns Study (DOPPS) was designed to evaluate facility practices that can be associated with the improved health and longevity of patients with ESRD. **(Robinson et al., 2008)**

Since the inception of DOPPS, its primary aim has been to identify practices that extend survival and improve (HR-QOL) for hemodialysis patients. The DOPPS has yielded research findings directly relevant to patients, health care providers, and policy makers. **(Robinson et al., 2012)**

DOPPS practice areas:

The DOPPS investigates a large number of practice patterns to detect new evidence for modifiable treatment factors that are associated with improved outcomes. **(Pisoni et al., 2004)**

It continues to provide numerous important findings that are relevant for patients and practicing clinicians alike. It has published a comprehensive collection of descriptive statistics spanning more than a decade of longitudinal DOPPS data collection, illustrating trends over several practice areas which include:

- Anemia.
- Co-morbidity.

- Demographics.
- Dialysis Prescription and Practice.
- Medications.
- Mineral Metabolism.
- Diabetes &Nutrition.
- Patient Centered Care & Quality of Life.
- Vascular Access.
- Health Economics and Policy.
- Cardiovascular Disease & Inflammation.

A decade of DOPPS:

Data collection for the study has been ongoing since 1996 and has yielded detailed data on more than 55,000 patients in over 600 dialysis facilities.

- ***DOPPS I*** (1996-2001) has included 308 hemodialysis units and 17,034 hemodialysis patients from 7 countries.
- ***DOPPS II*** (2002-2004) has included 322 hemodialysis units and 12,839 hemodialysis patients from 12 countries.

- ***DOPPS III*** (2005-2008) has included 300 hemodialysis units and 11,170 hemodialysis patients from 12 countries.

- ***DOPPS IV*** (2009-2011) has included 380 hemodialysis units and 15,528 hemodialysis patients from 12 countries.

- ***DOPPS V*** (2012-2015) includes 465 hemodialysis units and more than 15,528 hemodialysis patients from 19 countries.

(Robinson et al., 2008) & **(Nancy Ginsberg, 2010)**

It was recently announced, the expansion of the DOPPS into Turkey and Russia.

The Benefits of the study:

The DOPPS can evaluate whether the target levels that are chosen in the guidelines are in agreement with outcomes such as elevated risk for mortality, hospitalization, and vascular access failure. Although an observational study cannot prove causality, DOPPS suggests large opportunities to improve care and outcomes of dialysis patients. The international perspective of DOPPS assists in the new efforts for international guidelines. Some encouraging trends in recent years are documented in these areas. **(Friedrich K. Port et al., 2006)**

Given its large, representative, and international patient sample, this observational study has been able to; contribute to many aspects of practice in hemodialysis. It is widely recognized that more randomized, controlled studies are needed as they allow inference of causality and provide the "gold standard" of evidence. However, such studies tend to be rare and often have a limited sample size. If underpowered, then this may lead to negative findings. Furthermore, large and nationally representative HD patient samples such as those in the DOPPS allow results to be pertinent to all types of HD patients and provide a reflection of current national practices. **(Friedrich K. Port et al., 2006)**

In contrast, randomized, clinical trials often are not performed with a nationally representative sample, potentially limiting the generalizability of study findings. In addition, many components of dialysis therapy do not lend themselves to randomization for ethical reasons; for example, randomization to a high phosphorus level or catheter use would be difficult to justify. Observational studies require experienced and thoughtful adjustments with the goal of simulating randomized, clinical trials. **(Port, 2000)**

As numerous trials and observational studies have provided a growing body of evidence, guidelines have been

produced through expert panels in the United States as Dialysis Outcomes Quality Initiative (NKF-DOQI initially, later broadened to Kidney Disease as K/DOQI); in Europe as the European Best Practice Guidelines; and also in Canada, the United Kingdom, Australia, and other regions. These expert panels conducted extensive literature reviews to define levels of evidence. They often clarify that some guidelines are opinion-based, whereas others are based on various levels of evidence. Evidence is higher for randomized, controlled trials than for observational studies. **(NKF, 1999)**

It is reassuring to note that recent DOPPS findings are in remarkably close agreement with the published regional guidelines regarding the recommended target levels of laboratory values. It has become clear that the science- and evidence-based care of patients with kidney failure should be independent of geographic location or national borders. Therefore, a new initiative was created by international experts to develop truly international guidelines under the new acronym KDIGO, Kidney Disease—Improving Global Outcomes. **(Eknoyan et al., 2004)**

As many of the regional guidelines for HD were published several years ago, it is of interest to study the levels of compliance in representative samples by region

and to evaluate time trends from before to after their publication. The DOPPS is ideally suited to evaluate the level of deviation from the guidelines over time and by country. The DOPPS is also in a position to evaluate whether the target levels that are chosen in the guidelines are in agreement with outcomes such as elevated risk for mortality, hospitalization, and vascular access (VA) failure. **(Friedrich K. Port et al., 2006)**

The DOPPS Research Approach:

The facility sample from several countries consists of hemodialysis centers in which patients are treated. A random sample of patients is selected thus far for more detailed longitudinal data collection. Departing patients are replaced during the study using random selection. A study coordinator at each dialysis facility collects baseline and longitudinal patient data. Patients are asked to complete a questionnaire that addresses quality of life on a yearly basis. The medical director and nurse manager in each facility complete a practice pattern questionnaire. Preliminary data are presented concerning the sample facilities and the census of patients treated in each facility at the start of the study. Dialysis facilities vary widely in size and type (freestanding vs. institutionally-based) across countries. Variation is also seen in patient age, sex distribution, and diabetes mellitus as the attributed cause of end-stage renal disease (ESRD). **(Young et al., 2000)**

The Methodology of the DOPPS

1. Study design

DOPPS is a prospective study of hemodialysis patients and facilities in several countries. The countries were selected on the basis of geographic diversity, variation in practices and outcomes, and relatively large numbers of ESRD patients. With assistance from investigators in each of the countries where the study has taken place; a nationally representative sample of dialysis facilities is enrolled in each country and a random sample of hemodialysis patients was selected within each participating center. Practice patterns are determined at the facility and patient levels. Demographic, laboratory, co-morbidity, and outcome data are ascertained at the patient level.

The basic study design and study instruments are shared across all countries with minor local modifications as necessary. Institutional review boards approve the study in each country or facility, as required. Informed patient consent is obtained in accordance with the requirements of each country, review board, and dialysis center. Data collection is performed in a fashion that maintains patient anonymity at the coordinating center. **(Young et al., 2000)**

2. Facility sampling

A stratified random sample of chronic hemodialysis facilities was selected to achieve variation in practice patterns and outcomes. The initial sampling frame consisted of a random subsample of dialysis facilities. For each dialysis facility, a measure of mortality was estimated. A representative description of dialysis facilities can be obtained using the random sample or the overall sample weighted by the probability of facility selection. **(Young et al., 2000)**

Random sampling to enroll a representative sample of dialysis units, was quite novel among epidemiologic studies at study launch. This approach supports the accurate description of actual practice in national hemodialysis populations and ensures that findings can be generalized to these populations. It also maximizes variation in practices and outcomes in order to enhance the analytic ability to identify important, potentially causal associations. We have learned much from the often surprising differences in practice among participating countries. **(Robinson et al., 2012)**

3. Patient sampling

At the start of the project, the study coordinator in each participating facility listed the census of prevalent in-center hemodialysis patients older than 17 years. This census listing included basic patient information such as age, race, sex, and the cause of ESRD. At regular intervals of approximately every four months, the census is updated to indicate all new and departed patients since the last census update. The date and reason for each departure are entered on the census form. Within each participating facility, the census listing was used to select a random sample of 20–40 patients, varying according to the size of the facility. Detailed longitudinal data collection was performed for this representative sample of patients. Departed patients were replaced approximately every four months, using random selection from the patients entering the dialysis facility during the interval. **(Young et al., 2000)**

4. Data collection

The DOPPS relies on a number of study instruments in order to gather detailed data on facilities and patients:

1-The ***Cumulative Hemodialysis census (CHC)*** form: completed at the unit's entry into DOPPS; maintained throughout study participation. Complete census of all