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INVESTIGATING THE FEASIBILITY OF CREATING A DISEASE REGISTRY IN EGYPT: A CASE STUDY OF DEMENTIA

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The American University in Cairo

School of Global Affairs and Public Policy

INVESTIGATING THE FEASIBILITY OF CREATING A DISEASE REGISTRY IN EGYPT: A CASE STUDY OF DEMENTIA

A Thesis Submitted to the

Public Policy and Administration Department

in partial fulfillment of the requirements for the degree of
Master of Public Administration

By

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Shimaa Adel Heikal
Supervised by
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Abstract

The increased interest in evidence-based medicine led to the emergence of disease registries worldwide to help tackle the impact of chronic diseases by providing accurate data on several aspects of the disease care process. Age-associated diseases, particularly dementia, are growing worldwide with several implications and increased economic burden, especially in lower-income countries. In Egypt, there is a lack of accurate dementia prevalence and statistics data which hinders the establishment of appropriate disease management and care strategies. A national dementia registry would provide a massive valuable source of patient data that will significantly advance the disease management strategies and quality of patient care and impact health policy and decision-making. This study investigates the feasibility of creating a disease registry for dementia in Egypt by interviewing 24 relevant national and international experts to evaluate their perceptions, knowledge, and opinions, then provide recommendations for the most appropriate registry model to be developed in Egypt. Several core themes emerged from the analysis of experts' interviews discussing many points that should direct the creation of any registry in Egypt. Learning from other successful registries, comparing their experiences, and applying them to Egyptian culture imposes an excellent opportunity for the registry establishment. The findings clearly provided the proposed best practices to be followed while initiating a national registry in Egypt in terms of functionality, planning, comprehension, governance, ethics, and challenges to avoid. The initiating process should start with a leading institution that brings together the potential stakeholders and defines the clear purpose and objectives of the registry to direct the planning and design. A research registry that focuses on collecting both clinical and demographic patients' data, as well as diagnostic tests, is the most recommended in Egypt. A primary piloting phase should be the first step to test the functionality and effectiveness of the process then expansion of data and coverage can be a second step. To start collecting data for the first pilot, a few sites from the leading institution's network can be included as the primary participants to ensure their involvement. A minimum data set is then developed to identify the data elements to be collected in the registry. The registry administrators should regularly monitor the data collected to ensure its integrity and develop a clear plan for providing access to users. Taken together, developing such a dataset is beneficial to the Egyptian healthcare system, which makes the investment worthwhile. Support and collaborative work from all stakeholders, along with suitable funding, are essential elements of the proper implementation of the project. Yet, it might seem to be an opportune time for initiating this kind of registry to address the needs and, at the same time, benefit from the strategic opportunities.

Keywords:

Disease registries; Aging; Dementia; Egypt, Aging policy; Registry recommendations; Registry Governance; Registry Management; Dementia datasets; Registry design

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List of abbreviations

RCT: Randomized Clinical Trials
NIH: National Institute of Health
WHO: World Health Organization
AD: Alzheimer’s Disease
NCRP: National Cancer Registry Program of Egypt
MIPAA: Madrid International Action Plan on Aging
ELSA: The English Longitudinal Study of Ageing
HRS: Health and Retirement Study
TILDA: The Irish Longitudinal Study on Ageing
SHARE: Surveying the Health, Aging, and Retirement in Europe
AL-SEHA: A Longitudinal Study of Egyptian Healthy Ageing
MCI: Mild Cognitive Impairment
CERAD: Consortium to Establish a Registry forAlzheimer'ss Disease
CDCR: Camberwell Dementia Case Register
SCADR: South Carolina Alzheimer’s Disease Registry
WVADR: West Virginia AD Registry
GARDR: Georgia AD/Related Dementia State Registry
ReDeGi: Register of Dementia in GironaSwedenm: Swedish Dementia Registry
NACC: National Alzeheimer’s Coordinating Center
CREDOS: Clinical Research Center for Dementia of South Korea
PRODEM: Prospective Registry on Dementia in Austria
HIPAA: Health Insurance Portability and Accountability Act
MDS: Minimum Data Set
MMSE: Mini-Mental State Examination
CAPMAS: Central Agency for Public Mobilization and Statistics
MOH: Ministry of Health
MOSS: Ministry of Social Solidarity
UHI: Universal Health Insurance
UHC: Universal Health Coverage

Introduction

The imperative to evaluate and improve the outcomes of disease management strategies in healthcare system settings has led to the increased interest in evidence-based medicine. The need to promptly assess the interventions used for different groups of patients has increased the recognition of the role of observational studies and medical datasets. Conventional randomized clinical trials (RCT) have shown critical gaps in evaluating the safety of the developed intervention and failed to rein in its effectiveness with an extensive array of the population over prolonged times (Dreyer & Garner, 2009a). In addition, the lack of real-world patient data hinders research in different areas, which hampers our knowledge of chronic and rare diseases, their risk factors, epidemiologic and economic burden, and, most importantly, the best practices to tackle them (Richesson & Vehik, 2010). Moreover, the availability of accurate information on health outcomes is crucial for policymakers to support the development of health spending strategies to improve the value of healthcare services while decreasing costs (Larsson et al., 2012).

A systematic and comprehensive approach to caring for patients with chronic diseases has already shown great potential in improving the quality of patient care, which will lead to a decrease in disease costs that represent a global health burden in disease registries (Larsson et al., 2012). Disease registries are effective tools that provide the required systemic and comprehensive data, which help healthcare providers integrate and use this information in their care settings (Recommendations, 2010). A well-established disease registry enables providers to track cases in their country and analyze their data to manipulate patients' treatment effectively.

A disease registry, as defined by the National Institute of Health (NIH), is “the collection of information about individuals who have a specific disease or condition, they provide their data voluntarily, and the registry can be sponsored by a governmental agency, nonprofit organization, health care facility or a private company" (NIH, n.d.). Registries are considered one of the ways to cost-effectively collect longitudinal patient information to provide datasets that can be analyzed to give insights into different perspectives of the disease (R. E. Gliklich et al., 2012). The availability of accurate patient datasets, together with the big data analytics advancements, will tremendously impact the determination of disease causes and risk factors, resulting in the identification of improved practices for disease management and prevention (R. E. Gliklich et al., 2014c).

As the world's population is aging and people are living longer due to improvements in healthcare services and other living conditions, the incidence of age-related diseases is increasing (Sorbi et al., 2012). Age-associated chronic diseases, including Dementia and Alzheimer's Disease (AD), are a vast and growing problem for human society (Weiner et al., 2018). The World Health Organization (WHO) defined Dementia as "A syndrome, usually of chronic or progressive nature, caused by a variety of brain illnesses that affect memory, thinking, behavior and ability to perform everyday activities" and considered it a public health priority as the number of people with dementia was estimated to continue growing, especially among older people and in countries with demographic transition (WHO, 2012a). Dementia is challenging for both health and social activities. The disease dramatically impacts the person's life by affecting his cognitive and physical activities depending on the stage of disease progression. The more progression of the disease, the more health and social services are required to allow them to manage their daily life activities (Kerpershoek et al., 2020). The total number of people diagnosed with dementia is projected to increase from approximately 50 million to 152 million people in 2050 (WHO, 2018).

Moreover, the total cost of dementia care was estimated at $ 818 billion in 2015, with lower costs per person in lower-income countries; the cost per person was estimated as $32865 in high-income countries, $6827 in upper-middle-income countries, $3109 in lower-middle-income countries such as Egypt and $868 in low-income countries (WHO, 2015, 2017). Alzheimer's disease (AD) is the most common type of dementia, with a prevalence of 5.4 million in the United States (Weiner et al., 2018; WHO, 2012b). The WHO classified Alzheimer's as a form of dementia manifested by memory disorders and a gradual decline of cognitive functions. The epidemiological data regarding dementia and AD are mostly accurate when provided from high-income countries, while most low and middle-income countries rarely have national data and rely on regional or international estimates (Nicaise et al., 2016; WHO, 2012c). Conversely, Egypt has a national prevalence study that the WHO recognized as a reference for the prevalence studies developed by the Middle East or North Africa region countries (Farrag et al., 1998; Nicaise et al., 2016). Yet, the study did not cover the entire country and only focused on a few cities in Upper Egypt.

The current study aims to generate a discussion to assess the feasibility of creating a disease registry in Egypt and garnering the most suitable approach to create the registry taking dementia as our case study. Specifically, this research aims to provide recommendations on the requirements of the best model of a dementia registry that will fit the needs of the Egyptian context through interviewing the relevant expert stakeholders and decision-makers, analyzing their perspectives regarding 1) Registries and their importance; 2) The potential benefits and risks of such an initiative in Egypt; 3) The challenges that could arise while initiating the process.

Chapter One: Background

1.1. Disease Registries

Several types of registries differ in the purpose and the type of data collected. These include research registries that collect data for research purposes, pre-clinical registries that are designed for emphasizing clinical studies, quality of patient care registries that focus on patients' data and the quality of their status after receiving healthcare services, and finally, the demographical registries, which focus mainly on giving insights on the prevalence of a disease in a country (Krysinska et al., 2017c). Importantly, there is a great need for quality of patient care registries despite the existence of all the different types internationally (Hooper, 2017). Yet, a registry that combines both the demographical and quality of patient care data will significantly benefit patients and healthcare providers, which is the focus of this study.

The registry data is usually used to fulfill various health and research objectives. The aims and objectives of patient registries include: 1) informing public health policymakers and providing them with the evidence that allows them to evaluate their healthcare system and continuously improve their strategies for the best enhancement of the healthcare services; 2) improving patient care through containing comprehensive medical records that enable creating individualized care plans for the better management of each patient; 3) supporting research in different aspects of the disease and facilitate the initiation of research studies that describe or analyze patients' data and; 4) facilitating diagnostic procedures and health technology assessment (R. E. Gliklich et al., 2014c; Krysinska et al., 2017a).

Best practice guidelines were developed through the years and after the emergence of the new and existing registries to provide an idea about the essential points that should be considered when initiating a new registry, including the purpose, type of data, data collection and management, registry governance and required legislation (Hopper et al., 2016).

1.2. Egyptian Dementia registry as a case study

Dementia is a type of neurodegenerative disease that is growing in Egypt with increasing estimations, but unfortunately, there are no accurate statistics published regarding the national prevalence (Farrag et al., 1998; Nicaise et al., 2016). In addition to the lack of precise statistics, dementia is among the underdiagnosed diseases globally because of the poor and unequal diagnostic measures, particularly in a population with lower socio-economic classes (Lang et al., 2017). The under-reported number of cases is another constraint that results in the underdiagnosis of the disease due to many factors, including the misdiagnosis of other diseases or the decreased awareness of people who usually consider their symptoms as normal signs of aging (Amjad et al., 2018).

In 2017, Elshahidi et al. investigated the prevalence of dementia in Egypt. They stated that the under-reporting of dementia cases in Egypt is one of the limitations that might affect the accuracy of the study and that other studies with larger samples and datasets will provide a more accurate estimation of the disease prevalence in Egypt (Elshahidi et al., 2017). In addition to determining the prevalence, the under-reporting of cases makes it difficult to accurately estimate the cost of treatment and the economic burden of the disease. Therefore, a national disease registry containing data on patients with dementia is significantly required to help improve health care services provided to patients, enhance their quality of life, and provide physicians and researchers with the information needed to improve their diagnostic and management techniques.

Tackling dementia and collecting patient information to develop a national registry is a complicated process that requires extensive planning and involving various stakeholders to guarantee the registry's effectiveness, success, and sustainability (R. E. Gliklich et al., 2014d; Newton & Garner, 2002). Therefore, both the Global and the Egyptian contexts need to be assessed to understand the function and challenges of dementia registries in the different contexts and the most suitable approach that will benefit the national needs, then provide reliable recommendations accordingly.

1.3. Problem statement

One of the main problems of dementia management care in Egypt is the lack of a well-established national disease registry that provides accurate, evidence-based information that helps improve the provided care services and the relevant decision-making policies (Elshahidi et al., 2017; Heikal et al., 2022; Nicaise et al., 2016).

1.4. Egyptian Context

1.4.1. Review of existing initiatives in Egypt

During the last decades, Egyptian researchers have exerted efforts to conduct national demographic studies, and some of them tried to establish registries for specific diseases. In 2007, a cooperation protocol between the ministries of communications and information technology, health, and scientific research agreed on establishing the National Cancer Registry Program of Egypt (NCRPE). The project covered ten cancer centers by establishing an e-portal for information exchange, but it is still located in some governorates as pilots before the spread nationwide (NCRPE, n.d.). In 2014, a group of physicians at Ain Shams University started a study to establish a multi-center Egyptian database of information for inherited and acquired neuromuscular diseases in infants and children from 0 to 18 years of age. The study observed 200 patients and was estimated to end in 2020 (Hassanein, 2014). In 2015, an analysis of clinical trial registries showed that the contribution of Egyptian clinical trials was low and that the registries did not accurately reflect the clinical research conducted in Egypt (Zeeneldin & Taha, 2016). Other initiatives were started to tackle the issue, but most of them were individual studies, and nothing covered the national level (Elshehabi, 2013; Farouk et al., 2015).

1.4.2. Initiatives tackling Dementia and AD

Yet few initiatives tackled neurodegenerative disease, dementia, and AD, although this data was eagerly needed. In 1998, Farrag et al. explored the prevalence of AD and dementia in 11 locations at Assiut-Upper-Egypt and reported that dementia was frequent with a 4.5 prevalence ratio (Farrag et al., 1998). Several studies, hence, proved the same result that dementia is frequent in Egypt by studying the prevalence of dementia in several Egyptian governorates, including Zagazig, New Valley, Red Sea, and Qena (H. N. el Tallawy et al., 2012, 2014; H. N. A. el Tallawy et al., 2010, 2013; El-Tallawy et al., 2013; E. Khedr et al., 2015; E. M. Khedr et al., 2012; Zaitoun et al., 2008). In 2017, a systematic review by Elshahidi et al. reported that the prevalence of dementia in Egypt ranges between 2.01% to 5.07%, with a higher ratio among illiterate groups. They emphasized the need for more epidemiological studies to address the knowledge gap in the field (Elshahidi et al., 2017).

More recent studies have explored the disease prevalence, types and different predictors, and association with psychiatric symptoms and mental health disorders(el Razek et al., 2019; H. N. A. el Tallawy et al., 2019; Odejimi et al., 2020; Sabry et al., 2021; Salem et al., 2020). Yet, none of the studies provided an accurate estimation of the national prevalence. Most of them highlighted the lack of data and small samples as the main limitations of their studies. In addition, none of the initiatives investigated establishing a registry for dementia or the limitations of the project.

1.4.3. Aging policies and practices in Egypt

Regarding legislative laws and regulations, the Egyptian constitution does not contain any regulations on the issue of registries, and the Egyptian legislative system has no direct law for constructing patient registries. The only relevant initiative was the clinical trial law regulating medical and clinical research. The law was discussed in the Egyptian parliament and approved in 2018 before receiving a letter from the office of the presidency with some provisions.

However, a draft law on the care of the elderly was passed to the parliament in 2018. It was approved recently, which specified the vulnerable elderly Egyptian citizens and covered the different aspects of their care. The law consists of 24 articles that constitute most of the Madrid International Action Plan on aging objectives (MIPAA, 2002). The objectives of the MIPAA action plan included the development of older persons, advancing their health and well-being, and ensuring enabling and supportive environments. The Egyptian law was developed to encompass social, medical, and economic issues that affect the lives of older people.

1.5. Egyptian Health System Transformation

1.5.1. Universal Health Insurance (UHI)

Until recently, 60 percent of the Egyptian health expenditure constituted out-of-pocket payments which made it difficult for a large segment of the population to access health care while pushing other populations below the poverty line due to spending on healthcare. In 2018, the universal health insurance law was endorsed in order to transform the Egyptian healthcare system and achieve Universal Health Coverage (UHC). The new health insurance system was planned to be rolled out in 6 phases over 15 years, starting with the Port Said governorate. The Egyptian healthcare system transformation is a huge project which requires technical expertise and institutional support (*Development Projects : Supporting Egypt's Universal Health Insurance System - P172426*, n.d.; *Egypt | Universal Health Coverage Partnership*, n.d.; *WHO | Programme Budget Web Portal*, n.d.). The WHO has supported the planning and implementation of the UHI by providing the Egyptian government with a multifaceted health systems approach, including policy briefs on governance, costs and pricing strategies, support on field implementation, as well as assessment and policy advice for organizational transformation. Since 2018, when the program started, Egypt is making great advancement in implementing the UHI law, which is considered progress toward achieving the UHC (*Implementing the Universal Health Insurance Law of Egypt: What Are the Key Issues on Strategic Purchasing and Its Governance Arrangements?*, n.d.). All in all, the advancement in the Egyptian healthcare system, as well as the presence and involvement of international stakeholders, make the current time an opportune time for transforming the system for managing chronic diseases to better strategies using evidence-based approaches.

1.5.2. 100 million Healthy Lives Campaign

Since 2016, The Egyptian government has been actively focusing on identifying the cases of Hepatitis C virus (HCV), as Egypt was known to have the highest prevalence of the disease in the world. It was estimated that 6 million people in Egypt are living with HCV, yet most of them are unaware of their infection (*100 Million Healthy Lives Initiative*, n.d.; *WHO | Programme Budget Web Portal*, n.d.). The government led several initiatives that led to the diagnosis and treatment of 1 million patients by the end of 2018. However, many people were not diagnosed and consequently did not seek treatment. To tackle this problem of increased HCV prevalence, and with the support of the UHC initiatives, the Egyptian government considered eliminating the hepatitis C virus a high-level priority (*100 Million Healthy Lives Initiative*, n.d.; *WHO | Programme Budget Web Portal*, n.d.). In October 2018, the Egyptian MOH, with the support of the WHO and the World Bank fund, released the presidential campaign "100 Million Seha" as a nationwide mass screening for HCV infections. In addition, the campaign also collected data about non-communicable diseases (NCDs), including hypertension, diabetes, and obesity, as they were shown to be responsible for 84% of the deaths in Egypt. The campaign was launched in 3 phases and depended on huge mass media campaigns to raise awareness of the benefits of participation in order to increase the national percentage screened. Yet, the government had also to use the carrot and stick approach to enforce the participation of people as they announced that having the screening card would be mandatory for entering any governmental organization or receiving any public service (*'100 Million Seha' Initiative Saved Lives of 2.2. Million Egyptians-SIS*, n.d.). The evaluation of the 100 million seha campaign showed a huge success in diagnosing and treating HCV towards its elimination. In addition, the campaign helped develop a database for the distribution of NCDs, which facilitated the establishment of a national roadmap to control and prevent NCDs with better allocation of resources and best use of interventions (*Egypt's '100 Million Health' Initiative Has Screened 20.8 Mln Women so Far: Health Ministry - Health - Egypt - Ahram Online*, n.d.). Learning from the 100 million seha success story opens up the way for future initiatives that focus on generating national datasets for supporting policymakers as well as healthcare practitioners in the process of chronic diseases management.

1.6. COVID-19 pandemic and the urge to have information datasets

The COVID-19 pandemic was a great example that highlighted the significance of data in influencing policy and decision-making. The lack of consistent data approaches in the early days of the pandemic led to uncertain actions in many countries and difficulty in making evidence decisions (Hopper & Bowen, 2021). The situation was not effectively improved unless the different systems collaborated, taking leadership actions with a clear purpose to solve the issue (Kuznetsova, 2020). Therefore, one of the significant learning lessons of the pandemic is that the availability of datasets tremendously facilitates reporting and tracking of the disease leading to improved analysis and comparisons, which result in more developed outcomes. Likewise, the availability of a national dementia registry will provide an accurate framework for data and information on the disease, which is essential for generating reports that advance the disease knowledge, management, and decision-making.

1.7. Research Objectives

Currently, there is a need for a systematic approach to collect data on dementia and analyze them to fulfill several needs of the Egyptian healthcare system. In this regard, the overall objective of this study is to address the feasibility of establishing a disease registry for dementia in Egypt by creating an expert discussion that provides evidence-based recommendations for the appropriate registry model to follow.

The specific objectives are to:

1) Review the different initiatives that tackled Dementia and Aging problems to evaluate the impact of having large sets of patients’ data/registries on disease management.

2) Provide an expert-opinion analysis to identify the importance, structure, governance, challenges, and other points that concern the process of developing a dementia registry.
3) Provide evidence-based policy recommendations of the best practices to advance the structuring of the registry

1.8. Research Question

Based on the above-mentioned objectives, the study's main research question can be formulated as follows: What are the best practices for developing a successful registry for dementia in Egypt?

To answer this question, the data collection process will be guided by the following specific research questions:

1) What are the benefits of developing a national dementia registry in Egypt?
2) What are the challenges or constraints that will hinder the procedure?
3) How to create a registry structure which perfectly satisfies the needs in Egypt?
4) How to best manage a national dementia registry?

The answers to these questions will significantly contribute to the advancement of the registry planning process.

1.9. Research Outline

The present study is divided into five chapters as follows:

Chapter One covers a brief background on disease registries, their types, and their importance. They are followed by a discussion about aging and dementia as global health problems. Then, the Egyptian context is presented through a review of several Egyptian initiatives.

This is followed by the research approach that defines the current research’s objectives and questions.

Chapter Two covers a quick review of the literature tackling the longitudinal datasets on aging, dementia registries, and datasets and how they impacted the advancement of disease management. We searched the online databases to include research articles, reviews, organizational reports as well as institutional webpages that contain information about longitudinal studies, especially on dementia, as well as the impact of registries on disease management.

Chapter Three presents the conceptual framework of the study showing the theoretical concepts adopted and their application in creating a national registry in Egypt.

Chapter Four describes the study's research methodology, including the research design, sampling strategy, data analysis, and study limitations.

Chapter Five presents the research findings and discussion, showing the main themes generated through data analysis.

This is followed finally by the conclusion of the study and the policy recommendations for the best practices to develop a registry in Egypt.

Chapter Three: Conceptual Framework

5.1. Theoretical Concepts

It is worth noting that registries provide a massive source of data that brings out several necessary information for patients, local/national governments, policymakers, healthcare providers, and researchers. Registries provide an important source for planning and evidence-based decision-making regarding a specific disease or services provided. The data also helps the improvement of disease management, and the quality of patients' lives and facilitates research (Krysinska et al., 2017a). In addition, the WHO highlighted the importance of developing a dementia information system in order to improve dementia services and contribute to the development and implementation of national dementia strategies and policies "*By building and/or strengthening information systems for dementia, the functional trajectories of people with dementia, their careers and families can be improved*"(WHO, 2017). Therefore, this research aimed to develop recommendations for the best practices of creating a national registry for Dementia in Egypt.

5.1.1. Registry definition and framework

For this regard, the research adopted The US Agency for Healthcare Research and Quality (AHRQ) registry framework definition to analyze and interpret the data produced. The AHRQ defined a patient registry as an "organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes" (R. E. Gliklich et al., 2014c). Based on the AHRQ definition, a registry should possess some features, including:

1) A specific plan of the registry's purpose and objectives should be determined prior to the collection of data
2) The data elements included/ data set should also be defined prior to the collection.
3) The data collection process should occur in a consistent manner.
4) The registry should include data that reflect the clinical status of the patient as well as other non-clinical-related data.

5.1.2. Registry Planning

Moreover, Gliklich et al. discussed ten initial steps that assist in the planning of a registry as follows (Figure 2) (R. E. Gliklich et al., 2014d):

1) Articulate the registry purpose to help define the data required and assess the right approach to develop the registry (Dreyer & Garner, 2009b; Solomon et al., 1991).

2) Determine if a registry is an appropriate means to achieve the purpose by considering the availability and accessibility of the data required (R. E. Gliklich et al., 2014d).

3) Identify key stakeholders as the registry development process is a multi-stakeholder process that requires the collaboration of several parties to proceed in planning, creating, and funding the registry, as well as ensuring its effectiveness and sustainability (R. E. Gliklich et al., 2014d; Zaletel & Kralj, 2015).

4) Assess the feasibility of the registry by exploring the costs of the registry, the potential funding sources, and whether the funding process is limited to one stakeholder or will likely be a

partnership. Determining the available fund will affect the determination of the registry scope and size (R. E. Gliklich et al., 2014d).

5) Build a registry team that includes consultants from different backgrounds and expertise needed for registry planning and management.

6) Establish a governance and oversight plan that ensures the transparency of the registry's operation, reports, and findings to the relevant stakeholders. The governance model adopted should also accommodate all the involved teams and provide the general working system to achieve the registry objectives.

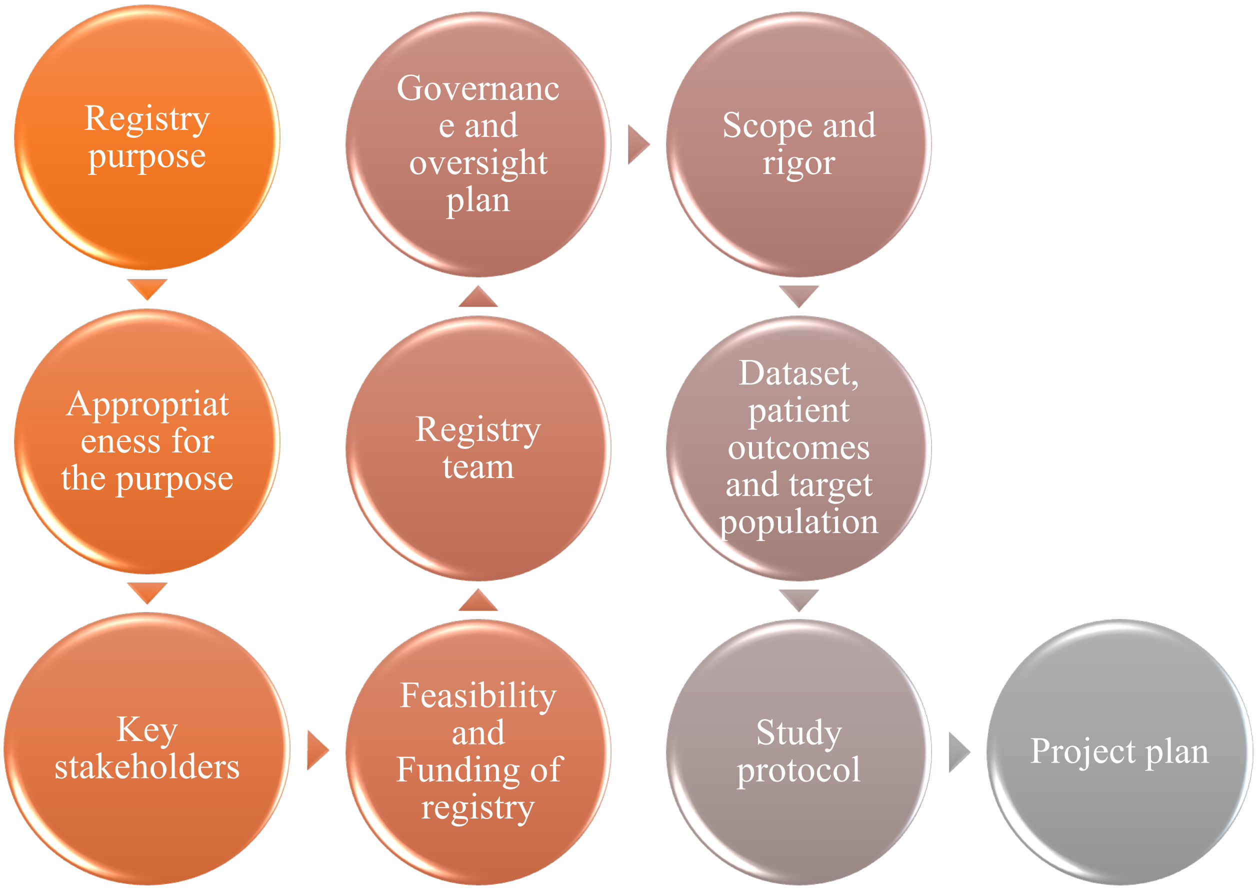
7) Define the scope and rigor needed, including the size of data, its setting, duration of data collection, geographical inclusion, etc.

8) Define the data set or the elements of data that are required to achieve the objectives without being all-inclusive. The patient outcomes should also be defined to be able to prioritize the goals and hence, focus on the primary needs first. In addition, deciding on the target population is an essential step in the planning phase to determine how the results of the registry can be applied or generalized.

9) Develop a study plan or protocol to document the type of registry, objectives, design, selection criteria, data collection, governance, data analysis, and reporting.

10) An overall project plan can finally be developed to provide a guideline for the implementation of all the planning efforts.

Figure 1: Initial steps of registry planning



Source: Author compilation based on (Gliklich et al.. 2014b)

5.1.3. Registry Outcomes

Establishing a registry provides numerous outcomes depending on its purpose and objectives that benefit various stakeholders, including the clinical care providers, researchers, policymakers, and regulatory officials. The registry data can be used for many purposes to provide outcomes in different fields and sectors, i.e., Patient advocacy groups, research field, clinical care field, policy, and decision-making sectors (Figure 3) (Krysinska et al., 2016). The information provided by disease registries can be used to improve the diagnosis or help predict the disease by discovering new early biomarkers. The data can also help improve the disease management plans for a better quality of patient care. In addition, the quality of patient life is also impacted by enhancing life expectancy and decreasing the risks. Researchers can also use registry data to facilitate new research studies and discoveries. Eventually, the registry reports contribute to improved disease outcomes when used correctly by decision-makers (Figure 3) (Krysinska et al., 2016)

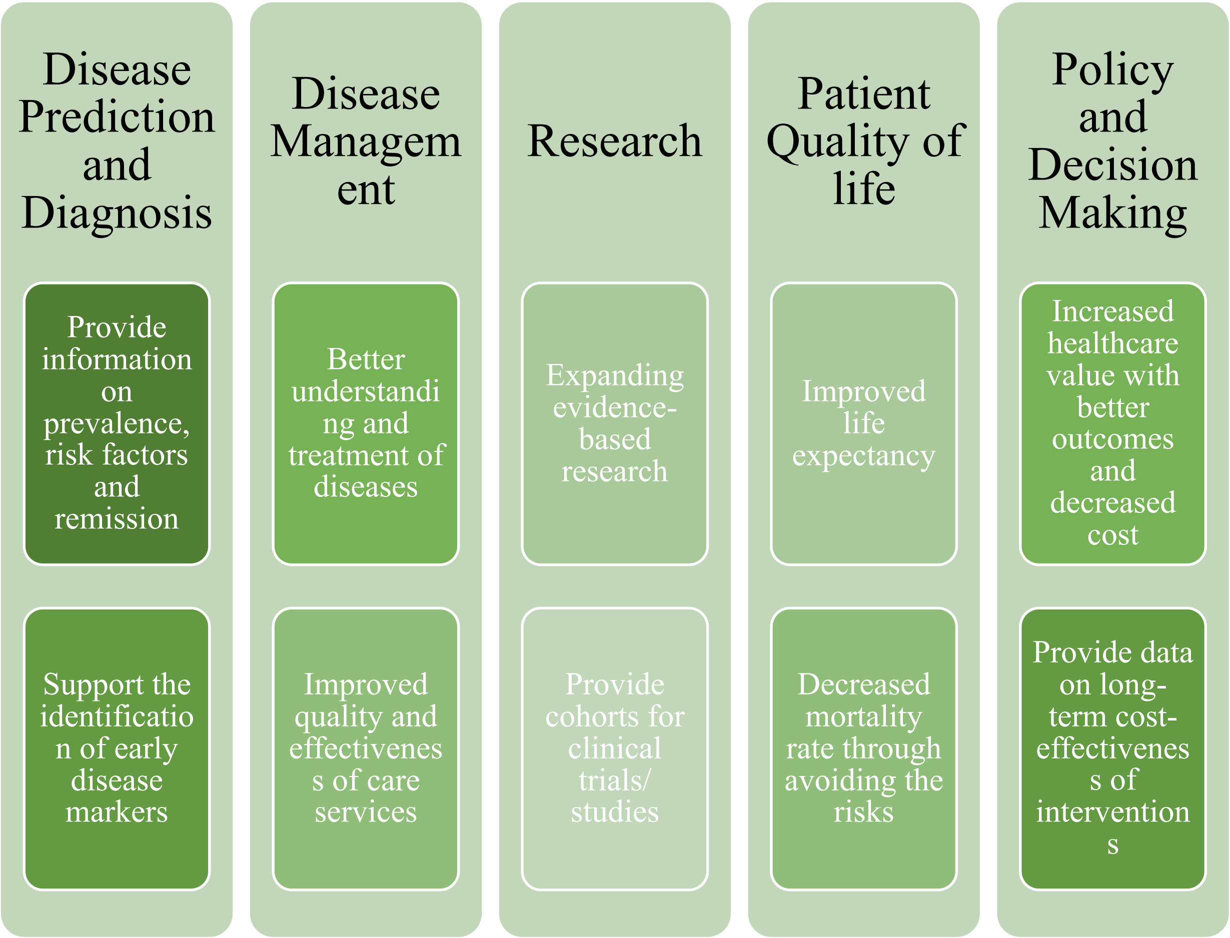
The data of disease observation in different patients over a long period helps the clinical practice field a lot in terms of figuring out more accurate diagnostic tools that help in the early detection of the disease, as well as the prediction of the characteristics of people who might be at risk (S.-M. Fereshtehnejad et al., 2015a; Garre-Olmo et al., 2016; K. M. Park et al., 2019). In addition, registries provide data on the appropriateness of patient management, quality, and effectiveness of the guidelines and procedures followed, which leads to an improvement in understanding disease treatment and the quality of provided care services (Calvó-Perxas et al., 2013; R. E. Gliklich et al., 2014c).

A better understanding of the nature of the disease, its causes and risks generated from the data provided by registries, as well as the improvement of management strategies and quality of care services, benefits the individual patients themselves, in addition to their caregivers and advocacy groups (R. E. Gliklich et al., 2014c; Martín-García et al., 2013). Studies have analyzed data from registries to provide conclusions on the risks of disease mortality to develop the appropriate strategies to decrease the mortality rates of the disease and improve the life expectancy, quality and health outcomes of patients (Heikal et al., 2022; Hoque et al., 2017).

Research, as well, tremendously benefits from registries. For researchers, registries are valuable sources of data consistently collected from a large number of patients, which enable them to conduct community-based research and provide evidence-based conclusions (Krysinska et al., 2016). In addition, many studies and clinical trials either build on the analysis of pre-collected data from registries or benefit from the large cohorts registered to carry on a new study (R. E. Gliklich et al., 2012; Heikal et al., 2022).

From a decision maker's point of view, registries provide a rich source of data that contributes to better health decisions with improved outcomes and lower costs (Larsson et al., 2012). The analysis of data from the real world and the longitudinal reports of registries data help improve healthcare value as well as the health economics research and outcomes through the development of economic models to estimate the burden and costs of the disease (Larsson et al., 2012; Wimo et al., 2013). These estimates are utilized for the cost-effectiveness and cost-utility analyses to provide information on the implication of the applied practices and determine the strategies for future improvements (Green & Zhang, 2016; Winblad et al., 2016).

Figure 2: Registry Outcomes



Disease Prediction and Diagnosis	Disease Management	Research	Patient Quality of life	Policy and Decision Making
Provide information on prevalence, risk factors and remission	Better understanding and treatment of diseases	Expanding evidence-based research	Improved life expectancy	Increased healthcare value with better outcomes and decreased cost
Support the identification of early disease markers	Improved quality and effectiveness of care services	Provide cohorts for clinical trials/ studies	Decreased mortality rate through avoiding the risks	Provide data on long-term cost-effectiveness of interventions

Source: Author compilation based on (Krysinska et al., 2016)

5.1.4. Data sources

With the establishment of a registry that provides the above-mentioned outcomes, data can be collected from various sources depending on the purpose of the registry and the availability and accessibility of data. Data are usually collected from many places, i.e., public, and private hospitals, memory clinics, elderly houses, etc. The data sources include primary or secondary data according to the purpose of collection (R. Gliklich et al., 2020). Primary data are the data collected specifically for registry purposes by caregivers or clinicians following a prospectively planned protocol. This method includes collecting data from hired volunteers or cohorts, as well as the reports that the clinicians provide for entry into the registry platform. Primary data improves the completeness and accuracy of registry data, consequently impacting the registry's validity and reliability. However, some limitations, including patient recruitment, time and work burden on clinicians, costs, and inclusiveness of more data, require the use of secondary data(R. Gliklich et al., 2020).

Secondary data are the data collected for other purposes but can be included in the registry platform as archived medical records, insurance data, electronic health records (EHR), administrative databases, birth/death certificates, and, most importantly, the databases of other registries (R. Gliklich et al., 2020). These secondary data can either be imported into the registry platform and be part of the registry database or be linked to the registry data to provide larger datasets for the investigation of more factors and correlations. Although secondary data can provide comprehensive sources of data with a lower burden on clinicians, the main constraint of including secondary data is that it lacks completeness as they were collected with protocols different than the registry standard data collection protocols. In addition, secondary data require more checks, filtration, and validation prior to data entry(R. Gliklich et al., 2020).

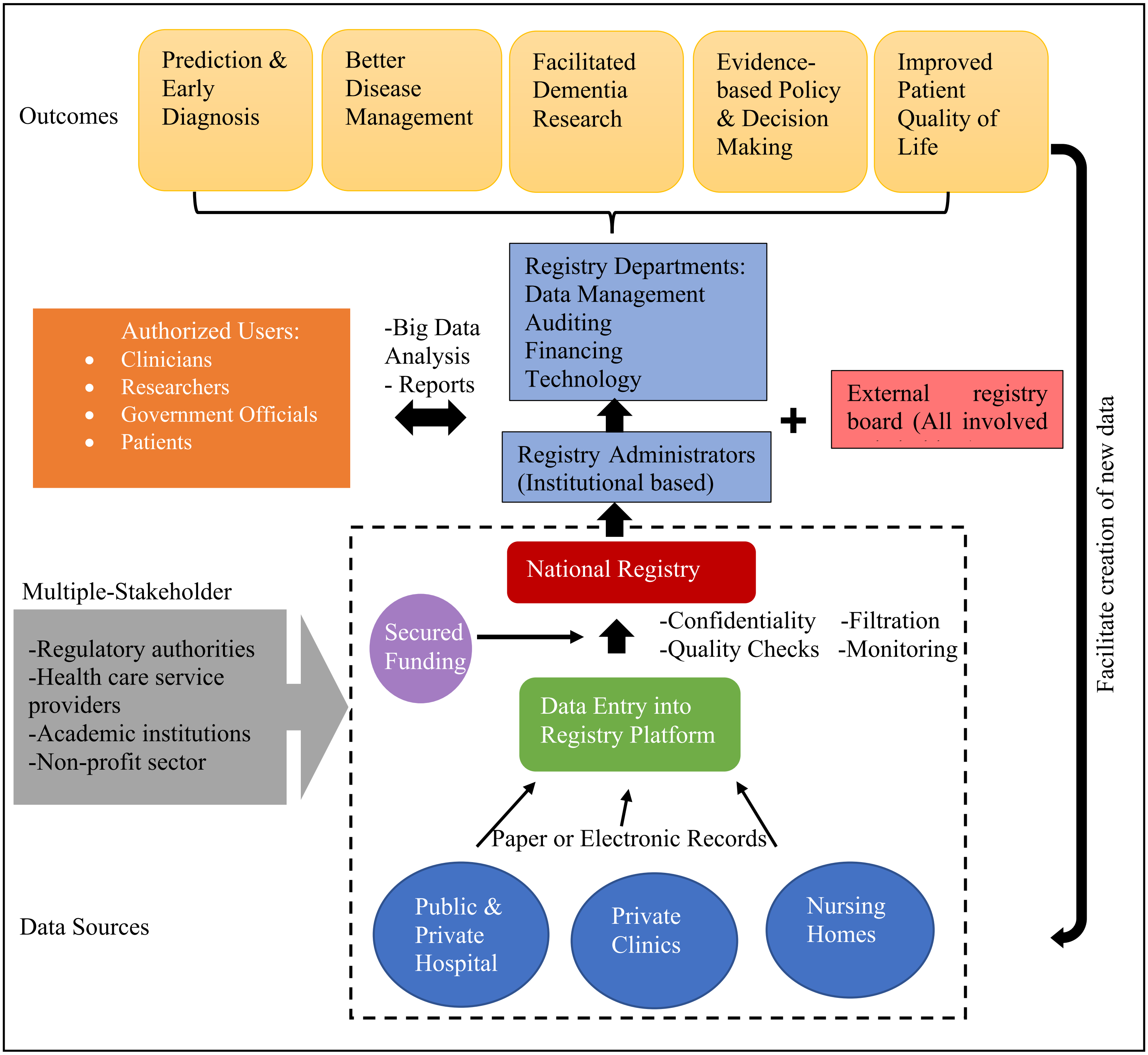
5.1.5. Stakeholders

Stakeholders of the registry are those who would benefit from the registry data, and they can be either end-users of the data or early contributors to the registry planning and implementation. Identifying the potential stakeholders from the early stages of planning the registry is extremely beneficial to incorporating their input and perspectives in the process. The registry development process is considered a multi-stakeholder process as the collaboration of many parties is required to build a successful registry (Zaletel & Kralj, 2015). Stakeholders can also be divided into primary and secondary parties according to their roles through considering those who participate in the registry planning and funding as primary stakeholders while those who benefit from the data generated out of the registry or be impacted by the registry outcomes as secondary stakeholders (R. E. Gliklich et al., 2014d).

Typically, primary stakeholders may include the regulatory authorities, healthcare service providers, academic institutions, and the non-profit sector. On the contrary, secondary stakeholders usually include patients and their caregivers, clinicians, researchers, and government officials. Considering all the stakeholders can influence the design and structure of the registry to satisfy their needs(R. E. Gliklich et al., 2014d).

5.2. Research Conceptual Framework

Figure 3: Conceptual Framework of Registry Function



Chapter Two: Literature Review

2.1. Aging and Dementia as global concerns

The aging research field became widespread interest in the developed world, with a larger share of elderly people due to demographic change – the increased life expectancy with decreased fertility rate. Studying the change that happens in aging and understanding its complexities was essential to identify the challenges that face the populations, especially since the implemented systems were designed to suit the young and growing people and are no longer compatible with the older ages (Börsch-Supan et al., 2018). Determining the social, environmental, and medical factors contributing to aging deterioration or problems is extremely crucial to help anticipate the population change and efficiently respond to it (Kaiser, 2013). Therefore, longitudinal panel studies were developed to collect data on population aging and investigate different aspects to promote our understanding of the aging process and the change it derives from all over the world (Alasuutari et al., 2012; NIA, 2013).

2.1.1. Global Longitudinal Aging initiatives to face the challenge

The studies that included longitudinal data differed in their design and the type of collected data to either collect data on all aging populations or only focus on Alzheimer's disease or dementia. Yet, data collection methods included personal interviews, questionnaires, home-based instruments, household panel surveys, cross-sectional surveys, and enhanced and computer-assisted interviews (Kaiser, 2013).

The Health and Retirement Study (HRS) is a multidisciplinary, representative, and longitudinal survey established nationally in the US twenty-eight years ago as the largest academic behavioral and social science project. The survey started in 1992 with follow-ups every two years and has covered more than 43000 individuals over 50 years old to provide data in four broad areas: income and wealth - health, cognition and use of healthcare services - work and retirement – and family connections (*AHCJ | Resources: Growing Older in America: The Health & Retirement Study*, n.d.; Fisher & Ryan, 2018; Sonnega et al., 2014). More than 5500 papers were written using data from the HRS to discuss different aspects associated with aging, including retirement age, wealth, health status, etc. (*Analysis of Dementia Risks among African Immigrants Compared with Caucasian Americans in Retirement | Health and Retirement Study*, n.d.; Fisher & Ryan, 2018). Langa et al. used HRS data to compare the prevalence of dementia in the US in 2002 and 2012. They reported a significant decline in dementia prevalence despite the increased age expectancy and showed that educational achievement was associated with the deterioration (Langa et al., 2017). Comparing the differences and trends like sex, race and age showed that dementia prevalence declined according to cognitive tests but increased according to diagnostic codes, implying the need for improved measurement of dementia, especially among racial or ethnic minorities (Zhu et al., 2020). Terracciano et al. found that personality traits, including extraversion, openness, and agreeableness, are also associated with the risk of dementia and cognitive impairment (Terracciano et al., 2017). Investigating the risk of mortality in the US revealed that the mortality burden associated with dementia is underestimated according to death certificates (Stokes et al., 2020).

Studies similar to HRS are now conducted worldwide to develop more informative data with national and international efforts. These studies include The English Longitudinal Study of Ageing (ELSA), Survey of Health, Ageing and Retirement in Europe (SHARE), The Irish Longitudinal Study of Ageing (TILDA), and many other longitudinal studies (Fisher & Ryan, 2018; Kaiser, 2013). SHARE is a multidisciplinary and cross-sectional panel database covering 27

European countries and Israel with more than 140000 individuals. The goal of SHARE is to cover older people's lives -50 years and older- with a focus on key areas like health, social and economic circumstances. In addition, the strength of SHARE is the combination of subjective and objective data as the panel includes more health measures like physical activities, biomarkers, and cognitive ability tests (Börsch-Supan et al., 2013, 2018). Studying the European profile indicated that older Europeans with dementia had very unfavorable health and well-being status. They were less physically active, had a higher prevalence of comorbidities and chronic diseases, consumed more medications, and had lower education levels. Therefore, Interventions that target dementia people and improve their lives are required (Ferreira et al., 2020). Foverskov et al. used SHARE data to prove that there is an association between education and dementia as education may slow cognitive decline (Foverskov et al., 2018), and gender differences in education attainments didn't contribute to the decline. However, women's cognition showed a high tendency to improve over time due to other socio-economic and country-specific factors (Angrisani et al., 2020). Retirement age, late-life depression, and early parental death were also proved to be factors associated with the risk of dementia in older individuals (Celidoni et al., 2017; Conde-Sala & Garre-Olmo, 2020; Wu et al., 2020).

TILDA is one of the unique longitudinal studies on aging that collects physical, cognitive, and mental health data. TILDA looks at 8504 people as they grow older and sees how the aging process will change their lives over ten years (Cronin, O'Regan, Finucane, Kearney, & Kenny, 2013; "The Irish Longitudinal Study on Ageing (TILDA) - Trinity College Dublin," n.d.; Whelan & Savva, 2013; Wilkins, Best, & Evans, 2015). The data gathered helped to understand the changes associated with aging, which enabled the development of better economic, health, and social policies that benefit elder people (*The Irish Longitudinal Study on Ageing (TILDA) - Trinity College Dublin*, n.d.). Although most of the studies excluded dementia patients when addressing the association between aging and other factors, some used the dataset to compare dementia and non-dementia patients in their response to a specific test or a disease (Donoghue et al., 2018; Kenny et al., 2013; Maguire et al., 2018; Mayburd & Baranova, 2019; McGarrigle et al., 2019; Power et al., 2019; Vaughan et al., 2016).

Recently, a longitudinal study for aging was initiated in Egypt as the collaboration of the American University in Cairo (AUC) with the Global Brain Health Institute (GBHI), TILDA, HRS, and SHARE to carry on " A Longitudinal Study of Egyptian Healthy Ageing" (AL-SEHA) (Salama & Roe, 2020). The project was initiated in 2020, adapting the SHARE survey translated into Arabic with the further back translation then conducted in five different places in Egypt, intending to cover 500 subjects in this pilot phase.

2.1.2. Specific initiatives for Dementia and AD

Although most of the aging longitudinal studies contained data on dementia, more specific datasets that require standardized diagnosis of dementia among the inclusion criteria were eagerly needed to provide more accurate data on disease diagnosis and management. Disease registries are tools that were established to ongoingly collect and document patients' data with a particular disease to provide information on the disease causes and pathogenesis (Richesson & Vehik, 2010). Frank et al. reported that Scandinavian countries, including Denmark, Finland, and Sweden were the first to develop registries for different diseases (Frank, 2000), while the first registry developed specifically for dementia was the Consortium to Establish a Registry for Alzheimer's Disease (CERAD) in the USA (Krysinska et al., 2017b). The registry was developed recently and was particularly for AD patients in response to the increased prevalence of the disease among elderly individuals in the USA. CERAD was the nucleus of dementia registries which helped the standardization of evaluation and diagnostic procedures of AD. The standardized tools that CERAD developed are used until now in the USA and internationally (Fillenbaum et al., 2008).

In 1999, the national institute of Aging in the USA (NIA) funded the National Alzheimer's Coordinating Center (NACC) as one of the older registries that support and collect standardized data on AD (Beekly et al., 2004). The database included massive standardized longitudinal information that was used to facilitate different research studies in the field of dementia, including the investigation of the disease progression, characteristics of patients, correlation with other diseases, development of symptoms, and the risk factors of the disease (Heikal et al., 2022).

Following that, some research initiatives started in Canada and Europe focusing on dementia and AD. The IMAGE project in Canada was a multidisciplinary-research population-based study on AD patients (de Braekeleer et al., 1989). On the other hand, the Camberwell Dementia Case Register (CDCR) in the UK was established in 1992 to focus on dementia, the diagnostic criteria of dementia subtypes, as well as the management procedures (Holmes, 1996). However, these studies are no longer collecting data.

Consequently, many national, international, and local register-based dementia studies started to set up to advance research on dementia worldwide. In 2005, The Clinical Research Center for Dementia of South Korea Study (CREDOS) was established as a longitudinal dementia research study focusing on the diagnosis of dementia subtypes, including AD, patients' demographics, as well as the disease prevalence (Kim et al., 2014; H. K. Park et al., 2011). Similarly, A longitudinal cohort of AD patients' study was established in Austria in 2008 called The Prospective Dementia Registry Austria (PRODEM) (Seiler et al., 2012). PRODEM focused on collecting clinical evaluation data that had a significant role in advancing the research studies on cognition, functioning, co-morbidities, and caregivers' role in dementia and the studies on AD diagnosis.

Today, a variety of dementia registries exist around the world, and many registries are being developed to support and benefit healthcare services. However, no ideal model has been identified so far to establish the registry. Until now, the design of the registry depends on the aims and objectives that the registry needs to achieve (Alonso-Gonzalez et al., 2015). South Carolina Alzheimer's Disease Registry (SCADR) is one of the oldest and most comprehensive state-wide registries that were established in the USA to collect data on patients with Dementia and AD. It is a population-based registry implemented in 1988 and has identified more than 285000 cases of ADRD in South Carolina (Arnold School of Public Health, 2016; Macera et al., 2016). The registry, as in the case of the three statewide USA registries, is linked to other data sources with permissions to link and collect data of patients diagnosed with AD or Dementia. The aim of the registry is to provide accurate information on the prevalence of the disease in the USA. Yet, the main challenge is still getting complete data. Despite the numerous data sources available for them, they face the same problems as all registries in terms of incomplete diagnosis or undetected cases (Arnold School of Public Health, 2016).

The laws in the USA that exempt the data collection of health and well-being from the Health Insurance Portability and Accountability Act (HIPAA) facilitated the establishment of more state-wide registries that also collect population-based data to provide accurate prevalence estimates of AD and dementia (Hopper et al., 2016). West Virginia AD Registry (WVADR) and Georgia AD/Related Dementia State Registry (GARDR) were established in 2011 and 2014, respectively, to contain data similar to the South Carolina registry in West Virginia and Georgia. Both registries follow the model of SCADR and collect data on newly diagnosed cases from healthcare providers to inform policymakers and researchers (Leonard et al., n.d.). In 2015, WVADR included almost 28000 cases with the assistance of the medical insurance programs that facilitated the registration (*West Virginia Alzheimer's Disease Registry*, n.d.).

Another similar population-based study was conducted in Girona, Spain. The Registry of Dementia of Girona (ReDeGi) was established in 2007 as a local registry in Catalonia to collect data on all newly diagnosed dementia cases in the hospitals included (Calvó-Perxas et al., 2012). The establishment of the registry included on few hospitals, but currently, the registry is showing success in expanding as it now covers the majority of the Girona region. The data has also provided researchers with a rich source for more investigational studies, especially in terms of patient characteristics and treatment. (Turró-Garriga et al., 2021).

In addition to the population-based registries, some registries emerged in Europe to focus on collecting data for the quality of patient care. Danish Dementia Registry (DCDR) was created in 2005 to collect dementia-related data using quality indicators with the objective of improving the quality of healthcare. The quality indicators that were used included the frequency of demented patients, the percentage of patients evaluated within three months, whether the workup included blood tests, Mini-Mental State Examination (MMSE), brain scan, and activities of daily living, and the percentage of patients treated with anti-dementia drugs. The use of these clinical indicators is shown to assist in standardizing and harmonizing the process of patient evaluation and hence help improve the quality of the services provided (Foverskov et al., 2018; Johannsen et al., 2011).

Another example of the quality-of-care registry is the Swedish Dementia Registry (SveDem). SveDem was established in 2007 as an online platform for registering patients with dementia in order to evaluate the quality of the care services they receive and the adherence to the national guidelines. The registry has expanded since 2007 to contain almost 74000 patients by

2017, with data about diagnostic work-up, treatment, and community support (Religa, Fereshtehnejad, Cermakova, Edlund, Garcia-Ptacek, Granqvist, Hallbäck, Kåwe, Farahmand, Kilander, Mattsson, et al., 2015). SveDem is currently covering almost all of Sweden, representing the most comprehensive dementia registry we have (Hopper et al., 2016). The quality indicators for SveDem are quite different from those of DCDR, including the percentage of patients diagnosed in a year, the proportion of patients undergoing basic dementia work-up, the proportion of patients treated with cholinesterase-inhibitors and/or memantine, proportion of patients treated with antipsychotics in nursing homes, proportion of patients with day-care at diagnosis, proportion of patients living in nursing homes and proportion of patients followed-up at least once a year (Religa, Fereshtehnejad, Cermakova, Edlund, Garcia-Ptacek, Granqvist, Hallbäck, Kåwe, Farahmand, Kilander, Winblad, et al., 2015). SveDem data has also greatly influenced research in different areas of the disease, including diagnosis, clinical aspects, treatment, risk factors, and costs (Cermakova et al., 2017; Enache et al., 2016; Religa et al., 2012a; Rosén et al., 2015; Wimo et al., 2013). All SCADR, WVADDR, GARDAR, ReDeGi, DCDR, and SveDem were identified to be active dementia registries that are still recruiting cases and meet the inclusion criteria for dementia diagnosis (Hopper et al., 2016).

Moreover, many small initiatives for dementia are in the sort of local, hospital-based, or university-based registries in several countries. There are also national registries that are in the stage of planning and implementation as the dementia registries of Cuba and Ireland (Cáceres, 2015; Hopper & Bowen, 2021).

2.2. Types of Dementia registries

According to Kyrinska et al., dementia registries can be classified according to their aims into three main categories: 1) Registries that facilitate research, including preclinical research registries and registries recruiting research volunteers. 2) Registries that collect epidemiological data, and 3) Registries that focus on the quality of patient care. Table 1 presents the different aims of each of the registry types (Krysinska et al., 2017a).

Research registries are usually created to support research in the dementia field by recruiting patients and collecting the information required for providing evidence on the disease progression and management outcomes as a source for researchers. The data could be used to develop more accurate diagnostic measures, suitable interventions, and new management techniques. There are two subtypes of research registries according to the focus or the participants. The preclinical research registry focuses on conducting preclinical trials, and the research volunteer registry collects data from cohorts of dementia patients along with healthy volunteers. Another type of registry is the epidemiological registry which collects data across a specific region to provide information about the prevalence, incidence, and risk of the disease. There is also the quality of care registry that follows specific criteria for patients' quality of care and provides information on the effectiveness of the available interventions (Table 1) (Krysinska et al., 2017a).

Table 1: Types of dementia registries

Category of registry	Aims
Dementia research registry	• To support research into causes and risk factors for dementia. • To provide data on the natural history of dementia, determinants of progression, and their implications for clinical management. • To develop and measure the effectiveness of interventions to reduce the risk and incidence of dementia, its treatment, and management. • To evaluate and refine the diagnostic criteria for dementia to standardize and validate screening instruments and diagnostic tests.
Preclinical dementia research registry	• To optimize the conduct of clinical trials in preclinical stages of AD/dementia, to accelerate cohort development and trial recruitment.
Dementia research volunteer registry	• To identify people with dementia, their carers, and healthy volunteers willing to be involved in research studies and clinical trials.
Epidemiological dementia registry	• To collect epidemiological data on the prevalence, incidence, and risk of dementia.
Quality of dementia care registry	• To monitor the quality of dementia care. • To provide information on utilization and cost of health and aged care services and carer support and inform planning and development of dementia services.

Source: Author compilation based on (Krysinska et al., 2017)

2.3. Benefits of Registry Data

Disease registries have proved to significantly improve the knowledge and research on dementia. The availability of massive datasets on patients with dementia opens the opportunity for researchers and clinicians to deeply investigate situations and outcomes to inform the policymakers or governmental authorities regarding the required actions. The use of registries' data to investigate different areas of the disease was studied in order to evaluate the impact of dementia registries on advancing the knowledge of the disease. The use of observational, cross-sectional, and longitudinal data from the various national and international dementia registries has greatly impacted several aspects of the disease (Figure 1) (Heikal et al., 2022). Registries' datasets facilitated the emergence of research studies that quantify the disease burden to report on the prevalence, incidence, risks, and mortality rates in different regions. Having this information is essential to be able to identify the patients at risk, decrease the risk of mortality and reallocate the resources according to the disease prevalence in each area (Heikal et al., 2022).

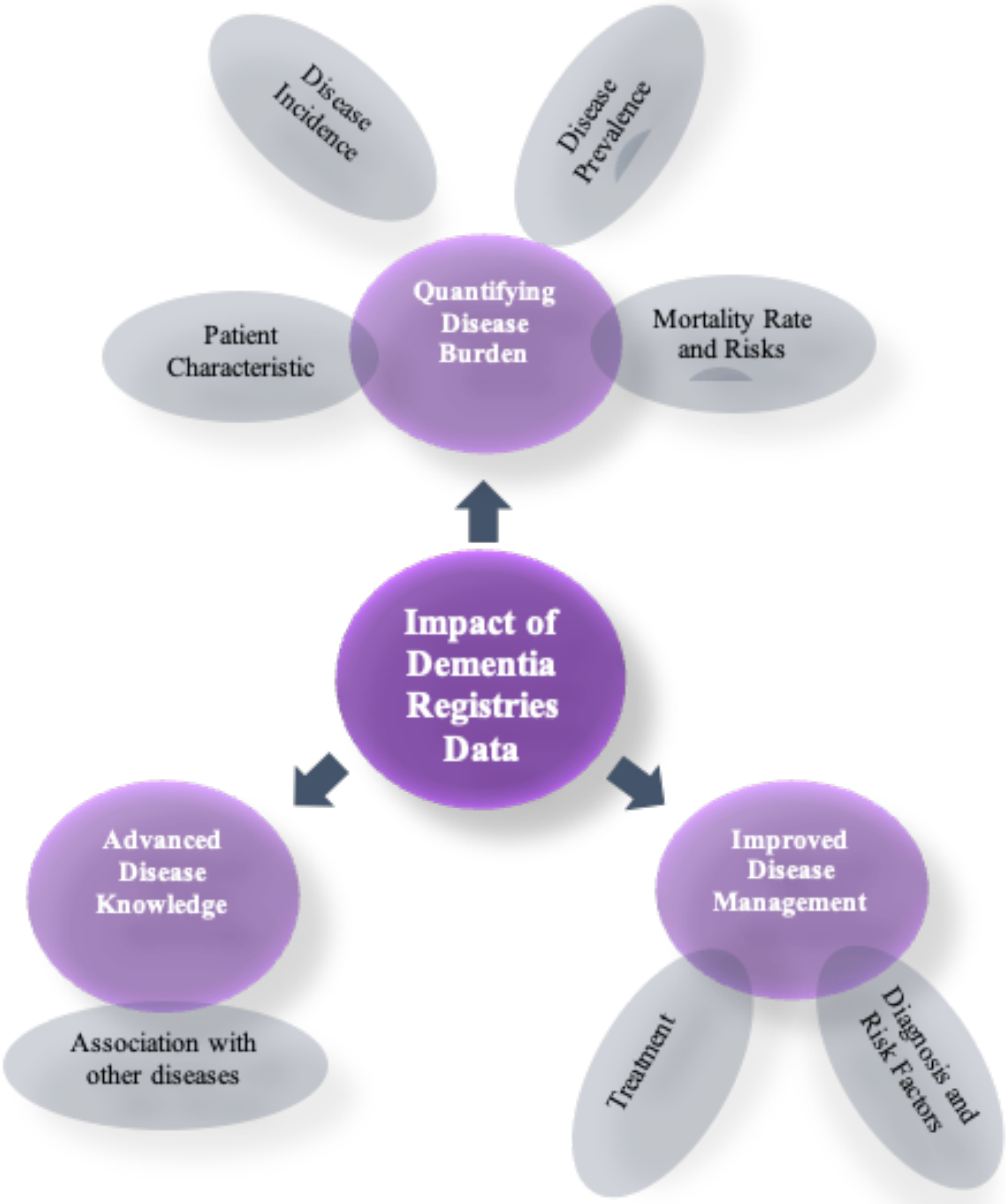
First of all, understanding the quantifying measures of dementia is the major benefit of registry data in terms of calculating the disease prevalence, incidence, characteristics of patients, and mortality rates. For instance, many studies were conducted using SveDem, and ReDeGi data provided valuable information on the prevalence of the disease in a country, the mortality rates and risks which is essential to develop algorithms that predict the disease and develop plans to improve patient survival (Calvó-Perxas et al., 2012, 2019; Garcia-Ptacek et al., 2014; García-Ptacek et al., 2014; Religa et al., 2012b; Stokes et al., 2020).

In addition, registry data extensively benefited the disease management processes, including disease diagnosis and treatment. Data from NACC, PRODEM, and CREDOS were investigated to identify the modifiable and non-modifiable risk factors of dementia. Determining the risk factors of the disease is crucial to facilitate the early detection of dementia which is greatly valuable for improving patients' outcomes. Also, the tracking of the outcomes of using different interventions and treatment medications would significantly benefit the development of more precise treatment plans (S.-M. Fereshtehnejad et al., 2015b; Garre-Olmo et al., 2016; Myung et al., 2017; Religa et al., 2012b).

Moreover, advancing our knowledge in terms of exploring the association of dementia with other diseases would help determine more appropriate strategies for managing these elderly patients. They usually suffer from different comorbidities and require more careful interventions. Data from NACC, ReDeGi, DCDR, and SveDem were used to analyze the outcomes of using treatment interventions in the absence or presence of comorbidities to compare the results and identify the most precise approaches with the ultimate goal of improving the quality of dementia patient lives (S. M. Fereshtehnejad et al., 2014; S.-M. Fereshtehnejad et al., 2015b; Martín-García et al., 2013).

Given all the benefits of dementia registries, the importance of having this kind of dataset, and their contribution to enhanced health outcomes, all countries should start developing a plan for establishing their own registries of data to support their planning, policymaking, service provision, and clinical care practice.

Figure 4: Impact of Dementia Registries Data



Source: Author compilation based on (Heikal et al., 2022)

Chapter Four: Methodology

4.1. Study Design

To investigate the feasibility of creating a disease registry in Egypt, the author aimed to generate an evidence-based study that addresses the national needs and identifies the most suitable registry model to be followed in the Egyptian context. Thus, the study followed a qualitative research design to explore the different aspects and dimensions of creating a national disease registry and specifically delve into the situation of Dementia in Egypt as a case. The qualitative design also aimed to explore both the national and international contexts to identify the different constraints that the registry might have and the learned lessons that the registry can benefit from. The topic of disease registries is widely broad and requires collaboration from different stakeholders. This required interviewing key experts with a wide range of expertise to reach a comprehensive conclusion and better recommendations on how to create this first national registry in Egypt.

Understanding the situation in Egypt and the experiences of the leading countries is crucial prior to developing the registry. Thus, the qualitative research design was selected as it is perfectly used to holistically study interpretations and processes (Punch, 2006), enable human interaction (Marshall & Rossman, 2015), and investigate human experiences to answer the how's and why's (Silverman, 2016).

The study also provides expert, evidence-based policy recommendations for improved structuring of the registry and dementia in Egypt. The author and the committee have a good background in the field of aging, and lead and participated in many workshops. Therefore, a strong network of experts in the field, both nationally and internationally, was established, which made the data collection process easier.

4.2. Methodology

To garner a wide range of views and aspects of the research topic, the researcher did a quick literature search to review the policy documents and the published studies that discussed the topic. Then, the main research methodology was conducting expert interviews with national and international registry experts, dementia researchers, government specialists, clinical specialists, and other stakeholders to investigate the idea of creating a disease registry in Egypt, its potential impact, proposed challenges, and most appropriate structure of a registry to generate. The interviews were not about the experts or their patients but to evaluate the expert’s knowledge and expertise in the field as key informants about the impact of disease registries. All data collected were primary data depending on the expert's kind of knowledge and experiences based on his area of work, types of responsibilities, and their specific functions in their organizations. In this regard, we divided the areas of expertise that we needed to interview people who have knowledge into 1|) Existing Dementia registries around the world; 2) Health policy and governmental regulations; 3) Clinical management of dementia patients in Egypt; 4) Training and research in neuroscience, Aging in Egypt; 5) Social research, especially with aging and dimensions, and 6) NGOs advocate for old-age patients and the services provided for them (Table 2).

Table 2: Areas of expertise for interviewees selection

Area of expertise	Sub-categories
Existing registries around the world	• International Dementia and Alzheimer's Disease Registries • Other neurodegenerative disease registries in Africa • Aging longitudinal databases
Health policy and governmental regulations	• Ministry of Health • Health Policy Faculty
Clinical management of dementia in Egypt	Neurology and Geriatric Consultants and staff of: • MOH Governmental hospitals • Universities Public hospitals • Private hospitals • Mental Health Secretariat Hospitals • Memory Clinics
Aging neuroscience research in Egypt	• Neuroscience Researchers • Aging and Dementia Researchers
Social and public health research	• Social Health Faculty • Social Researchers on Aging • Public Health Researchers
Training	• Training Consultants of Geriatric Physicians
NGOs for old-age individuals	• Nursing Homes • Health NGOs
Data Collection and Analysis	• Data Collection/ Analysis Consultant

4.3. Sampling

An initial list of interviewees was purposively created based on the knowledge of the advisors, including representatives from the international registries, known Egyptian researchers, and clinicians in the field. The researcher first determined preliminary criteria relevant to the objectives of the research to guide the selection process. These criteria included: all participants should have the knowledge and experience in one or more areas of expertise mentioned above (Table 3), Diversity in the field of expertise, the sub-field, position, gender, and work organization were taken into consideration as much as possible. Additionally, the data collection involved triangulation as it employed multiple sampling strategies, including purposive sample, typical case, key informant sampling, and confirming and disconfirming cases (Marshall & Rossman, 2015). The selection of interviewees depended on many ways, starting with the networks of the advisory panel, the discussions with people in the field, recommendations from the interviewees themselves, as well as the literature. In addition, the available database of the specialist participants and collaborators of the TEC-MED project for elderly care and the preparatory meetings for the Egyptian longitudinal aging study (which are both coordinated by the advisory panel) was used to select the interviewees.

Following the IRB approval (Annex 1), the selected interviewees (n=39) were contacted either by email or phone calls and were given an explanation of the research with a request for an interview. However, the list was not fixed from the beginning of data collection, and some potential experts were added based on the interviewees' recommendations or based on the results of the primary analysis. Out of the 39 experts in the list, those who accepted to participate in the study with oral or written consent were individually interviewed (n=24) (Table 3). Unfortunately, some experts on the selected list were unavailable for formal meetings (n=15) for various reasons.

Table 3: Interviewees' Profiles and Codes

	Gender	Field of Expertise	Region	Code
1	Male	Neuroscience Research	National	NR 1
2	Male	Neuroscience Research	National	NR 2
3	Male	Health Policy	National	HP 1
4	Female	Public Health Research	National	PHR 1
5	Female	Social Research	National	SR 1
6	Female	Social Research	National	SR 2
7	Female	Clinical Neurology	National	CN 1
8	Male	Clinical Neurology	National	CN 2
9	Female	Geriatric NGO	National	GN 1
10	Female	Data Consultant	National	DC1
11	Female	Geriatric Training	National	GT 1
12	Male	Geriatric Training	National	GT 2
13	Male	Clinical Neurology	National	CN 3
14	Male	Registry Specialist	International	RS 1
15	Female	Registry Specialist	International	RS 2
16	Male	Aging Research	International	AR 1
17	Female	Registry Specialist	International	RS 3
18	Female	Clinical Neurology	National	CN 4
19	Female	Registry Specialist	International	RS 4
20	Male	Registry Specialist	International	RS 5
21	Male	Registry Specialist	International	RS 6
22	Female	Registry Specialist	International	RS 7
23	Female	Registry Specialist	International	RS 8
24	Female	Registry Specialist	International	RS 9

4.4.Interviews

Data was collected using semi-structured in-depth interviews with the selected experts. In-depth interviews are the most common qualitative method that facilitates the discussion of participants' knowledge, opinions, and experience, which is perfectly fitting with the study objectives (Mack et al., 2005). The interviews were mainly by telephone or zoom according to the interviewee's availability and place. Very few interviews were conducted face-to-face due to the COVID-19 pandemic constrictions at the time of data collection.

Interview questions were designed to provide a deep idea of the expert's opinion and experience regarding developing a dementia disease registry in Egypt (Annex 2). The questions were semi-structured to investigate more insights specific to each expert's case and let them speak without restrictions. The questions also included qualitative and quantitative points for determining their background in disease registries, their opinions about the importance of the idea, their understanding of challenges, and their ability to help in creating the registry. The questions were categorized into main themes following a similar study conducted in Ireland (Hopper et al., 2016) (Table 4). Questions regarding costs, funding, sustainability, and policy implications were added whenever relevant to the expert's knowledge. When the conversation tended to skew in an unwanted direction, probing questions were used to return to the relevant discussion. In addition, sometimes, follow-up emails were conducted with the interviewees when specific questions emerged.

Table 4: Main themes of interview question

Personal experience of registries	Data inclusion	Data ownership and governance
Challenges for piloting a registry	Data collection	Ethical considerations

4.5. Data Analysis

All interviews were audio-recorded or video-recorded when on Zoom. The international interviews were conducted in English and transcribed intelligent verbatim. The interviews with Egyptian experts were conducted in Arabic, transcribed then translated into English. All interviews were anonymized with every effort, but given the nature of expertise and the limited number of experts in the field, some experts might be identified from the context. However, we have used codes indicating the area of the interviewee's expertise instead of the normal interviewee profile and without mentioning the position or organization for better anonymization. The transcripts were then analyzed using the inductive approach as shown previously(Elo & Kyngäs, 2008; Hsieh & Shannon, 2005). We first divided the transcripts into several sections, then used open coding, and derived and grouped the themes from the text. After creating the thematic index, cross-checks were obtained to guarantee the validity and understandability of the codes and themes. Moreover, some data were coded following the Irish study as we found many similarities in the derived themes taking into consideration the different contexts.

4.6. Ethical Consideration

An IRB approval from the American University in Cairo committee was obtained for this research. All interviews were conducted in the period between January and October 2021 after the

IRB. An informed consent form was used to notify the participants about the purpose of the study, either written or verbally. Participation in this study was voluntary, and we obtained permission from the interviewees prior to recording the meeting. All the interviews, transcripts, and recordings are confidential, and only the authorized access them. The author made all the transcription, interpretation, and analysis procedures with no external help to assure the confidentiality of the data.

4.7. Study Limitations

The limitations of this study could be the difficulty of collecting data and the initial resistance of participants in specific fields, especially government officials. The interviews were limited to 20 to 30 minutes as we interviewed experts with hectic schedules. Another main constraint was the COVID-19 pandemic restrictions which affected the interview procedure as we had to conduct most of the interviews via Zoom, even with the participants from Cairo. The Zoom meetings, in any case, were limiting as some participants were not comfortable using the camera, and this made it difficult to see their reactions which could give insights on what else should be asked. We otherwise depend only on their answers to the questions. The pandemic restrictions also made it difficult for some potential experts to participate in the study. However, the diverse selection of the list enabled us to get input from experts in all the required areas.

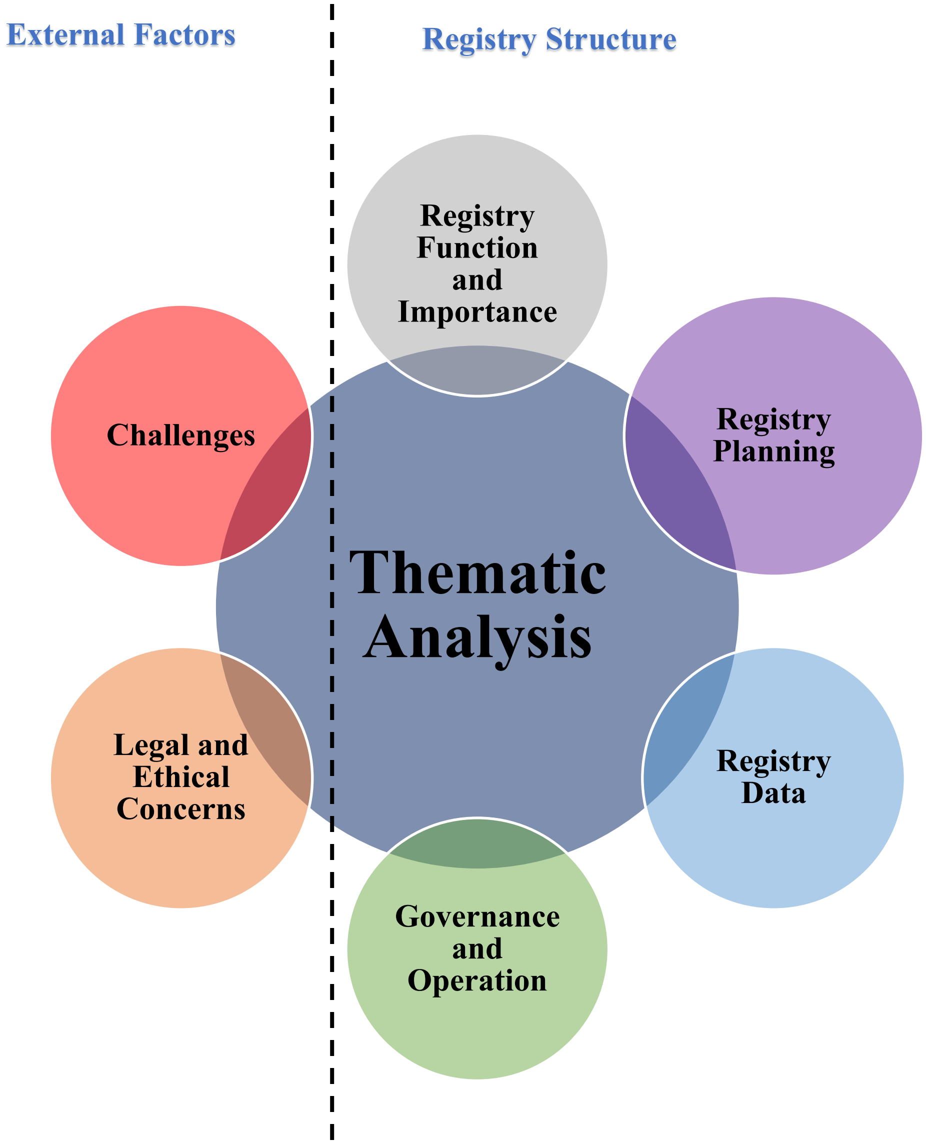
The study, as well, was done on a small sample population and can not be generalized. However, it gives us a brief insight into the feasibility of the construction of such a registry and what our next steps should be.

Chapter Five: Findings and Discussion

Disease registries are crucial for enhancing the record of medical knowledge and health care development. However, registries can be expensive and require the involvement of many stakeholders due to ethical and logistic concerns (Newton & Garner, 2002). Thus, carefully planning the registry that obtains specific objectives that satisfy a country's needs is essential to guarantee its success and sustainability (R. E. Gliklich et al., 2014d). Putting this in mind, the research's main objectives were to undertake the analysis of relevant experts' perceptions and opinions to 1) Identify the model of the registry that perfectly fits the Egyptian context and 2) Provide evidence-based policy recommendations for the registry planning structure and development. The analysis of the in-depth interviews conducted through this study revealed several findings that constitute six main themes covering the registry structure and the external factors affecting its development (Figure 5). The themes are: 1) Registry Function and Importance, 2) Registry Planning, 3) Registry Data, 4) Governance and Operation, 5) Legal and Ethical Concerns, and 6) Challenges. Figure 5 presents a graphical representation of these themes.

> *"Starting, one has to strategize and possibly borrow from experience from other people so that you don't necessarily have to make the mistakes that others have made but also understand the pros and cons of whatever method you choose at the end the d (Registry Specialist, RS3, International, Sep 2021)*

Figure 5: Thematic Analysis of Expert Interviews



5.1.Registry Function and Importance

All experts agree that dementia registries are important tools with several useful functions. They related the functions to numerous benefits that will impact different fields, including research, quality of patient care, disease knowledge, and policymaking. The consensus is that they are essential in collecting information about dementia patients, which will inform the practitioners of all these fields. A neuroscience researcher and university professor, who works at one of the biggest research institutions in Egypt, and who worked for part of his life in top universities in the United States pointed out that having a disease registry has many benefits for managing the disease in a country. He stated:

> *"So the benefit of the disease registry really can be summarized in two points: 1- Is that it actually facilitates research for intervention and then for sustainable solutions. 2- Is that actually it helps you to track the success and how do you use your limited resources in terms of funding and provide the best services" (Neuroscience Researcher, NR2, Cairo, January 2021)*

The neuroscience researcher is confirming that registries are beneficial in many aspects other than research as they assist in developing interventions, tracking the outcomes, and allocating resources for the best use of these limited resources, providing the most needed services with limited funding. The researcher's remarks pinpointed that tracking the outcomes of interventions and measuring their success is important to be able to provide the best services and overcome the problem of limited resources. Previous studies showed that disease registries could contribute to better disease outcomes in ways beyond research, such as contribution to clinical management and policy-making (Heikal et al., 2022).

5.1.1. Improve Research

Many experts discussed the value of having a national registry for advancing research in the field of dementia. Most of them agreed that registries providing data on the incidence and prevalence of the disease would help initiate more research studies. The neuroscience researcher elaborated on the importance of having accurate statistics for conducting research studies. He mentioned:

> *"You need to keep statistics on what is the incidence of disease, so you as a researcher, when you do research or when you say one out of a hundred people will get cancer A per year, where did you get this information?" (Neuroscience Researcher, NR2, Cairo, January 2021)*

The neuroscience researcher's remarks showed that any researcher would need to have accurate statistics of the disease incidence or prevalence to be able to build on them while doing research in the area of the disease. He clarified that researchers should have evidence from the country that states the disease situation so that they can prioritize working on some areas and be able to predict the disease or have valid data that supports their studies.

Similarly, another neuroscience researcher who works as a neuroscience faculty at one of the biggest universities in Egypt discussed the same idea of advancing research, especially association studies. He stated:

> *"The second thing is the association studies. If I have a registry or proper method of stratifying the patients, then ... I can say that area X from Mansoura ...has a high incidence of this disease, then start figuring out why. ...It can make our life a lot easier" (Neuroscience Researcher, NR1, Cairo, January 2021)*

The researcher highlighted the importance of having accurate numbers that will inform us about the geographical representation of the disease. Considering that will help researchers investigate the causes and determinants of the disease that led to the exacerbation of the problem in one area. In addition, a clinical neurologist who works at a hospital with one of the biggest geriatric departments in Egypt and is working on dementia research with some international collaborators emphasized the idea of the critical role of registries in attracting funds for research. So, other than knowing the incidence and prevalence, the registry data will help evaluate the importance of studying this specific disease to allocate funds. He mentioned:

> *"There is no doubt that registries are critical. They are basic practices, as we say. It is impossible to know prevalence or incidence to evaluate funding for specific disease management or even implement any sort of research without a registry. So, if you need funds to do research on dementia, is dementia important to the extent that it costs them this fund or not? So, all we have now is a very wide range of assumptions and data that cannot be generalized." (Clinical Neurologist, CN2, Cairo, Jan 2021)*

The neurologist's remarks revealed how accurate numbers will give an idea about the existence of the disease in the country, how the research would impact the disease outcomes, what is the most important studies to be implemented, etc. All of this would help identify and manage the funds granted to this kind of research.

Moreover, the neurologist presented the problematic situation in Egypt as there is no accurate data on the prevalence of dementia in the country. We currently depend on some small studies that 1) provide a very wide range of assumptions which is confusing in many cases, and 2) were conducted in small cities or limited geographical areas, which cannot be generalized to the Egyptian population (Elshahidi et al., 2017).

5.1.2. Impact Quality of Care

All experts agreed that collecting patients' data in a national registry would extremely impact the clinical care of patients and improve the quality of the services provided to them. Most of them emphasized the concept of benefiting patients as the main objective of any disease registry.

Assessing the data of patients with dementia and tracking the outcomes of used interventions help the healthcare providers identify the needs of patients and improve the services provided to them. In addition, the registry contributes to the proper distribution and organization of services which also impacts the quality of patient care. One of the experts involved in a quality of care international registry confirmed that the main objective of creating any disease registry is to improve the quality of patient care. She mentioned:

> *"To register is to improve quality of care, quality registries assess the data from a quality radius, it could be used for like research or statistics. But the primary goal is to prove quality of care of people with dementia." (Registry Specialist, RS9, International, Oct 2021)*

The specialist quote mentioned that the data definitely arise to get statistical information and for research purposes, but the quality-of-care perspective is an essential part of a registry. All of this is in line with the previous studies that investigated different patient registries and their impact on the quality of care of patients (Hoque et al., 2017).

In the same manner, A social researcher who has a medical background and works at one of the biggest social research centers in Egypt mentioned that one of the ways to think of or use a registry is to figure out the needs of these patients and start responding to that based on the information you have of what will work and what will not. She stated:

> *"It is more important to think about this registry as a way of identifying the needs of people who are suffering from these diseases and respond to them in a more proper way and on a scientific basis." (Social Researcher, SR2, Cairo, Jan 2021)*

From the researcher's point of view, providing services based on science and evidence we have would be of great benefit in terms of the value of health services provided. Similarly, a researcher in the public health field discussed the importance of collecting data, particularly for these elderly patients, to be able to support them in the most proper ways they usually have needs beyond the clinical services. She mentioned:

> *"A registry is something you keep in all the information about people suffering from a specific health condition, as in your case, dementia. It is very important because these people suffer, they have chronic conditions, they need support not only clinical, they need the help of clinical practice, maybe they have social needs, psychological needs, etc." (Public Health Researcher, PHR1, Cairo, Jan 2021)*

The researcher confirmed that the patients with this disease, as is the case with any chronic condition, suffer from a lot of issues that affect their quality of life. They usually need many interventions, not only clinical but also require social and psychological interventions. Having registered data would assist in identifying these needs and responding to them properly.

One other benefit of a registry regarding the aspect of improving quality of care is the organization or the structure of work. A registry specialist who works at one of the well-established international registries outlined her experience with clinicians who used data from registries. She stated:

> *"The registry helps them to get the structure of the work. Because they see we should do this and based on back reports we missed this, MMSE or we didn't do the clock test, and we have to start doing it ... They will have less unspecified demand. When basic demands investigation goes out the unspecified, the misdiagnosis goes down." (Registry Specialist, RS8, International, Oct 2021)*

The specialist's quote highlighted that the registry helped the clinicians in her country organize the work they do and identify the most and least important procedures so that they can decrease the unspecified demand. In addition, when the clinicians follow the basic investigation procedure identified by the registry, they will help accurately diagnose patients and hence, provide them with the proper interventions.

In the same regard, a clinical neurologist who works in one of the biggest private geriatric hospitals in Egypt with also international experience as he worked for two years in the UK related the same problem to the Egyptian context. He mentioned:

> *"We don't depend on GPs; the specialist or consultant is the one organizing the service. So, I think the first thing a registry would do is that it will help distribute the service and understand the different needs ... We know what services they need and how to allocate them." (Clinical Neurologist, CN3, Cairo, March 2021)*

The neurologist's comment clarified that our system does not depend that much on the general practitioners putting all the hectic process of identifying and diagnosing patients on the shoulders of the specialists or consultants. This, in turn, leads to the increase of un-detection or late detection of cases. A registry is important for organizing the structure of this work, putting basic investigation measures which will facilitate the process of diagnosis. This finding is in line with the experiences learned from the well-established international registries mentioned above.

5.1.3. Provide Accurate Information

Most experts agree that dementia registries provide numerous useful information. The standards and regulations of the development of registries assure the provision of high-quality or validated data that gives us information about different aspects of the disease. The fact that we still do not have any accurate prevalence of dementia in Egypt and that we rely on estimations is challenging for healthcare providers and policymakers in terms of proper planning.

A registry specialist who is involved in an international dementia registry and who has a good background in the Egyptian health system from his research collaborations discussed the importance of having accurate information for planning disease interventions. He mentioned:

> *"Doing this on a national basis, we will be able to track the numbers and the outcomes for these individuals, and it is very important in terms of getting a handle on the numbers of people that actually have the condition, looking at the healthcare utilization by these individuals, and track their outcomes over time. In terms of planning for health service provision, it is important to have the national numbers but also the resources that they require and the interventions that they need" (Registry Specialist, RS1, International, May 2021)*

The specialist highlighted the importance of a registry to have accurate numbers that allow you to calculate the prevalence and incidence of the disease. In addition, the information provided enables tracking the disease outcomes over time, which is essential to understanding the needs of patients, the interventions they need, and hence, the services they require.

In addition, another specialist involved in an international registry elaborated on how the registry data can be updated to provide accurate data regularly. She stated:

> *"So, what we do on a yearly basis, we pull the new diagnoses each year, so, then we can calculate the prevalence of the disease, and release an annual report every year, so that's the report that goes out to the public, anyone can access it." (Registry Specialist, RS4, International, Oct 2021)*

The specialist note clarifies that not only the registry users can have the numbers of the disease at a time, but they can also update their calculations regularly based on the follow-ups they do so that they can track the outcomes over time. This greatly impacts the planning process and service provision as having the information will make it easier to identify the needs and suitable interventions.

Similarly, a data consultant who works in healthcare-related areas emphasized the role of having data in identifying the causes of disease. She mentioned:

> *"So, when you do big data analysis at the end, you will discover that there are determinants that cause the disease in a specific geographical area or in a specific population" (Data Consultant, DC1, Cairo, Jan 2021)*

The consultant's note clarifies the importance of using the current advanced big data analysis techniques to be able to dive deeply into data and discover new insights regarding the causes, the determinants, or the distribution of a disease in specific geographical areas. This, again, sheds light on the importance of identifying the determinants of the disease in each community as there are factors that might associate with specific populations and not others. There is evidence from previous studies that support this idea of the variation of disease causes in different geographical areas (Russ et al., 2016).

Another powerful aspect of a registry is the standards and regulations they follow. A neuroscience researcher working in Egypt highlighted the advantage of being able to have information regarding the data collection, protocol, sampling, and source of data. He stated:

> *"The disease registry imposes certain standards, so it tells you that your study has to be approved by the IRB, the data you are collecting, the protocol for collecting samples that will be information included in this database. So, you know, there is some level of quality assurance, quality control of the data, improvement, and so on. And whether that sample is coming from Assuit, or from Aswan or from Port Said ... There you're reducing bias" (Neuroscience Researcher, NR2, Cairo, January 2021)*

The researcher's comment pinpointed that the registry data is also powerful due to the fact that they were collected according to specific standards and protocols. This information ensures the validity and quality of data as well as reduces bias.

Moreover, the experts agreed that there is a great need for this kind of information in Egypt in order to support and improve the healthcare system, especially since we lack any sort of information regarding the geriatric population. A clinical neurologist working in a geriatric hospital highlighted the fact that millions of elderly individuals are living in Egypt and that their percentage in the population is expected to increase in the coming decades. He stated:

> *"According to the latest census, the number of geriatrics in Egypt is at least 7 to 8 million. We are unaware of all their social aspects, their medical aspects, financial or functional aspects." (Clinical Neurologist, CN2, Cairo, Jan 2021)*

The neurologist's statement indicates that geriatric patients in Egypt are expected to increase, which was also mentioned in previous reports (Gadallah, n.d.). However, we do not have any information regarding any aspects of these individuals' not only medical but also social and financial aspects. This situation is problematic as elderly individuals are vulnerable. They need more special care and provision of services. This idea confirms the importance of the availability of information that helps advance healthcare system planning.

Many experts discussed, as well, the need for having accurate prevalence numbers in Egypt to determine the disease burden and identify the need to develop specific goals, plans, and interventions that help properly allocate the resources and services while saving efforts and money. An Egyptian neurologist who works in one of the biggest public dementia hospitals in Egypt and who is also working on dementia and neurodegenerative diseases' research expressed from her point of view how we lack data on dementia and how that affects our response to the needs of the patients. She stated:

> *"It is very important. I do not have the epidemiology of the disease in Egypt, so I cannot describe the burden of the disease. do not know the prevalence, if it is common or not, to be able to work and provide services and inform the policymakers how much the number of patients is predicted to increase and what services they need" (Clinical Neurologist, CN1, Cairo, Jan 2021)*

The neurologist's comment revealed how the lack of data is impacting the clinical work on dementia in Egypt. She highlighted the problem that she, as a clinician, does not have any evidence to help her request the resources she wants in her hospital that are sufficient for the number of patients.

In the same manner, a geriatric training consultant working in one of the research academies specialized in providing training for geriatric practitioners and who also is a professor of geriatrics in one of the biggest universities stated that these epidemiological data and tangible numbers are essential for the determination of Egyptian needs in order to set the appropriate goals or plans. She mentioned:

> *"Speaking of the epidemiological studies, to have a prevalence of the disease is essential to figure out where you are, what are the services that should be provided, what should you do or what is your goal, to have a clear plan with clear targets. Tangible numbers are important for Egypt." (Geriatric Training Consultant, GT1, Cairo, March 2021)*

In addition, another geriatric training consultant working at the same academy and who has experience as a medical practitioner abroad discussed the importance of having data about Egypt to identify which interventions we can adopt from international practices. He stated:

> *"Having data helps a lot in interventions, so we do not invent the wheel, that extremely saves time, efforts money and everything" (Geriatric Training Consultant, GT2, Cairo, March 2021)*

The consultants' notes pointed out that the availability of information helps clinicians provide services based on our information. From their point of view, clinicians should not invent interventions without evidence. Instead, they should understand the status of their patients and develop plans accordingly.

Furthermore, the main fact that every population is different from the others is also a problem for the Egyptian context. A clinical neurologist who works in one of the biggest dementia hospitals in Egypt presented her experience with elderly patients. She mentioned:

> *"Another thing is that what we have is not exactly what is in the textbooks. So, not everything we read in books can be applied to our patients in terms of onset of symptoms, progression, survival rate, or so on. Genetics, environment, and many things affect the phenotype of the disease. So, including all the patients will help us understand the nature of the disease and compare what we have to what is there in the world. I cannot build assumptions on one or two cases; I have to collect a very large number of cases to be able to analyze" (Clinical Neurologist, CN1, Cairo, Jan 2021)*

The neurologist's comment expressed how the situation of not having accurate national data could be problematic as what is known globally about disease development, progression or survival should not exactly apply to our population. She also stated that depending on small sets of data is also useless because it will only provide inaccurate assumptions. This information harmonizes with what was mentioned earlier regarding the importance of collecting national data of Egyptian patients to provide accurate numbers and statistics, as well as being able to compare our patients to international populations (Elshahidi et al., 2017; Salem et al., 2020).

5.1.4. Support Policy and Decision-Making

Most experts agreed that having a registry that provides national data on dementia will be a good source of information that influences policy and decision-making. A registry provides evidence-based data that assist in developing appropriate plans, strategies, and policies. An Egyptian health policy consultant who works as a government official and who is involved in many health-related committees pinpointed the importance of integrating a national registry into the healthcare system. He mentioned:

> *"Registry it is very important for health authorities and for also scientific research and for education in general … it is very important to know the exact numbers and profile of any disease … so that our resources can be.., if we have for example breast cancer… the percentage in Egypt is higher than for example pancreatic cancer, so we will have more financial resources to combat breast cancer. It is very important to plan for the health in general as payment or as prevention and to put the health plans" (Government Official, HP1, Cairo, January 2021)*

The consultant explained from his experience how the policymaking process could benefit from having accurate national numbers of the patients, their distribution, and their characteristics. He also highlighted how this information could support the planning process in terms of allocation of services, budgeting, and developing the general health plan.

Similarly, a specialist involved in an international dementia registry indicated that the information provided by registries is essential for the health authorities and for the litigation processes. She mentioned:

> *"From the registry itself, this information is important for health authorities because they now hold the patients arrived at the public health system, the survey at which the number of individuals in different places and the problems. That information is useful for help on litigation." (Registry Specialist, RS6, International, Oct 2021)*

The specialist's comment clarified how the registry data could be used to inform policymakers regarding the number of patients, their distribution, and their problems which helps the policymaking processes. All of this data is in line with the published benefits and outcomes of disease registries, as illustrated previously (Krysinska et al., 2017a).

5.2. Registry Planning and Design

There is no doubt that planning a registry is an essential step that helps define a clear registry structure, guidelines, and roadmap to follow during the implementation process (R. E. Gliklich et al., 2014d). Experts agreed that the proper planning of the registry would be crucial to guarantee its success. Starting from the involvement of interested stakeholders to include their input when designing the registry, determining the goals and objectives to design the registry accordingly, identifying the data sources to be used and the type of data to be included in the registry, then implementing a pilot of the registry for evaluation prior to expanding it into the national level.

An expert involved in one of the international registries has clarified the difference between the registry types and related that to her experience. She mentioned:

> *"So, there are clinical registries where there's more specific information, for you know, a certain subset of individuals, and then there's a population-based registry. We have a population-based registry, so we look at the entire population and basically determine the number of cases within that entire population. Now we are able to follow up with certain subsets of individuals, so if we do want to do a follow-up study or even a retrospective study, we are allowed to do that. We can contact individuals within the registry." (Registry Specialist, RS4, International, Oct 2021)*

It is clear from the expert's quote that the type of information you need the registry to provide is going to determine the type of registry. In addition, she explained from her experience how there is overlap between the registry types as a registry that was created for the purpose of epidemiology can be used after that for providing specific clinical information and assisting the initiation of research studies. This can be related to the aforementioned 100 million Seha initiative, as the initiative was launched to collect data about Hepatitis C patients in Egypt. Yet, the data collected also gave insights into the prevalence of other diseases including diabetes, high blood pressure, and obesity. Understanding this idea is extremely important so that stakeholders will be sure that even if the registry is designed to focus on specific outcomes, it will also benefit them in one way or another. This data is in harmony with what was mentioned earlier of how the different types of registries have impacted all the areas of research, quality of patient care, and policymaking (Heikal et al., 2022).

5.2.1. Involved Stakeholders

There is no doubt that researchers and clinicians should be included in the registry development process as main stakeholders and potential end-users. Hence, we tried to raise the discussion on who else should be involved, especially from the high authorities. Many experts agreed on the importance of involving the Ministry of Health (MOH) as one of the potential partners that should collaborate as government bodies to influence the process. The Ministry of Social Solidarity (MOSS) is also a potential partner as they have the mandate of providing social care for elderly individuals. Experts also suggested the inclusion of CAPMAS in the process as they would be a beneficial partner when collecting population-based data. In addition, including patients and caregivers in the development process to consider their input and opinions while establishing the registry plan. A clinical neurologist working in one of the biggest geriatric institutions in Egypt discussed from her experience the stakeholders that should be involved in the processes of developing a registry. She mentioned:

> *"MOH just started to raise the issue of geriatrics and old age now, but they are not yet fully aware of the area of dementia, I think. So, it would be beneficial to have a partnership. This area of dementia is between MOH, MOSS, and the mental health secretariat. MOSS had a committee once called the geriatric committee, which worked on the geriatric law that was recently released. These are the places that have authority in this area." (Clinical Neurologist, CN4, Cairo, Sep 2021)*

The neurologist's remarks revealed that both MOH and MOSS have started to raise the issue of the needs of elderly individuals. Despite not being fully aware of the situation of dementia, there are plans in both ministries that consider the elderly populations, for example, the recently released law of elderly care. This means that the government is already trying to address the problems of elderly people, which will make them potential collaborators.

In the same manner, a social researcher who has a medical background and has a huge experience in similar research projects added that in addition to MOH and MOSS, CAPMAS also could be a potential collaborator. She mentioned:

> *"Collaborate closely with government bodies that are interested, MOH, MOSS, national planning or combination of them. You should also investigate the positivity that CAPMAS is responsible for data collection and be a partner. They are usually beneficial in data collection" (Social Researcher, SR1, Cairo, Jan 2021)*

The researcher's comment clarifies her point of view on how involving CAPMAS in data collection would benefit and ease the data collection process.

However, one of the training consultants for geriatric physicians who are also working in a governmental position had an opposite point of view regarding CAPMAS involvement. She stated:

> *"Speaking of epidemiology on the national level, that would definitely require MOH as you will have to obtain approvals from CAPMAS to collect data, and that will not be done without the cooperation with MOH. Research or quality of care registries will be different. CAPMAS approvals are for population-based studies or surveys. Collecting patients' data from hospitals will only require institutional approvals and IRBs" (Geriatric Training Consultant, GT1, Cairo, March 2021)*

The consultant's note indicated that the involvement of CAPMAS can be at a later stage as they only require approvals when collecting population-based data. The collection of data from hospitals will only require the involvement of institutions for ethical approvals (Refer to theme 5.1 for more details on approvals and regulations).

On the other hand, an international registry expert emphasized the concept of patient public involvement to include the patients' and caregivers' voices in the process of developing the registry. He mentioned:

> *"It's a useful thing to do. You know the concept of PPV or PPI, patient public involvement. When you are thinking of developing a registry like this, it is a good idea to talk to the clinicians, to the experts but also to patients and caregivers and so they give their input in terms of practical issues… so that you could develop your protocol and your information based on that. They may tell you important things you did not think about that would encourage them to sign up for the registry. PPI is very important and very powerful to have that voice of people with dementia and caregivers when you are planning and developing a registry" (Registry Specialist, RS1, International, May 2021)*

The expert explained the concept from his experience in doing longitudinal studies, and he stated that patients could tell you the practical tips to do in a registry that will encourage them to participate. The inclusion of caregivers is also beneficial to identifying their needs, designing the registry in a way that helps convince them to sign the consent and give you the missing data. This data is in line with the study of Gliklich et al., which was published earlier, discussing the steps of planning a registry (R. E. Gliklich et al., 2014d).

5.2.2. Registry Type

Determining the type of registry that is most needed in Egypt is an essential step that will guide the whole planning, design, and implementation process. As mentioned earlier, dementia registries have several types that depend on the focus or objectives of the registry, including research registries, quality of care registries, and epidemiological registries (Krysinska et al., 2017a). To determine the most suitable registry type, experts discussed the issue of identifying the registry goals and objectives, as well as the needs in Egypt.

Registry Goal

It is worth noting that defining the registry goals and objectives is a critical step that guarantees the success of the registry in satisfying its needs. Experts agreed that the registry should have clear goals and objectives to be able to design the development process appropriately. An expert involved in an international registry emphasized the idea that the type of the registry will depend on the goal and objectives of the registry so that it is built to achieve the expected outcomes. She stated:

> *"It depends on what your goal of the Registry is. So is your goal to identify individuals for intervention or for clinical trials, or that kind of thing, or is the goal of your registry to actually take a look at Egypt and say, okay, this number of individuals 65 and over have dementia? I guess that would have to be like a major first step to really figure out which direction to go." (Registry Specialist, RS4, International, Oct 2021)*

The expert mentioned that one major goal to start with should be identifying the accurate numbers of patients with dementia in Egypt. She stated that having the numbers is the major first step that will determine the further directions of the process.

Experts as well agreed that identifying the goal and objectives is a collaborative process that should include all the stakeholders to analyze the needs. However, it is a very critical step as the needs of the stakeholders are different, and hence, their opinions will vary regarding the determination of objectives and expected outcomes. An expert involved in an international registry explained her experience in involving different stakeholders to identify the objectives as:

> *"It starts to change a little bit depending on whether you're a doctor or policymakers or a person with dementia, you might want slightly different things or a family, you know, a husband or wife of someone with dementia, let's say, and so" (Registry Specialist, RS2 International, May 2021)*

The expert's statement highlights the importance of being careful when involving stakeholders in the planning process. She stated that each of the stakeholders has different needs, which will influence his opinion regarding the type of the registry and the outcomes to be achieved. In this regard, one should be very careful during the planning process to be able to analyze the needs and prioritize them to figure out the most needed outcomes for the country.

Needs in Egypt

It should be noted that understanding the needs of the stakeholders, their opinions, and perceptions regarding the type of registry to be developed is extremely important. Experts have discussed the needs in Egypt from their point of view. They highlighted the importance of several registry types. However, most of them agreed that a quality-of-care registry is the most needed one in order to benefit the patient, which is the ultimate goal of any healthcare-related initiative.

A clinical neurologist who works in a large geriatric hospital in Egypt confirmed the idea of benefiting patients as an ultimate goal. He mentioned:

> *"The point of impact in all medicine and all research is the human being. If you did anything that would not serve the patient, that would be in your own interest. So, you should fund it away from the public. We all are interested in the Egyptian patients" (Clinical Neurologist, CN2, Cairo, Jan 2021)*

The neurologist's statement revealed that the point of impact of medicine and research is the patients. Hence, considering the benefits and outcomes that will impact the Egyptian patient's life should be the major objective of this initiative.

Similarly, a training consultant who works in a training academy specialized in training geriatric physicians in Egypt stated that although all information is important, having data that impact the quality of patient care is the most required. She mentioned:

> *"Everything is important for different perspectives. But I think a quality-of-care registry is more required to know what is there, plan and build upon. Any initiative will have to give opportunities for people, therapeutic opportunities, not to import, not to invent the wheel, we need to use the resources in our community." (Geriatric Training Consultant, GT1, Cairo, March 2021)*

The consultant's comment emphasized the concept of having actual valid data on the Egyptian patients first to provide them with the opportunities they need and then building on it further to include more data. In addition, the experts' remarks endorsed the previously mentioned concept that the needs will vary according to the expertise of the stakeholder. Although the experts agreed on some specific points that benefit the patients, they all discussed the needs that are relevant to their area of expertise.

On the other hand, a social health researcher who is working on health-related research projects indicated her interest in a registry that focuses on the epidemiology and includes data on caregivers. She mentioned:

> *"I am into epidemiology and quality of care. A research registry is going to be limited with the people who are able to analyze it, but the epidemiological one is wider open, and you can use it for research as well. The quality of care is very important, as well as talking about the caregiver. No one in Egypt talks about caregiving, how difficult it is, how it affects the life of the people who are taking care of the person" (Social Researcher, SR2, Cairo, Jan 2021)*

It is very clear from the expert's statement that she is focusing on addressing the gaps that represent problems in the public and social health field. Although she confirmed the same idea of benefiting patients, she has also raised the problem of caregivers in Egypt, especially for dementia patients. Including data on caregivers in the registry would certainly be beneficial, but more analysis on the feasibility of collecting this data should be discussed.

In the same regard, a clinical neurologist working in an Egyptian public dementia hospital and a policymaker who works in health-related governmental positions recommended having a registry that is a mixture of all types. They mentioned:

> *"In Egypt, we need a registry that includes a mix of all the types. We should include data that can be used in research in epidemiology. Including data about the environment, the caregivers, and so on will also help in the quality of care. And let me tell you, no one will be encouraged to help you unless you are doing something for research." (Clinical Neurologist, CN1, Cairo, Jan 2021)*

> *"It should be a mixed one. If I'm speaking about the ministry of health, they need patient care for treatment and prevention. If I am speaking about universities, then the research is much more important, so a combined one is very important." (Government Official, HP1, Cairo, January 2021)*

The experts' quotes highlight the problem of lacking any information about the disease in Egypt. Hence, there is a need for all kinds of data to support many aspects. In addition, a combined model would be of benefit in terms of attracting and convincing the stakeholders to participate. However, the idea of having an inclusive registry that combines everything is the requirement of setting specific objectives and expected outcomes for the registry in order to guarantee the success of its implementation.

Moreover, there are usually overlaps between the different types of registries, as mentioned earlier, so developing a registry with a clear goal would also impact everything. An international registry specialist who has experience in the Egyptian health system has confirmed this concept as he mentioned:

> *"A longitudinal cohort registry that will give you clinical information, cognitive clinical, functional information, would be useful from a research perspective but also be useful from a clinical perspective. I mean, it should inform clinical practice. And I think any information you will collect will inform practice, inform outcomes, and tell you about the cost of care. You are going to be able to figure out a lot and educate out a lot of this." (Registry Specialist, RS1, International, May 2021)*

The expert indicated that creating a registry that focuses on the clinical, functional information while following up the included patients longitudinally will be of great impact on the quality of clinical care and practice but will also impact research, planning, and policymaking. The expert's note pinpoints the fact that planning the registry according to a specific goal is essential, but also that all the data collected as a first step would be beneficial to all sectors. Yet, having a longitudinal cohort that is followed up regularly will give information that can be used for research as well as clinical practice. This finding is in line with the registry design and benefits discussed earlier (R. E. Gliklich et al., 2014g).

5.2.3. Data Sources

Conflicting opinions emerged regarding the data sources that should be used to assist the data collection process in the early stages of developing the registry. Different opinions arose in terms of the sources that would provide the best and easiest way of collecting data. Experts discussed the multiple data sources that we can collect or retrieve information from, including the service providers, the medical providers, patient cohorts, and other resources, in addition to the discussion of the Egyptian context in terms of the availability of this information. Many experts raised the discussion of the many challenges related to these multiple sources of data (Theme 6.3). However, the positive side is that having these different options is advantageous, especially if including data from multiple sources would be possible and manageable.

Service Providers

Many experts agreed that data could be collected from multiple sources or by connecting several service providers. A clinical neurologist who works at a private geriatric hospital in Egypt discussed the importance of including cases from hospitals and clinics, but also nursing homes. He mentioned:

> *"Everything can be collected from the nursing homes, neuropsychiatric clinics, and hospitals." (Clinical Neurologist, CN3, Cairo, March 2021)*

Similarly, an international registry specialist listed, from her experience, all the sources that can be used to collect cases. She mentioned:

> *"So, any individuals that are within a nursing facility, information from clinics either rural, health clinics, mental health department, mental health records, and other aging and elderly sort of resources that we can pull from to gain all of the Alzheimer's diagnoses" (Registry Specialist, RS4, International, Oct 2021)*

Moreover, a clinical neurologist who works in one of the biggest geriatric hospitals in Egypt expressed her opinion of connecting several specialties to be able to collect the largest number of patients. She stated:

> *"For dementia, you have to make connections with different specialties: geriatrics, neurologists, psychiatrists, and maybe family medicine. So, the spectrum can be wider. You can also consider the primary healthcare as they are expanding to be able to provide the primary services to geriatrics including screening for dementia." (Clinical Neurologist, CN4, Cairo, Sep 2021)*

The experts' remarks clarified the different care providers' places as sources of cases, including hospitals, clinics of different specialties, nursing homes, etc. In addition, the experts also indicated the importance of including care providers with different specialties to be able to collect a large number of cases.

On the other hand, a registry specialist that also has experience in longitudinal dementia studies expressed his opinion on collecting data, especially in the first stages of the registry development. He mentioned:

> *"What you can do, say in Cairo, you look at all the clinics there, you have some experts, neurologists, psychiatrists who can make the diagnosis. When people come and make the diagnosis, you will ask if they are willing to get involved in longitudinal follow-up registry, and if they agree, then they will be part of it." (Registry Specialist, RS1, International, May 2021)*

The expert's statement indicates the importance of depending on the network of clinicians for collecting cases, especially in the beginning to facilitate the process of the pilot's initiation while avoiding barriers (Theme 6).

The previous opinion is in line with the experiences of many registry specialists, especially those from countries that do not have legislative mandates that support data collection, as in Egypt's case. A registry specialist involved in one of the well-established international dementia registries discussed his experience in collecting data in the primary stages. She mentioned:

> *"It was on memory clinics because we were kind of interested in population, it started in small scale some years then we added primary care" (Registry Specialist, RS8, International, Oct 2021)*

Similarly, a registry specialist that is involved in international dementia registry and longitudinal studies explained his opinion of starting on a small scale and then expanding the involved service providers. He mentioned that:

> *"You are bringing a consortium, so you are working with neurologists or kind of experts who are willing to work with you. If they were able to recruit X number of people from their clinics into the cohort or registry, very soon, you would have a very large number of people to follow, and then you will have to decide to follow them in six months or a year. And then you have this cohort" (Registry Specialist, RS1, International, May 2021)*

As indicated from the expert's notes, these registries started in a few clinics, either hospital or institutional clinics depending on networking efforts. Then once the registry was initiated, many other data sources were included.

Medical Records

Different experts identified medical records as a major source of data collection. Many experts involved in international registries indicated that depending on patient records to collect data of all the cases previously diagnosed with the disease. One of the registry specialists mentioned:

> *"That's why for us it's easier to access the records, and then, we always have their updated information because last time they went to the doctor, it is recorded. So we can always kind of update their progress over the years … I would even just take a sample of maybe some doctors' offices people go to." (Registry Specialist, RS4, International, Oct 2021)*

The expert's note indicates that using patients' medical records that are available at the doctors' offices is an easy process for collecting data. It also allows for updating the information when patients visit the doctor for follow-up. However, this process depends mainly on the availability of medical records and the accuracy of the information collected in these records according to each system (R. Gliklich et al., 2020).

Regarding the availability of data or medical records of patients, many Egyptian experts indicated that there are large amounts of data recorded in the hospitals or clinics that as it is a common practice for clinicians to record all the data required for a patient, especially during the investigations of geriatric patients. The experts confirmed that the data of patients would be available in hospitals, especially the inpatients. All hospitals have their kind of office that store these records. In addition, they mentioned that the records usually include sufficient data of the patients combining different elements of patients' history and diagnosis that would be very beneficial if there is a possibility to be retrieved. A neurologist who works at one of the biggest geriatric hospitals in Egypt indicated that:

> *"All hospitals, with no exception, have medicolegal that they must register all inpatients and relatively the outpatients. Private hospitals are more powerful in this. They fully document everyone, including the outpatients. For the public hospitals, they all have an office for patient records, so there is registration for inpatients, but as the flow of the outpatients is high, they cannot tolerate documenting them." (Clinical Neurologist, CN2, Cairo, Jan 2021)*

The expert's comment reveals that all hospitals in Egypt are forced to register the patients' data. However, mostly, the public hospitals register only the inpatients' data due to the large numbers of outpatients who visit daily and the limited time. Oppositely, private hospitals, in many cases, are more powerful as they have records for inpatients and outpatients.

Similarly, a neuroscience researcher who has a medical background and works in collaboration with many hospitals for his research added:

> *"We don't have a registry in the sense of it's a registry. All we have is clinical data recorded in certain departments…This information is there, and it just needs someone to go and file it properly and makes a registry" (Neuroscience Researcher, NR1, Cairo, January 2021)*

It is clear from the expert's comment that patients' records in Egypt are available and can be retrieved from the responsible department to provide information for the registry. Regarding the sufficiency of data available on these medical records, the clinical neurologist mentioned:

> *"There is the comprehensive geriatric assessment that we usually do to all geriatric inpatients. It is one of the gold standards maneuvers that we can do for all geriatrics to collect sufficient data on personal history, past medical history, medication history, surgical history, history of present illness, physical examination, and some important screenings (Depression, fall risk, malnutrition, home safety, other conditions) So it gives very rich data" (Clinical Neurologist, CN2, Cairo, Jan 2021)*

It is obvious from the experts' statements that clinicians in the Egyptian public or private hospitals usually use the comprehensive geriatric assessment to document many components of both the evaluation and management of geriatric patients (*Comprehensive Geriatric Assessment - UpToDate*, n.d.). The experts indicated that this information would be promising if retrieved. However, due to the high flow of outpatients in public hospitals, the documentation process is complete and more regular for only the inpatients.

Even though the Egyptian health care system does not adopt any electronic interface for recording data as the Electronic Health Records (EHR). Yet, depending on the paper medical records available is a valid process, as indicated by many registry experts. One of the experts involved in an international registry mentioned:

> *"We go through the medical records in each hospital to extract the data, you know we don't have a web-based where the professionals registered their own cases, and I believe we collect all the data from the medical records manually." (Registry Specialist, RS6, International, Oct 2021)*

The expert revealed her experience that they depend on data collected from medical records, although they do not have electronic or web-based records. They collect the data manually using the available paper records.

Similarly, another expert involved in one of the recently established dementia registries discussed the idea of depending on memory clinics, especially in the first pilot. She mentioned:

> *"Initial sort of prototype or pilot can be with memory clinics, because they tend to be, even though they're all different from each other, they need to be recording a lot of the same kind of information. They're writing it down on their assessment sheets or in the patient files" (Registry Specialist, RS2 International, May 2021)*

The expert's note confirmed that depending on medical records for creating a registry is also depending on the type and sufficiency of data collected for these records. From her experience, the data collected differ from one place to another. For example, the memory clinics can be involved as they have to record all the assessments that are already done on patients as required for their diagnosis. This finding is in line with the previous discussions of depending only on records when they have complete or sufficient data.

In addition, a clinical neurologist that has experience working in both university and public hospitals in Egypt advised depending on the patient records from university hospitals instead of the public hospitals, especially in the beginning. He mentioned:

> *"The public hospitals are easier for collecting cases, they have many cases as well, and they come on a regular basis ... Using medical records is more practical in university hospitals than interviewing patients to standardize the data and to save time." (Clinical Neurologist, CN3, Cairo, March 2021)*

It is clear from what the neurologist has mentioned that the documentation process in the hospitals affiliated with universities is more accurate and complete, which will be an advantage for the data collection process.

However, regarding the issue of data completeness, another clinical expert with experience in different geriatric hospitals and memory clinics recommended using patient records together with collecting data from the patients themselves to complete any missing data. She mentioned:

> *"You will always have missing data when extracting data from the medical records. The idea of doing retrospective studies in Egypt is that the records are not always complete. So, I recommend that you do both, you collect the data of the patients who have clear records, and you can definitely complete what is missing if you can." (Clinical Neurologist, CN1, Cairo, Jan 2021)*

As indicated from the quote, depending only on medical records might have some limitations, including incomplete data. Consequently, collecting data from patients by including patient cohorts would also be of great benefit.

Patient Cohorts

In addition to medical records, collecting data directly from patients is also valuable. The fact that prospective data collection will provide more accurate and complete data would greatly improve the outcomes of the registry. Many researchers agreed that collecting data from patient cohorts would be worthwhile. A registry specialist who is involved in one of the international registries indicated that collecting data from patients is particularly advantageous in the absence of EHR. She Mentioned:

> *"We are actually done collecting the data prospectively, so you can be sure about the quality of the data you're collecting because sometimes most of the hospitals don't have electronic medical records." (Registry Specialist, RS3, International, Sep 2021)*

Another registry specialist expressed her opinion about selecting the cohort from patients who are already diagnosed by physicians. She stated:

> *"So, if these physicians' offices or the memory clinic or the hospitals, if they're willing to work with you, I would prepare an informed consent and then try to contact individuals that have a demented diagnosis and see if you can follow up with them individually and try to get some information." (Registry Specialist, RS4, International, Oct 2021)*

Similarly, one of the registry specialists who also worked in many longitudinal studies and who has experience in the Egyptian system stated that:

> *"The other way is if you have access to certain Alzheimer's disease clinics around Egypt, where there are people seen by a neurologist, that might be a better way as experts make the diagnosis and that you put them into a registry and follow them prospectively as a cohort" (Registry Specialist, RS1, International, May 2021)*

It is obvious from the experts' notes that depending on patient cohorts would be more advantageous, especially when there are no or incomplete EHR. Depending on patients' cohorts would also allow the selection of patients to be included in the registry based on the specific criteria put by the registry board. In addition, the data collected would be completer and more trusted as the patients are already diagnosed by a physician.

In addition, patient cohorts are also advantageous as there will be an opportunity to talk to patients and include more data that cannot be found in patients' records. However, dementia patients are usually unable to give information depending on the severity of their case. In this regard, the experts agreed that talking also to the patient's caregivers or families would help fill the missing data. One of the registry specialists who have experience in planning dementia registries stated that:

> *"We have in our model, and it had been our intention to go out to families, you know, to see what sort of data they would be able to give us, how reliable would it be, and how accurate. The data that relates to people's care, some of our data asks, do you go to a daycare service and know it talks about different services that people use or different supports that they have." (Registry Specialist, RS2 International, May 2021)*

The expert's comment revealed how important it is to collect data from patients and families in addition to the doctors. Talking to patients would allow collecting more information about the needs, services provided, and support that the patient gets.

In addition, another registry specialist added that talking to caregivers would be important in many cases when the patients are severely demented and cannot give accurate information. She stated:

> *"Now the issue is if they are severely demented, you will have to talk to their caregivers" (Registry Specialist, RS4, International, Oct 2021)*

The previous quotes clearly indicate, from international experts' point of view, the importance of involving patients in their families or caregivers in the process of data collection.

Regarding the Egyptian situation, a clinical expert who has experience in both public and university geriatric hospitals indicated that collecting prospective data would be more practical to avoid the hectic process of getting approvals for accessing previous records. He mentioned:

> *"I think that a prospective registry would save time and funds compared to the retrospective. The retrospective is time-consuming, requires persons that are fully dedicated for the work, requires more sophisticated approvals plus the point that the data are not standardized as the records differ from one hospital to another." (Clinical Neurologist, CN2, Cairo, Jan 2021)*

From the expert's point of view, collecting data from patient cohorts is advantageous in terms of time, effort, and money. The expert also discussed the different limitations of depending on retrospective data as in collecting the data from medical records. This includes the sophisticated regulations for getting access to them as well as the variability in the data recorded due to the lack of standard diagnosis and management protocols in the Egyptian hospitals.

Other Sources

Some experts indicated the fact that not all elderly patients with dementia are actually diagnosed and visit a clinic or a hospital. To collect most of the cases in order to have national coverage, different sources other than clinics and hospitals should be included. Nursing homes are among potential data sorts as they contain many elderly patients who might be undiagnosed and need care. Many experts agreed that the registry should include data on the elderly people living in nursing homes as many dementia patients are not diagnosed and screening them would help discover more cases. One of the researchers who is specialized in aging and who has worked in several international aging studies mentioned that:

> *"In a register, not everybody is in a hospital, there are quite a few demented people outside hospitals, and nobody takes care of them" (Aging Researcher, AR1, International, Sep 2021)*

Similarly, a clinical neurologist who works in one of the biggest geriatric hospitals in Egypt discussed his opinion of including nursing homes. He stated:

> *"I would recommend the nursery homes, they are big and include many cases, but that will require communication with the patient's family, who, in many cases, might refuse to help. And you will also need a physician to diagnose the cases" (Clinical Neurologist, CN3, Cairo, March 2021)*

The expert's comment revealed that many dementia patients in Egypt are staying in nursing homes. However, to be able to collect their data, they would need to communicate with their families for consent which would be difficult as, in many cases, the families refuse to disclose any information. In addition, the nursing homes in Egypt do provide medical services, but not necessarily neurological specialties. Hence, to be able to include the cases in the registries, a physician will be required to diagnose those who have dementia.

In addition, experts discussed the situation of the disease after COVID 19. A clinical neurologist who works in a geriatric hospital in Egypt stated that nursing homes and other elderly communities would be advantageous as not all patients can access hospitals. He expressed how the situation deteriorated after COVID 19 as he mentioned:

> *"Usually, the mainstream patients have difficulties in reaching hospitals in terms of transportation and funding. The COVID situation made it worse as they now fear going to hospitals. So, we should think out of the box. We can go to the people outside the hospitals, old age communities, nursing homes, etc." (Clinical Neurologist, CN2, Cairo, Jan 2021)*

It is clear from the experts' remarks that many factors affect the under detection or diagnosis of dementia among the elderly, especially after the COVID 19 pandemic when people started to fear visiting hospitals. Hence, including data from other sources that contain elderly people like nursing homes. They expressed the importance of looking for those patients who are living alone and need care.

Overall, all experts confirmed that there is no one-standard source that provides all the data regarding dementia as the diagnosis occurs in many different settings. Although most of the international registry experts agreed that including primary healthcare data is essential for creating a registry, they also raised the challenges in controlling the retrieval of primary data as well as the efforts required to identify dementia patients. The situation in Egypt is a bit different as the diagnosis of dementia is usually a secondary healthcare procedure, giving rise to the importance of connecting to them for collecting cases. Yet, the development of a comprehensive registry that includes representative data would require involving more than one data source in the collection process.

5.2.4. Data Included

The discussion regarding data that should be included in the registry raised several issues relevant to different aspects comprising the coverage of data collected, the inclusion criteria of who should be added to the registry, the required data elements to be collected, in addition to some talks on the process of preparation prior to starting data collection. Although a comprehensive registry that includes everything about the patients might be a dream, all experts agreed that for the registry to be established, only functional and effective data should be included. Further expansion of data can then occur based on the primary outcomes of the established registry.

Data Coverage

The experts' opinions regarding the coverage of data were straightforward. All experts agreed that collecting a wide range of representative data that covers the national level is not feasible when establishing the registry. Some of them suggested the idea of including limited data sources that represent the different geographical areas in the country, while the majority indicated that representation is not a major issue as, at this step, the purpose is the establishment.

A registry specialist who is involved in a recently established registry has explained her experience regarding the original plan. She mentioned:

> *"With respect to whom we include, of course, nationally representative data is best ... So, our plan was that, even if we're not including every single hospital, which is not feasible, that would at least have representation from each of the geopolitical zones, at the end of the day." (Registry Specialist, RS3, International, Sep 2021)*

The specialist indicated that including national representative data is crucial to accurately reflect the diverse population. However, she confirmed that collecting data from all sources is not feasible at this step. From her experience, she stated that the original plan of the registry was to include nationally representative data from all the geographical areas in the country. However, the registry pilot only started with one institution. Then, after the successful implementation, many places were included (Theme 2.5).

Similarly, many experts expressed the idea of how a registry should start up front. They confirmed that for the registry to be established, it should start with limited coverage to avoid any difficulties. A registry specialist involved in one of the well-established international registries stated:

> *"I think that the most important is a limited geographical area with a few hospitals, and it has not been especially difficult." (Registry Specialist, RS6, International, Oct 2021)*

Similarly, another registry specialist who has a good background in the Egyptian healthcare system through several research collaborations also indicated:

> *"I think the idea is that you really start in a hospital and maybe developing kind of a hospital-based registry, maintaining, and developing that from a clinical and research perspective. It is really a good way to go, and I think you could build on that." (Registry Specialist, RS1, International, May 2021)*

It is clear from the specialists' quotes that although geographical representation is essential, it is not feasible, especially in the beginning phases of the registry. Instead, starting on a small scale by including one or few hospitals and then expanding the data when possible is a more practical way of building the registry.

Consistently, a social researcher who has a medical background and works in one of the biggest social research centers in Egypt stated her opinion regarding establishing a new registry. She mentioned:

> *"You are starting something from scratch, so representation is not required at this step unless you perfect your methodology and you know it is functional. Then start thinking of involving patients that represent different social and economic backgrounds. Perfect your methodology, your questionnaire, and your dataset and how you will deal with it." (Social Researcher, SR2, Cairo, Jan 2021)*

It is clear from the expert's quote that representation of data should not be an issue in the beginning as the main purpose is to establish a registry. She indicated that including more representative and comprehensive data can be a second step after evaluating the success and effectiveness of the methodology. This data is in line with the registry models that were presented previously (R. E. Gliklich et al., 2014g; Hopper et al., 2016).

Inclusion Criteria

Regarding whom should be included in the registry, there were some conflicting opinions. While the international registry experts asserted that the key inclusion criterion should have a dementia diagnosis, many Egyptian clinicians also expressed the need to include people with mild cognitive symptoms.

One of the registry specialists involved in an international dementia registry and has experience in several dementia research studies expressed his opinion regarding the inclusion criteria. He mentioned:

> *"My understanding in the registry is having a database of all people with the clinical diagnosis and so for dementia would be having a registry of all people who have a diagnosis of dementia, let's say in Egypt" (Registry Specialist, RS1, International, May 2021)*

The expert's note reveals that dementia diagnosis is the main inclusion criteria for the dataset to be considered a registry. In addition, another registry specialist who works in one of the recently established registries added that the inclusion criteria should be a diagnosis of dementia but also specific criteria for each dementia subset so that anyone collecting or using the data can easily understand it. She mentioned:

> *"So, the thing with this dimension data, especially, is that you can have levels of the case as attainment. And so far, as long as you describe the criteria for each subset of diagnosis, so anybody who's using the data, seeing the data, understands that." (Registry Specialist, RS3, International, Sep 2021)*

It is clear from the experts' remarks that a formal dementia diagnosis is the main entry point for patients in the registry. They also stated the importance of dividing the registry according to the dementia subtypes. That said, many were worried about the difficulty of getting an accurate diagnosis due to the nature of the disease. Yet, getting an accurate diagnosis of the sub-type is a more complex and advanced step that was mentioned a lot as a major challenge. (Theme 6.2)

On the other hand, the discussions with Egyptian clinicians revealed the importance of including patients with all cognitive impairment problems for better tracking of their cases and to overcome the problem of lacking accurate diagnosis of patients in Egypt. A clinical neurologist working in a geriatric hospital in Egypt mentioned:

> *"You should include all patients with memory problems or what is called cognitive impairment. If you just included dementia, the number of cases would be very limited, and the data would be poor." (Clinical Neurologist, CN2, Cairo, Jan 2021)*

Similarly, another clinical neurologist working in a memory clinic in Egypt added that including MCI cases is essential as many of them develop dementia afterward. So, they are worth following up on. She stated:

> *"The registry should include people starting from mild cognitive impairment not only dementia, as some of them develop dementia after that, of course, some will not, but if we knew those who might be at risk of developing dementia, that would be beneficial as they would always be followed, their progression, their disease management and when following them we can figure out the risks" (Clinical Neurologist, CN1, Cairo, Jan 2021)*

The experts' notes revealed that collecting data on MCI patients is essential in Egypt as many dementia patients are not fully diagnosed while many MCI patients develop dementia after that. However, including data on people with MCI could increase the complexity of the registry and hinder the process of data collection due to the increased time and effort. In addition, the fact that many dementia registries are already well-established around the world, we should consider learning from their experience and following their successful steps without inventing the wheel.

Required Data Elements

The discussions on the elements of data to be included were straightforward. All experts agreed that the type and amount of data be added directly originate based on the main registry objectives and outcomes as mentioned earlier. One of the experts involved in an international registry indicated that the collected data elements would depend mainly on the objectives of the registry. He stated:

> *"It also depends on what you are most interested in understanding. I mean, do you want it to be health economic cost, so then you have to use the right tool and be able to pick up the information? Is it really you wanted to see what the cognitive outcomes over time and the relationship to functional impairment and services are, so it depends on what your questions are?" (Registry Specialist, RS1, International, May 2021)*

It is clear from the expert's comment that setting clear objectives for the registry is essential to be able to determine the data elements to be collected. In addition, international experts presented their experiences with the different established registries around the world and how defining a limited set of data was essential in establishing the basic registries. A specialist working on one of the well-established international registries explained from his own experience how defining a limited set of data is important to achieve the registry objectives while maintaining patients' participation. He mentioned:

> *"Another key factor that has been very important for our registry is the number of variables that we collect… And we define a very limited set of variables related to demographics or patients, few information related to the type of clinical diagnosis, information about Community function using them, the mental state score, and the rest of the mentor-writing the scale. In addition, we also collect information related to medical comorbidities. But no more than 30 variables to not allow the amount of data we need to collect from each case." (Registry Specialist, RS6, International, October 2021)*

The expert's quote indicated that defining a limited set of variables is crucial for the continuation of the data collection process and to avoid the demotivation of participants due to a large number of variables or questions.

Similarly, another registry specialist who works in a recently established registry indicated that using a basic set of data is more practical in the beginning. She mentioned:

> *"The basic registry was to document the number of patients with the disease and to have some basic idea about the age of onset, the demography, the gender distribution, whether they were on medication or not, the duration since diagnosis, and whether they had a family history or not. So, it was very basic." (Registry Specialist, RS3, International, Sep 2021)*

In addition, a specialist involved in similar studies added that even the included functional assessment tools should be determined. He mentioned:

> *"There is certain demographic information you have to include, age, gender, level of education, occupation … functional assessment tools, you are going to use the Arabic version of MoCA or MMSE, or you are going to try something else." (Registry Specialist, RS1, International, May 2021)*

The experts' remarks indicate that collecting a limited number of variables with a focus on the basic data was crucial for the success of the registry establishment. They also stated that patient history, demographics, diagnostic and management procedures are the essential type of information required. In addition, the required diagnostic data should be identified and adapted to suit the patients and to avoid collecting unnecessary information.

Similarly, clinical experts from Egypt who work in different hospitals that have geriatric departments and who have experiences in both private and public sectors agreed on collecting these basic elements, they mentioned:

> *"I think it should start with the way and level of diagnosis, the clinical investigation, and which tests were done, then the demographic factors, name, age, social status, the attending physician, the entity responsible for the treatment." (Clinical Neurologist, CN3, Cairo, March 2021)*
>
> *"I think the registry should contain the inclusive geriatric assessment, including the cognitive assessment, depression, etc., and the tools of investigation, because you will not be able to know the situation you have or to make the differential diagnosis without having the core investigations, at least for example MRI and lab tests, with the cognitive assessment definitely" (Clinical Neurologist, CN4, Cairo, Sep 2021)*

From the clinicians' thoughts, it is obvious that this kind of information that includes patients' history, personal demographics, and basic diagnostic measures will be beneficial in terms of informing all the users of the registry, including the clinical practitioners and patient families.

In addition, some experts expressed the need for including data about caregivers in the registry as, in the case of dementia, caregivers are highly affected, and there is no data available on the extent of how this impacts their lives and well-being. In addition, knowing information about the caregiving of the dementia patient is also beneficial as it can impact the progression of the case. A social researcher who has experience in health-related research studies agreed on the importance of collecting basic data but also highlighted the need to include caregivers. She stated:

> *"All of this is about the individual. We have also to talk about the caregiver, how they arrange the caregiving process, how they distribute the tasks, and what impacts their psychological wellbeing. They're trying to cope, but no one knows how they feel. They are suffering in silence" (Social Researcher, SR2, Cairo, Jan 2021)*

In the same manner, a clinical neurologist who works in one of the biggest memory clinics in Egypt indicated that collecting data about caregivers and their socioeconomic status is essential as they usually suffer from these types of chronic disabling diseases. She mentioned:

> *"The registry should not be only about the patient. It should be about the patient, the caregiver, and the environment around the patient. In dementia, caregivers are very important. This is the case in any chronic disabling disease. To know if there is a caregiver with the patient or if he lives alone or in an institute. The socioeconomic standards of the caregiver who takes care of the patient." (Clinical Neurologist, CN1, Cairo, Jan 2021)*

The experts' comments revealed that collecting data only about individuals is not the only goal. Instead, the registry should contain data about caregivers as well, their socioeconomic standards, their environment, etc. They believed that the families and caregivers of dementia patients suffer a lot throughout the course of treatment, and we should have data about their needs to be able to support them. This finding is in line with the data published before about the caregiver burden, particularly in dementia (Garcia-Ptacek et al., 2019; M. Park et al., 2015; Ransmayr et al., 2018).

On the other hand, a public health expert who has a medical background and works in health-related research studies in Egypt expressed her opinion of creating an inclusive registry that does not focus only on clinical measures but also includes the social determinants of health. She mentioned:

> *"If you only collect medical data, you are in the wrong direction, ... definitely, you need to collect everything even if you will go back to the policies of their workplace, policies of education, you should always relate them to the living environment and to the socioeconomic status and to the policies and culture in Egypt that led to the exacerbation of the problem." Public Health Researcher, PHR1, Cairo, Jan 2021)*

The expert's remarks reveal the importance of investigating the root causes that led to the aggravation of the condition among the population. She indicated that many factors could affect the dementia progression, including the socioeconomic status of the patient, occupation, level of education, environment, and policies. This concern is in harmony with the WHO conceptual framework of the determinants of health (Benach et al., 2010). However, collecting such data will put an extra burden on the clinicians and data collection personnel which will hinder the process as agreed by registry specialists above and as proved in previously established registries (Hopper et al., 2016).

Defining Minimum Data Set (MDS)

Regarding the previous recommendations on collecting limited or basic data in the establishment process, defining a minimum dataset for the registry will be mandatory to identify the essential data elements for the registry to function effectively.

One of the social experts who works on health-related research studies in Egypt warned about trying to include everything that is required by the stakeholders. She mentioned:

> *"We are not realistic, everyone will tell you that their area is the most important to collect, but you will have to formulate it in a realistic way as a roadmap out of the big picture. You should focus only on what can be done,*

> *and maybe you expand when you perfect that." (Social Researcher, SR2, Cairo, Jan 2021)*

The expert's opinion indicates that the main purpose should be to identify a realistic way of initiating the process in terms of the available resources. She mentioned that considering the stakeholders' needs should be cautious as building an all-inclusive registry is not possible.

Hence, most of the experts highlighted the importance of focusing on the main purpose of the registry as well as the available resources to identify a minimum dataset of elements that would be easily collected considering the limited fund. The registry specialists involved in different dementia registries around the world commented:

> *"The more data you want to collect, the more the cost going to be, the longer it will take ...So why don't we try to get a first version of the registry, as with the really important data that everybody wants" (Registry Specialist, RS2 International, May 2021)*
>
> *"You have to consider what people can reasonably do without much funding in terms of basic data collection. So, we also had to develop like a very basic data capture form." (Registry Specialist, RS3, International, Sep 2021)*
>
> *"When we started, we also wanted to collect everything about the patients and their families, but it's very difficult because you need to collect data in memory earlier away and because if not, there may be some information bias." (Registry Specialist, RS6, International, Oct 2021)*

The experts' comments indicate that defining a minimum data set is essential to decrease the needed budget for the registry and to avoid any data bias. When defining a minimum dataset, sticking with the most basic yet needed data is the most appropriate strategy.

Similarly, one of the geriatric training consultants working in a large private training academy for physicians agreed that prioritizing some data according to the registry objectives is crucial when the fund is limited. He stated:

> *"It has to be inclusive, but if there is a limited fund, then we should look at the context and define the goal to put down accordingly our objectives and priorities" (Geriatric Training Consultant, GT1, Cairo, March 2021)*

The expert's quote confirms the above-mentioned opinions, which are also in line with what was published in the literature (R. E. Gliklich et al., 2014g). In addition, many experts advised to consider the well-established international registries, look at the minimum datasets they use to compare them and be able to formulate the most appropriate setting that suits the Egyptian culture.

One of the specialists who is involved in an international dementia registry and has a background in the Egyptian health system stated:

> *"I think you have to figure out what we call a minimum data set (MDS). You look at some comparable registry studies, and you should make it at least comparable, not in all measures, but at least most of the measures." (Registry Specialist, RS1, International, May 2021)*

The expert's quote highlights the idea of benefiting from others by comparing the minimum datasets previously used by the already established dementia registries to select the items that will suit the Egyptian system and the Egyptian registry objectives. In addition, an Egyptian researcher who has a health background and works at one of the biggest social research centers in Egypt added:

> *"You can look at the data that are being collected in comparable registries, but we should analyze the factors or questions from our perspective, discussing them with Egyptian experts to figure out what will work and what*

> *will not. Then develop your own questionnaire or form that was taken from another culture but adapted to suit your community." (Social Researcher, SR2, Cairo, Jan 2021)*

It is very clear from the expert's opinion that although using minimum datasets from other registries would be beneficial, amending the questions to suit the Egyptian context is crucial. Egyptian healthcare specialists should participate in defining the minimum dataset to figure out what questions will work, what will not, and what needs to be adapted. As an example of how that could be done, one expert involved in an international registry explained her experience regarding the process they followed to develop the minimum data set. She mentioned:

> *"The data that all of the existing dementia registries capture mapped out against each other and against all of the data that everybody wanted to capture ... We asked people to do a sort of prioritization not on the actual data themselves, but on the questions that they would like to be able to answer, based on the data from the registry ... then we got people to prioritize them, and a few come right up to the very top" (Registry Specialist, RS2 International, May 2021)*

The expert's experience reveals that it is essential to combine both the analysis of external registries with the prioritized needs of the national stakeholders in order to figure out the data that are most needed for the national context.

Moreover, another registry expert suggested that defining the minimum dataset should start with an open discussion with clinicians to figure out what will suit them. She mentioned:

> *"I think it is important to talk with clinicians about the variables you want to collect. So, I can talk with them about the diagnosis process, how they collect information, and what kind of instruments they use ... in order to define meaning, data set that will not be extra work for the clinicians." (Registry Specialist, RS6, International, Oct 2021)*

The expert's suggestion highlights the idea of not imposing much burden or extra work on clinicians for collecting data to guarantee the success of registry implementation as well as the sustainability of the process. Hence, a discussion with clinicians will be required prior to defining the minimum dataset to understand exactly how they function, their process of diagnosis, the information they collect, and the instruments they use. So that, when defining the dataset, the physicians' actual processes will be taken into consideration to avoid any extra burden on them while collecting the registry data.

Developing Data Collection Form

The data collection process is critical for the integrity and validity of the registry data. Collecting unified data with determining standards and tools is crucial in order to avoid variability between the sources included as well as any personal bias. Many experts pinpointed the importance of carefully designing a data collection form that includes all the required data to be filled in as identified from the minimum data set, what exactly to fill in regarding the tests, for example, and the questions that should be asked to the patient or caregivers if needed. This form will help clinicians provide the required data in an easier and standardized way and help data collection personnel easily extract the required information from patient records.

A clinical neurologist who works in several geriatric hospitals in Egypt highlighted the importance of developing a data collection form. She stated:

> *"I think in the beginning, you have to have a unified form for data collection. So, whatever the entryway, you must have a specific manner of collecting the data to be unified from whatever place ... It must be very realistic and simple to be achievable. The more complicated it is, the far from being actualized. So, a very simple tool for screening that a person can do in a short time, they have easily cut off scores, and it is not hindering for them" (Clinical Neurologist, CN4, Cairo, Sep 2021)*

In the same manner, one of the specialists who work in one of the well-established international registries indicated:

> *"To serve the user, they don't have to report, like the result of the tests, they yes, have to report if they have done a test, you say yes or no. They have to have the score, but otherwise, a lot of other variables are yes or no, and some of them have don't know" (Registry Specialist, RS8, International, Oct 2021)*

The experts' statements asserted the concept of developing a very simple data collection in order to help clinicians do the work without having an extra burden. Having a complex data collection form will demotivate clinicians from reporting their patients' data to avoid the extra burden. In addition, the time factor is also crucial; most clinicians are very busy meeting many cases per day. Providing them with a form that only asks short answer questions with little details would be the proper strategy to encourage them to participate.

Expanding Data

Expanding the registry to include more data elements and types is a further step in order to satisfy more needs. All experts approved that for a registry to start, we can only depend on the available resources or types of data we have and then further expand our dataset when possible.

A clinical neurologist who works in one of the biggest public memory clinics in Egypt agreed on the importance of expanding the data. She mentioned:

> *"We can start with the data that are already available, complete what is missing from the caregivers. Then once we set our structure, we can further complete that during the follow-ups" (Clinical Neurologist, CN1, Cairo, Jan 2021)*

Similarly, a specialist who was involved in planning one of the recent dementia registries discussed her experience. She stated:

> *"Look, in the beginning, you can't capture everything, and it's very expensive to collect data…. You need to capture the data that's going to give you the most answers, that's going to be the most important and, over time, we can add in these other pieces of data" (Registry Specialist, RS2 International, May 2021)*

The expert highlighted, from her experience, that capturing everything is very expensive, and we can also start with the most important things. Expanding the data afterward is necessary to add the missing yet, required pieces of data. She then added:

> *"We can meet the reporting requirements with this smaller amount of data, and we'll come back and look at possibly putting the extra data in at a later stage but let's collect this small amount of data, first of all, and let's see what it's telling us, and if it's giving us enough information that we don't need the rest, if it's not then we'll add Some additional data fields" (Registry Specialist, RS2, International, May 2021*

The expert's quote indicated that longitudinal follow-ups with patients would help complete the missing data or add new information over time. Hence, keeping the contacts of the patient and caregivers together with informed consent is essential to open the opportunity for improving the registry afterward.

5.2.5. Piloting the Registry

Implementing a national registry is a complex and expensive process. In addition, there is no available perfect model of dementia registries to follow, and most of the available registries were designed to satisfy their objectives (Krysinska et al., 2016). Consequently, phasing the registry to start with a small pilot will help evaluate the process. Identifying what will work and modifying the protocol accordingly is very beneficial. Most of the experts agreed on the importance of dividing the implementation of the registry into phases, starting with a pilot and then expanding it into a national setting. Two experts who are involved in different international registries discussed the importance of phasing the registry. They mentioned:

> *"To pull everything together, the idea is to kind of develop a database of the whole information then develop recommendations for what might or might not work; this is a pilot of the registry. The idea is that the national registry is very expensive to develop and maintain. It is very costly" (Registry Specialist, RS1, International, May 2021)*
>
> *"Now the advantage of doing phasing is that first of all, from your own local experience with the registry, you can modify the protocol, you can also teach the people that you're adding on, you know how to navigate the system that you set up and so forth. It also ensures that I think basically it's about understanding the system and then scaling it up gradually." (Registry Specialist, RS3, International, Sep 2021)*

The experts' comments pinpointed the benefits of piloting the registry first as an initial phase before expanding it to the national level. First of all, having a pilot would allow the understanding of data and the evaluation of the procedure to determine what worked and what did not while avoiding the expensive costs of modifying a national registry. In addition, the pilot would allow modifying the protocol to add any missing data or amend any difficulties and ensure that the system is working perfectly prior to scaling up. This finding is supported by evidence from the literature (R. E. Gliklich et al., 2014g)

In addition, experts involved in different registries around the world have explained their experiences with phasing and piloting their registries and how that impacted the process. They mentioned:

> *“The second most important thing is phasing the registry. It was a strategy that we used, and it helped us because we started at our own institution as a pilot. Then we scaled it up to selected sites that we thought were most likely, from our own assessment, to succeed or most likely to cooperate. Then we expand that it's after that, so we went through an initial maybe three phases, and after the third phase of expanding it nationally, we still added one or two sites, there are some.” (Registry Specialist, RS3, International, Sep 2021)*

> *“Before it officially started, we started only collecting that thing at one hospital to check the viability of the information. We checked the flow trap of collecting this data. Then we started another pilot” (Registry Specialist, RS6, International, Oct 2021)*

> *“The pilot was just the disease been seen at our institution. That was the initial pilot. So, once we had gotten used to the website, how easy it was to navigate it, we invited other colleagues who were close to, whom we knew were used to doing research and wouldn't have difficulty.” (Registry Specialist, RS3, International, Sep 2021)*

The statements indicate that starting with a pilot was helpful in different cases in order to give insights into the registry outcomes and the information collected, as mentioned above. The experts explained how piloting the registry contributed to the success of the process and the ease of the data expansion after that. The experts highlighted that to develop their registries. They started with one or few sites to collect the data as a first phase, then when the system started to work, they expanded the process to include more sites. In addition, they also pinpointed that developing preliminary reports were valuable to attract and convince more clinicians and sites to get involved in the registry.

5.2.6. Expanding the Registry to National Level

While phasing the registry and starting with a pilot was the main concern, many Egyptian experts highlighted, as well, the significance of expanding the registry further to cover the disease nationally. A limited database will not be sufficient for the urgent needs of any stakeholders in the dementia field. A neuroscience researcher who has international experience and who currently works in one of the largest research institutions in Egypt expressed his opinion regarding this kind of small initiative. He mentioned:

> *"Yes, at the college level or the university level, you can start small, but you're going to stay small, and it's still not going to tell you about the prevalence or the incidence of disease as still not going to tell you about the incidence according to the lifestyle or socioeconomic status .... a nationwide disease registry will do that" (Neuroscience Researcher, NR2, Cairo, January 2021)*

Similarly, another neuroscience researcher who works in collaboration with several pioneer neuroscience institutions in Egypt added:

> *"The registry should be a pool for all the patients all over Egypt and not only one institution. And that will depend on the cooperation with people and how they would share their data together." (Clinical Neurologist, CN1, Cairo, Jan 2021)*

The experts' note revealed that the ultimate goal of the initiative should have a registry that represents nationwide data. Otherwise, the small initiative that started in one institution without expansion would be of less use at the end of the dataset and did not give the actual national situation.

In addition, a policy expert who is involved in the government as well pinpointed some opportunities regarding the situation in Egypt.

> *"I think they are in their pipeline but not in their priorities. But since we will have the implementation of the health insurance law by the end of the day, they'll have these policies and procedures and the registry also, as it will be all automated and registered ... by the end of the day within a few years you'll have registries for all diseases, especially what we call them the non-communicable diseases" (Government Official, HP1, Cairo, January 2021)*

The expert indicated that the concept of creating patients' datasets and registries is among the pipeline of the ministry of health, yet dementia might not be their top priority. However, establishing the new national health insurance system currently being developed in Egypt is a great opportunity as there will be policies and regulations for registering all the patients in the system. The registry can be used, built on, or even ked to this data at the end.

5.3. Registry Data

5.3.1. Data Collection

Registry data collection is a continuous process that requires regular evaluation and improvement. The fact that data can be collected from different sources, as well as the variability of these sources, opened the discussions on the appropriate practices of data collection from each data source as well as the opportunities and ways for improvement.

Data Extraction and Data Entry

There is no doubt that extracting data from the available data sources is a constructive procedure for building the registry. Many experts discussed the process in detail to highlight that delving through the medical records and entering the data into the registry is a simple process that does not require an expert or a clinician. Yet, medical background and training will be required prior to data collection to guarantee the validity of the process (R. E. Gliklich et al., 2014a).

An expert involved in one of the international dementia registries and who also has an experience in planning and establishing registries discussed her point of view regarding data collection. She mentioned that some data will be available in the files and will only take someone to sit down and read what is written to search for specific keywords to be entered. She stated:

> *"get data from the charts from the files, the person needs to have some clinical knowledge, but they do not have to be a consultant" (Registry Specialist, RS2, International, May 2021)*

The expert's note revealed that the data collection process does not have to be done by consultants. However, the personnel involved should be trained well to be able to read the files and extract the data required.

Experts in different international registries have also discussed their experiences on who should collect and enter the data. Assigned personnel who should be responsible for data collection differed among the registries depending on how the health system works in the country. One of the experts explained how their registry depends on the data collected by clinicians in medical records. She said:

> *"They collect the information during the clinical interview, and they put this information in the clinical records and electronic medical records, and then we roll through these medical records, and then we collect this information. The only extra work for the clinicians is that they have to request the informant's consent." (Registry Specialist, RS6, International, Oct 2021)*

The expert's note demonstrated how the availability of electronic medical records is an asset for their registry as they collect the registry data automatically from what the clinicians enter into the system. This data collection method is easier for clinicians as they do not have to do an extra load of work except for requesting the consent of patients to participate.

On the other hand, experts from different registries preferred other personnel than clinicians should extract the data as long as the electronic medical records are available. They mentioned:

> *"A person in each memory clinic did the data entry. Suppose you're training to be a psychologist, geriatrician, doctor, or nurse. In that case, you do a certain amount of placement time with different services, so the memory clinics always have a trainee of some kind, you know, sometimes it is an assistant psychologist, sometimes it is a training nurse, they can do their data entry for the pilot." (Registry Specialist, RS2, International, May 2021)*

> *"The clinic decides who should do it. So, it's up to them, and it could be both doctors and administrators, nurses or other for other professionals yeah." (Registry Specialist, RS7, International, Oct 2021)*

The experts' notes stressed the importance of following a data entry system that would not put extra load on clinicians. The availability of electronic patient records is an asset in this regard as training doctors and nurses would be able to extract the data and enter them into the registry system. The choice of the personnel to be responsible for entering the data should be left to the clinic so they can assign the most appropriate person without affecting the work procedures.

Yet, variability and missing data are challenges when the clinics enter the data using medical records. One of the experts explained how they depended in their registry on a central data entry approach to avoid any variability and handle the problem of missing data. She mentioned:

> *"They actually send the form to us, and we entitled central. Still, everybody like once every quarter, all those who have collected data will send the forms and clinical case report forms to us. So, a data entry person centrally enters all the data. As for any missing data with them, ask them to recollect it because we found that there would be too much variability if we asked them to enter inside themselves, and if they had missing data, they wouldn't let us know until it was too late." (Registry Specialist, RS3, International, Sep 2021)*

The expert's note shed light on the challenges that could arise while depending on local data extraction from medical records by the clinics, including variability of data entry and missing data. She explained how a central data entry by the registry administrators would help solve these problems while following up with clinics to collect missing data. This central approach is also suitable for the healthcare systems that do not have electronic medical records and collect their data manually.

Overall, the remarks of the experts showed different ways of assigning people. Some registries depended on the clinicians to collect and enter the data, others depended on trainees and GPs, some hired specialized personnel to work with the registry, and others left the decision up to the clinic. It is clear from the quotes that the process of collecting and entering the data should be designed according to the structure of the health system to be convenient for the healthcare providers.

The Egyptian experts have also raised the discussions on the data extraction and data entry process. They stressed, as well, the importance of identifying the data collection personnel. One of the clinical neurologists who works in a large memory clinic mentioned:

> *"Currently, in Egypt, because we do not have electronic records, there is no keyword to search with. So, if we are going to do retrospective data collection from records, we will need at least a GP or someone that has medical knowledge. And an officer or technician to help him" (Clinical Neurologist, CN2, Cairo, Jan 2021)*

The expert's note showed that the lack of electronic medical records in the Egyptian healthcare system means that the only way to search and extract data retrospectively is manually from paper records. That makes it difficult for a non-clinician to handle the data extraction process, and hence, a GP would be required.

In addition, another public health researcher who worked on many projects that collected data from the elderly explained that a full department is required for the data entry process. She mentioned:

> *"Data collection should be done through a full department. You should develop a work plan, prepare the questionnaires, then collect the data, do the*

> *quality control, enter data into a computer, analyze the data and disseminate them" (Public Health Researcher, PHR1, Cairo, Jan 2021)*

The expert's note revealed that data collection is multiple processes that would require expert personnel to extract, enter and analyze the data. Yet, a well-developed questionnaire and a planned data collection system are essential to guarantee a seamless data collection process.

All in all, the discussions on data collection and entry indicated that depending on clinicians to collect and enter the data would be a huge burden on them due to their many responsibilities. In addition, a minimum level of medical experience is essential so that they can delve into the data and extract the information without an electronic record. This data is in line with the registry data collection model that was presented previously (R. E. Gliklich et al., 2014a).

Patient Input

Many experts stressed the importance of including patient input while collecting the data as the hospital records will not be sufficient in terms of providing all required information. Suggestions on face-to-face discussions with patients, either by the clinicians themselves or by a registry specialist, would be valuable in filling the missing information. Hence, creating human interaction through the process of data collection would help convince people to participate and improve the outcomes of the registry.

> *"The hospital record is not sufficient to start the pilot, so you will have to talk to the caregiver anyway. You can then ask them for consent for participation" (Social Researcher, SR2, Cairo, Jan 2021)*

However, experts also emphasized the specific problem of dementia that patients are not usually fully aware of their case or history, and hence, many interviews have to be done in the form of proxy interviews.

> *"A lot of information will be in the basis of proxy asked by caregivers, and that could be sort of filled in. Give them the forms to fill in, and then they send them back by mail or, if many people have access to online, they could do online" (Registry Specialist, RS1, International, May 2021)*

The expert's no state that caregivers' input is also important, particularly in the case of dementia. When including severely affected patients, the information required can be filled by the caregiver or any knowledgeable informant that is fully aware of the patient's case.

Establishing Online/ Electronic System

The discussions on the development of an online or automatic system for data collection were upfront. All experts agreed that the implementation of an automatic data collection platform should be the long-term goal. However, depending on the availability of resources, manual data collection will also pay off as realized from different registries.

The registry experts explained the importance of establishing an online or electronic system from their points of view. An expert who was involved in creating a recent registry in one of the developing countries mentioned:

> *"There are two things on that registry website; one is they can download the hard copy of the registry form and the consent document, print it out and use it, and fill it out, while in the clinic. But there's also a matching identical electronic registry form on the website where they can fill in the information they've captured. They can fill it in real-time, or they can write it out in the hard copy and then fill it in at a different time." (Registry Specialist, RS3, International, Sep 2021)*

The expert's quote elaborated on the importance of developing an online platform for the registry data so that the participating clinics would be able to electronically enter their data directly to the platform or even print out the data collection sheet, collect the data manually, then enter them into the system at any convenient time.

In addition, she elaborated on the benefits of having an online system for the data analysis process as well as the registry control. She mentioned:

> *"The advantage of the electronic form was that we could then automatically generate an excel sheet from it, with all the registry data so far. So, we can track who's filling in information and so forth" (Registry Specialist, RS3, International, Sep 2021)*

The expert's quote revealed that having an online system for data collection makes it easier to generate sheets for data analysis. In addition, it also enables the tracking of data entry to monitor which participating centers are filling the data.

Moreover, an Egyptian clinical neurologist who works in one of the largest geriatric centers in Egypt explained how crucial it is to have user-friendly software to be able to create the registry. He mentioned that:

> *"We need user-friendly data, and that will not happen unless we have a universal software that we enter the data into or at least be confined to a place or a university, etc." (Clinical Neurologist, CN2, Cairo, Jan 2021)*

All the statements reveal that there are many benefits of the electronic data collection procedure, including the better arrangement of work so that the clinician can enter the data at any time, the easier and user-friendly process that will definitely impact the registry, and easier generation of reports that help tracking patients and their progress. This can be aligned with the benefits discussed by Gliklich et al. in their study of the general and specific dementia registries' data collection process (R. E. Gliklich et al., 2014a).

Experts involved in different registries presented their experiences in the pr*ocess of establishing the electronic system for their registries, as well as how they function:*

> *"We hired someone who has already done a number of registry websites for other diseases ... There are health-oriented companies are sort of IT companies who do produce patient registries and so because a lot of the functionality is very similar across different registries that also meant it was cost-effective for us to go with that particular roof." (Registry Specialist, RS2, International, May 2021)*
>
> *"We collect the data in internet platform, the domains and all of that from each hospital in one platform in here to maintain the data safe. But then when you have too busy clinicians with all the divisions to remember have in mind, we have to attain the contact with them because if not, then, losing cases" (Registry Specialist, RS5, International, Oct 2021)*

The statements indicate that the establishment of a basic electronic system does not have to be expensive. Yet, developing and maintaining the system will require stable funds. In addition, when it is functioning, it will significantly enhance the data collection process.

Moreover, some experts highlight the option of providing different capture models for collecting data by allowing clinicians to fill in the data manually or electronically to guarantee their convenience.

> *"Then the other thing was the models capture, so we give people two options. we set up our website and ... only those who have been accepted into the registry can access that link" (Registry Specialist, RS3, International, Sep 2021)*

On the other hand, due to the limited fund and resources, some experts indicated that although the electronic platform is a goal, manual data capturing is still working and can adequately lead to the generation of numerous reports and outcomes.

> *"When we designed our model for the registry, one of the reasons why we were so keen to have this sort of standardized set of data was that ... everybody would know this is the type of data that we need to capture for dementia so*

> *eventually, the hope is that, when everything does move properly on to electronic records, we can just sort of plug in the electronic system into the registry" (Registry Specialist, RS2, International, May 2021)*

> *"You can develop the online, but you collect them in paper first then, you transfer them then you might have both options. But I think if you can do online that probably would be excellent." (Registry Specialist, RS1, International, May 2021)*

The experts' notes revealed that although the electronic data collection system is optimum, we do not have to wait until the electronic system is established, in case of limited funds, to create a registry. Instead, depending on what is already available, we can start collecting the data manually until the funds are available and the online system is established. In this regard, the use of a standardized data collection sheet is essential to help enter the data into the system when eventually established.

Incentives to Facilitate Data Collection

It is worth noting that the buy-in from clinicians and healthcare professionals in terms of regularly collecting data is a major building block for the continuation of the registry. Seeing the benefits of providing data to the registry is beneficial to encouraging the clinicians to endure the process of data collection.

Many experts stressed the idea of providing healthcare professionals with different kinds of incentives to foster their involvement in the registry. An expert involved in an international registry mentioned money as one of the incentives provided to clinicians. She stated:

> *"When we implemented it was a premier project. So, they did get money for registration, the government gave the primary care money for that, but they don't have it anymore. Now they can use the data and reports from the registry" (Registry Specialist, RS8, International, Oct 2021)*

The expert's quote indicated that they used to use money as an incentive in the beginning until the registry was set, and then they used reports instead. However, giving money incentives will require funds, and it can also be problematic in terms of entering mediocre data in order just to fill in the forms. Another international expert explained:

> *"I think it's good to use reports. Because if they have money rewards. It will not be such good data. I guess it is good and it's bad. I don't like it so much if they get money, but they can have something else." (Registry Specialist, RS9, International, Oct 2021)*

In this regard, experts discussed other ways of providing incentives for clinicians. Most of them agreed that having access to the data and reports as well as being given the opportunity of being included in publications were among the best ways that worked and encouraged people to be involved and collect data.

One of the international experts explained how registry reports could be used as incentives to encourage the clinics to participate. She said:

> *"It would be one of the ways that we could actually give back to the clinics… the clinic themselves have access to all of that data that they've entered in an electronic way now so they can use it for their own report some kind of things." (Registry Specialist, RS2, International, May 2021)*

In addition, other international experts elaborated that being involved in the final publication is a way of encouraging physicians to participate in data collection. They mentioned:

> *"To convince them to participate in this registry, another important factor is that all our publications, all the participants appear in the manuscripts as a study group" (Registry Specialist, RS8, International, Oct 2021)*

> *"Any publications that came out of the registry, they would be given an opportunity to be participants." (Registry Specialist, RS3, International, Sep 2021)*

On the other hand, a neuroscientist who was involved in establishing a recent registry in one of the developing countries indicated that using money at the beginning was not the case as they had limited funds. She explained how their incentive system went as she mentioned:

> *"Once we initially started, the only thing that they had was the publication. But when we got the grants, we actually pay the party, we pay the other investigators. So, we pay them for their recruitment. But for the publication, what we do is when we draft the manuscript, we send it via email to the entire group, and we request them to contribute to the manuscript, critique it, and so forth ... mostly it's just a few of us that champion the match" (Registry Specialist, RS3, International, Sep 2021)*

The expert's quote stated that they started their registry with limited funding, and hence, including participating clinicians in the publications was the only incentive they could use. However, when they started recruiting funds, they preferred to pay the participating centers to be able to recruit patients and other needed investigators. It is clear from the expert's experience that there is not one perfect incentive. Instead, the registry investigators should decide which type to use depending on the available resources. Overall, the statements of the experts prove that showing the healthcare professionals some benefits of collecting the data for the registry is essential for maintaining and sustaining the process.

5.3.2. Data Management

Access to Data

There was harmony in all the experts' opinions regarding access to data. All experts from clinical, policy and research fields agreed that the data collected for the registry should be accessible, particularly for the healthcare providers, in order to achieve the goal of the registry of improving the quality of services and benefiting patients. However, the majority of experts stressed the importance of setting up a clear data access plan to set clear policies and regulations that control the access of registry users to patients' data in a way that guarantees the security and privacy of data. A government official who used to work for the Egyptian ministry of health mentioned:

> *"There must be regulations, who can see these records and how the privacy of patients especially if you are speaking for example about mental health" (Government Official, HP1, Cairo, January 2021)*

The expert's remark indicated that limiting the access to data to specific personnel is crucial for protecting the privacy of patients, especially in this type of disease.

In addition, a clinical neurologist who works at one of the largest memory clinics in Egypt explained his point of view regarding the institution's access. He stated:

> *"Regarding access, I think active researchers should have access which ends once they leave the place. The institution itself should have indefinite access. The debate will be on the access of patients and their families, for them to benefit but also with no harm to anyone. They should only get access to specific targets. Finally, the controlling institution or ministry will have access to the final analysis or reports" (Clinical Neurologist, CN2, Cairo, Jan 2021)*

The expert's point of view stressed providing unlimited access to the registry data for the participating institutions to be able to benefit from the data they collected. Yet, this unlimited access should end for a researcher once he leaves the institution. The expert also expressed that patients and their families should benefit from the data as well by getting access to only specific targets of their data, not to cause harm to any other patient. He also indicated that the other partners or decision-making institutions should get access to the final reports instead of the raw data.

In the same regard, many experts involved in international registries asserted that having a clear principle for applying to get access is a valid approach to controlling consumers' access to the specific data they need. One expert involved in a well-established dementia registry mentioned:

> *"If you want to have specific kinds of data, you have to apply for it ... You need the ethical approach to apply for data." (Registry Specialist, RS9, International, Oct 2021)*

The expert's note indicated that to access the data they collect for their registry, an application is required mentioning the purpose of use of these data. Hence, they can provide specific kinds of data to selected personnel based on their need.

Another expert involved in planning another dementia registry expressed a similar opinion. She stated:

> *"Well, we accept data applications. So anyone can really request data from us directly." (Registry Specialist, RS2, International, May 2021)*

On the same hand, an expert involved in one of the recently developed neurodegenerative disease registries explained how data access must be controlled in a registry. She stated:

> *"In terms of access to the registry data, each of the contributing neurologists can only see their own data, and you can't see another person's data. So, the only person that can see the full data is the principal investigator or whoever else to give access to everyone's collective data everybody else can only see the data that they've inputted ... if any of them has an idea of a publication, they can suggest, and you can discuss it. And then you can give them the summary data or give them the data set if you trust them." (Registry Specialist, RS3, International, Sep 2021)*

The expert's remark highlighted the importance of having a clear principle for providing access to data that the registry principal investigator or administrator should control. The main idea is to provide access to requesters for only specific items that satisfy their purpose. Yet, participating clinics should have full access to only the data they have entered. Hence, the privacy of other patients would not be affected.

All in all, the experts' opinions confirmed that providing full access to everyone refutes the ethical approach for tiered patient consent. Hence, they elaborated on the benefits of developing an application approach that assures sufficient access to the users' specific needs. It is clear from their statements that only the principal investigators should have full access to the data then all researchers, healthcare providers, and policymakers can access specific reports or apply a proposal stating the purpose of requesting specific raw data.

Data Confidentiality

Confidentiality and privacy of patients' data were also raised during the discussions as the major ethical concerns to protect the participating patients. Experts agreed that protecting the privacy of patients is fundamental during the process to prevent any consequences of data leakage, especially since dementia is a kind of disease that could cause many implications for the patients if the family used the data against them to take control of the patient's properties.

> *"There is also a medico-legal impact of this specific data depending on which purposes this data will be used for. Especially dementia that might you know raise the issue of guardianship or so on if used by the patient's family" (Geriatric Training Consultant, GT2, Cairo, March 2021)*

In addition, experts from international registries highlighted the ethical regulations that control data sharing and privacy, which should also be followed by the registry. These regulations stress the vital role of protecting all sorts of data privacy, particularly when sharing the data is allowed.

> *"So there is actually important regulation called HIPPA, which assumes the confidentiality of data, so essentially the patients' data is actually considered secret......see this is part of policy, but it's also part of enforcement ... so you apply this also to a registry" (Neuroscience Researcher, NR2, Cairo, January 2021)*
>
> *"In Europe, we have this GDP or this general data protection regulation so that data can be shared, for example, and health-related data can be shared among different people within the health system on our own without needing consent from the patient ... but as soon as you start to make data available outside of the health service, the only way is with the person's informed consent." (Registry Specialist, RS2, International, May 2021)*

Moreover, international registry specialists discussed varied ways of protecting data privacy through only releasing aggregates of data to prevent any possible identification of a patient's case and through coding the data registered to hide all the personal information that could reveal the identity of the person.

A registry specialist elaborated on the idea of releasing aggregates of data to protect confidentiality. He mentioned:

> *"We only release data in aggregate, so we can't release individual-level data, because of the identification, the possibility of identification and confidentiality and that kind of thing." (Registry Specialist, RS4, International, Oct 2021)*

In addition, international registry specialists stressed the importance of coding the data to hide patients' names. They explained:

> *"Confidentiality of data is important, so we usually code the data with numbers or something, and we remove the names ... You as a researcher can keep the names, but that should be kept in a secure place with a password, and so on, there are ethical codes to deal with this. So, nobody can access it except you or the principal investigator" (Social Researcher, SR2, Cairo, Jan 2021)*
>
> *"You see the code that official quote for the patient, but not the names." (Registry Specialist, RS5, International, Oct 2021)*

It is clear from the experts' remarks that data coding is a valid approach that is applied in many international registries. All entered data are stored in a secure place, giving codes to each patient instead of his personal information. This way, a data protection framework is in place that will maintain the data collection with secured confidentiality.

Moreover, experts mentioned that keeping the original patients' logs could be a part of the clinics' practices while they only enter the coded information into the registry. However, some other structures which assign devoted data collection specialists require storing and coding data at a secured place handled by the registry staff.

One of the experts involved in a recently established registry explained how they collect the data from the participating sites. She stated:

> *"The site keeps a log of the actual name of the patient, the hospital number, and the telephone number. That's kept at the site ... The only thing that is on the registry is the identified information." (Registry Specialist, RS3, International, Sep 2021)*

As recognized from the experts' statements, establishing proper guidelines and procedures for data management will ensure the privacy of patients, and hence it should no longer be a concern. This data regarding the processes for ensuring confidentiality is in line with the published studies that discussed the implementation of any general registries (R. E. Gliklich et al., 2014e, 2014f).

Data Integrity

There is no doubt that data integrity and quality are critical for determining the utility of the registry in informing multiple stakeholders. Obtaining data that meets sufficient quality criteria is crucial to being able to generate accurate reports based on evidence. Setting the procedures that ensure the quality and integrity of data is a critical step during registry planning to guarantee the effectiveness of the registry in supporting patient quality of care as well as health policymaking (R. E. Gliklich et al., 2014a).

Many experts stressed the importance of ensuring the quality of data to guarantee its reliability. Training the registry workers sufficiently on the different steps of the work is a very essential step prior to the implementation. A neuroscience researcher who works in one of the largest research institutions in Egypt explained how ensuring data integrity requires many factors. He mentioned:

> *"The integrity of the data is actually very important ... We have reliable data, and we can go back. This requires infrastructure, requires a lot of financial investment, but it also requires a lot of human investment,t and the most human investment is education, because you need a workforce that istrainede,d and so it's an investment in education, it's basically an investment in policy, it's an investment in coming up with the correct guidelines for the best practices, and it's an investment in enforcement" (Neuroscience Researcher, NR2, Cairo, January 2021)*

The expert's note stressed the idea that for the data to be reliable, many factors have to be taken into consideration. Investing in building a suitable infrastructure for data collection and storage, investing in educating and training the registry worker, and also investing in establishing policies that support the registry are all required to ensure the integrity and reliability of data.

In addition, the experts elaborated on their experiences and suggestions to improve the quality and integrity of data through using unified tools, especially when setting the required diagnostic criteria, so that data would be consistent across the different sites. They also explained how using standard forms for data collection is essential for the consistency, completeness, and quality of data. A neuroscience researcher who works at one of the biggest research institutions in

Egypt expressed his point of view that unified standards are required for the registry. He mentioned:

> *"If you are unifying standards and how data is collected for the registry, you also need to know that the people who are collecting that data, whether it's the technician, the physician, the pharmacist, etc., are working to standards" (Neuroscience Researcher, NR2, Cairo, January 2021)*

The expert's quote revealed that not only the establishment of unified standards for the registry data collection is important, but monitoring the work and ensuring that all participating sites are following the standards is also crucial.

In addition, registry specialists who worked for internationally established registries stressed the importance of monitoring the diagnostic measures to ensure that the cases entered are diagnosed according to specific criteria. Experts mentioned:

> *"The way we identify our cases is through ICD 9 and ICD10 codes … and then we are given a data set that has individual-level data for each individual that has a diagnosis." (Registry Specialist, RS4, International, Oct 2021)*
>
> *"We wanted to be sure that the neurologist recently looked at the diagnostic criteria and that we're using uniform diagnostic criteria. So, before they say the person has the disease, they have to indicate how the diagnosis, at least look at our diagnostic criteria and be sure that these are people who meet these diagnostic criteria." (Registry Specialist, RS3, International, Sep 2021)*

The experts' notes revealed that unifying the diagnostic criteria used to register patients into the registry is a critical step in order to ensure the integrity and quality of data.

Moreover, experts indicated the importance of doing audits regularly to monitor and evaluate the effectiveness of the data collection process. An expert who works at a well-established international dementia registry explained how audits are conducted. He mentioned:

> *"We also have audits working every three months that we send to all our collaborators. We have new information related to the mentor, so it's a way to remind clinicians that they are participating in the registry, and they need to collect all the data.) (Registry Specialist, RS6, International, Oct 2021)*

The expert's quote emphasized the importance of conducting regular audits to ensure the data quality as well as encouraging the participating sites to send the data they have.

To conclude the experts' notes, various procedures could be followed to help ensure the integrity of data, including 1) depending on a well-trained workforce in all the steps of creating the registry; 2) unifying the used tools in terms of diagnostic measures, data to be collected and the data collection form to ensure the consistency of data as mentioned earlier in theme 2.4; 3) setting audits procedures to monitor the whole process and minimize errors. These findings align with the quality assurance processes and structure presented earlier (R. E. Gliklich et al., 2014a).

5.4. Registry Governance and Operation

It is undeniable that the proper governance structure of the registry, together with the oversight plan, are significant steps that guide the high-level engagement of the registry and ensure the attainment of the main purpose (R. E. Gliklich et al., 2014d). Accordingly, experts raised the discussions on multiple aspects related to the registry governance, including the process of initiating the registry, the governance structure of the registry that guarantees its functionality, as well as the funding and sustainability issues.

5.4.1. Initiating The Registry

Conflicting opinions appeared through the discussion of the initiation of a registry. Many experts involved in research and clinical fields in Egypt agreed that the establishment of a registry should start with the high authorities, either ministries or presidential initiatives. They stated that the initiative should start with the government to facilitate access to the available data sources as well as put a sort of enforcement on the participation of sites for data collection. A neuroscience researcher who works at one of the largest research institutions and a clinical neurologist who works at one of the memory clinics in Egypt expressed similar points of view. They stated:

> *"It has to come from the top-down; I mean, if I own my own hospital, my own clinic, fine, how did I collect the data? What are the standards? ... The government has to start, but the government also facilitates access. If I recently to walk to a hospital, say I'd like you to do this, I have actually spent time in convincing you" (Neuroscience Researcher, NR2, Cairo, January 2021)*
>
> *"So, it should start from upside down; we communicate with high authority, get the approvals, have access to the institutions, then start collecting the data. Otherwise, doing the opposite can end up with a very limited study" (Clinical Neurologist, CN2, Cairo, Jan 2021)*

The experts' points of view indicate that the involvement of the governmental authorities in the first step of initiating the registry would be powerful in terms of easily getting approvals to access patients and records as well as imposing some sort of enforcement on the sites to collect the required data.

Likewise, many Egyptian clinicians and policymakers suggested that creating a committee that includes the interested stakeholders, including government officials, would be a promising way to start the registry. A clinical neurologist who works in a large geriatric hospital expressed her opinion on how to start a registry. She stated:

> *"The best way to start is to have a committee from the first beginning, including all the stakeholders, in order to cooperate and allow you to start. Usually, anything that includes collaborative work, people like to feel they have ownership of the project, so they want to help in this, and to feel it will be a win-win situation." (Clinical Neurologist, CN4, Cairo, Sep 2021)*

The expert's quote stressed the importance of initiating partnerships with all the relevant stakeholders from the first beginning to boost their feeling of ownership of the registry and hence, facilitate their engagement. In addition, a government specialist who used to work for the Egyptian ministry of health added:

> *"The initiative was usually done by the government, especially if you have a committee, a committee that has all the stakeholders ... representing the ministry of health, ministry of higher education, ministry of defense, private sector, all the stakeholders, so we have all the sectors" (Government Official, HP1, Cairo, January 2021)*

The expert's note revealed that having a committee that brings all the sectors together would help facilitate the process and ensure the success of the registry. Yet, including the ministry of health in the early discussions is also crucial to help support the registry initiation and enforce the policies needed. An expert involved in an international registry explained:

> *"What might be helpful, even if you don't have a formal link with the Ministry of Health, I think, having a conversation with them would be cool because they will have a view of the kinds of questions they want to know the answers to in relational friendship and that might help you when you're trying to figure out what data, do we collect and that that's where that became quite helpful for us, ... They are able to give very much that sort of national policy perspective on some of these questions" (Registry Specialist, RS2, International, May 2021)*

The expert's note revealed that the link with the ministry of health is crucial even if they will not lead the registry establishment. The discussions with the ministry of health will help identify the data collected usually as well as the data needed. In addition, they can support the registry if there is a need for any national policy decision.

On the other hand, other international experts and researchers indicated that the initiative has to start from an academic institution before seeking adoption by the government. A clinical neurologist who works at one of the largest geriatric hospitals in Egypt explained how the registry initiation should follow a hub and spoke mechanism. He stated:

> *"It is more of a Hub and spoke mechanism. So, for any project to grow, it should start as a nucleus and nests, then they unite with each other to form the big project. We can start the pilot with the personal networks and partner with them, and then when the project is done, it should be owned by the institution which you collected the data from. That will make them fund the training, sustain the registry after the grant is done." (Clinical Neurologist, CN2, Cairo, Jan 2021)*

The expert's quote explained a good approach to initiating a registry by depending first on the surrounding networks to collect data. Then when the pilot is successful, other sites and institutions can be included for expansion. However, the difference in the procedures required for data collection in Egypt should be taken into consideration. Although it was indicated above that CAPMAS approvals will be required for data collection from general population for epidemiological purposes, collecting data from patients will only require the institutional approvals. Hence, using the networking pilot approach could be suitable in the beginning to avoid the complexity of procedures while providing fast preliminary results to encourage the involvement of the rest of stakeholders.

Similarly, a social researcher who has great experience working on elderly studies expressed her opinion on how to start a registry. She stated:

> *"It has to start in your institution or research center, or you can partner with an NGO and give the functional or technical procedures. The government then can adopt that and take the ownership, but the initiative itself will not start unless in a research institution" (Social Researcher, SR2, Cairo, Jan 2021)*

The expert's opinion stressed the idea of starting the registry pilot from an institution to ensure the functionality and success of the process. Then, the government might adopt the project later to take its ownership in order to be expanded to a national level.

The mentioned quotes elaborate on the benefits of starting the initiative from research or academic institution as that would help the faster implementation of the first pilot. Starting with the data available in one institution and then adding other sites from the personal network would help initiate a pilot that would be connected and expanded for further coverage. However, involving the government officials even in an informal setting would be helpful to assist in the identification of needs and policy implications. Furthermore, involving NGOs in the initiation process could be useful in terms of providing access and fund. Nevertheless, after the initiation of the first step, the government should be involved in a formal context to enable the national expansion of the registry.

5.4.2. Governance Structure

Experts agreed that an early established dignified governance plan is necessary to ensure the development of a registry that functionally satisfies the needs. Within a governance structure, there should be a clear assignment of the overall responsibility and accountability of all stakeholders and registry personnel in order to fulfill the domains and competencies of the registry's functionality and operation. The majority of experts stated that a board that includes stakeholders' representatives would be the optimal structure.

A registry specialist who is responsible for one of the well-established international registries explained how the registry structure should be. She said:

> *"It must have a Center personal data representative. So definitely, it will be the board, university hospitals, and we also have to have a steering group ...*

> *All parties must also be connected to a competent center for the data. The steering group also decides what to be in the register what data" (Registry Specialist, RS9, International, Oct 2021)*

The expert's note shed light on the importance of having a steering committee that connects all parties involved in the registry and works as the central representative who takes the required decisions.

In addition, some experts indicated that although the registry should partner with several stakeholders, the registry should be housed in an academic institution or a medical authority. One specialist that works for an international dementia registry explained her experience on how the registry should be housed. She said:

> *"Well, there are multiple partners. So, the registry is housed, and our office is within the university. And then we work closely, as I mentioned, with another office that helps us the link and obtain the data ... You know, various entities that request the data, so they are the founders of the Registry basically, so it's really a partnership of various entities that come together for the registry." (Registry Specialist, RS4, International, Oct 2021)*

The expert's opinion showed that although the registry structure involved many parties, the registry data and the administrative house should be placed in one institution, then the representative personnel work closely with the other partners.

Likewise, another registry specialist who is involved in one of the most successful international registries added:

> *"The right set belongs to the medical authorities of the region. But I think it's very important to have collaborations with other institutions that can have even further registries in publications and even related to managing databases. The registry team might be owned by medical authority but need to be prorated with academic institutions." (Registry Specialist, RS8, International, Oct 2021)*

A clinical expert elaborated that the founders of the registry, who are usually researchers or clinicians affiliated with an academic institution, will be the keenest on maintaining and sustaining the registry.

> *"The idea is that those who founded the registry will be the keenest on maintaining it. So, I do not think that being owned by the government would be a good idea in the beginning. They can be involved to support and do audits or something, but the project to expand has to be owned by the founders." (Clinical Neurologist, CN1, Cairo, Jan 2021)*

It is obvious from the expert's note that the adoption of the government of the registry could impose some bureaucracy into the governance structure and the whole process, which should be avoided. This expert was particularly concerned that those who created the initiative would be the most enthusiastic about keeping the functionality of the registry over time.

In addition, an international expert stated that the team that holds and operates the registry should be connected to the owners, whether it is a medical or academic institution, to facilitate the communication processes and enable solving any problems.

> *"The register holder has to be connected to the owner." (Registry Specialist, RS8, International, Oct 2021)*

Nevertheless, a clinical neurology consultant who is affiliated with a university and also involved in one of the governmental authorities in Egypt stressed the importance of creating a separate independent entity that holds the registry. She mentioned:

> *"It requires a high committee like a board or steering committee and be under the umbrella of a certain organization that does not belong to anyone ... It is a separate entity connected to different stakeholders. They feed it with the information. So, no one will feel they are subordinate in it, and everyone will help to proceed in the project." (Clinical Neurologist, CN4, Cairo, Sep 2021)*

It is clear from the expert's statement that she is worried about the deviation of the stakeholders from participating in the registry if they feel that it belongs to a specific institution. She also elaborated that all the stakeholders we are talking about are representing different authorities, and feeling subordinate will discourage them from participating. Therefore, she emphasized the importance of building the registry as an independent entity that includes the interested stakeholders as the board to which the registry team reports.

Overall, there was little agreement that a board of partners entity should be responsible for the registry to guarantee its independence. The consensus that emerged was that an institution should take the lead in initiating the registry, which would help the progress of the implementation process. This data is also in line with the previously published plan conducted for the Irish dementia registry (Hopper et al., 2016).

5.4.3. Funding and Sustainability

Experts agreed that securing stable funds for the registry would be challenging. Funds are required to initiate the registry but also to maintain the process and ensure its sustainability. The experts complained that the fund for this kind of initiative is rare as there is not much awareness of the importance of large datasets. One of the registry specialists who was involved in the planning process of a new dementia registry expressed her opinion about funding. She stated:

> *"I think one of the biggest challenges is funding. It's where the money comes from to do this, and it's not immediately in a lot of the funding calls that we would see. And they're much more about interventions or the science behind a particular condition. There's not as much funding for things like registries or databases or sort of quality information." (Registry Specialist, RS2, International, May 2021)*

It is clear from the expert's note that although securing stable funding is essential for establishing a registry, it is not as easy as securing funds for studies that tackle specific conditions and their interventions.

In addition, the experts elaborated on the need for obtaining funds to proceed with the initial set-up and the daily processes. In addition, they listed some activities that will require stable funds, including the data collection process, data entry, and hiring personnel to manage the registry. The specialists working for international registries elaborated:

> *"So, one of the challenges we were going to have been finding the money to keep this running, so you have to, particularly if you go for people and outside of the memory clinics, let's say for doing the data entry somebody has to pay their salary. So, bring out where those funding come from, and that's a challenge for us certainly, and we don't have a very clear view on that at the moment" (Registry Specialist, RS2, International, May 2021)*
>
> *"They've established the registry, now you have permission basically to access medical records and to access that information, and as part of that, there needs to be a funded position for someone to manage it" (Registry Specialist, RS4, International, Oct 2021)*

It is clear from the experts' quotes that many steps in establishing the registry require funding. Collecting data from patients outside the memory clinics, assigning a position for data entry, paying the persons who will collect the data, in addition to securing positions for managing the registry data all require funding.

Moreover, some experts who have experience in international registries or longitudinal aging studies indicated that the health authority in the country, e.g., the ministry of health, can support these initiatives. However, it is not a long-term process, and the registry will need to obtain funds from a funding agency or an international organization to sustain itself for a prolonged time.

A registry specialist who has experience working on registry planning and aging studies mentioned that the government could initially be a source of funding. Yet, secured sustainable funding is required for the long term. She stated:

> *"The Department of Health is, I suppose, funding this, but they don't want to do that in the longer term. We need to figure out a way to actually make us almost like self-funding in some ways, and so that's a challenge" (Registry Specialist, RS2, International, May 2021)*

The expert's quote sheds light on the importance of securing stable funds for the registry to be sustainable in the long term. Likewise, a researcher who has experience working in one of the largest aging studies conducted in several countries worldwide explained how challenging registry funding is. He mentioned:

> *"We do collaborate in some countries. This is a funding issue. The survey has to be funded, and the European Commission is paying something, but each country pays the bulk except for the poorer countries, someone will pay. In most countries, these are ministries who pay, the ministry of health, in other countries the ministry of employment, labor, science, etc." (Aging Researcher, AR1, International, Sep 2021)*

It is clear from the expert's note that the funding agencies pay part of the costs to support this type of initiative, and the government ministries also participate in supporting the rest. Yet, in developing countries, when governments are not able to pay, funding agencies and institutions become the main source of registry funding. This finding is in line with what was done previously in the Egyptian 100 million Seha initiative, as the main source of funding for the initiative was the World Bank. This confirms the idea that for the registry to be implemented, the registry administrators do not have to depend only on governmental funds but also seek funds or grants from funding agencies that support similar initiatives.

Moreover, an expert involved in one of the well-established international registries indicated that they have to apply for funds every year and that the amount they get depends on their success and the effectiveness of their reports. She stated:

> *"But we have to apply every year, yes, we think we know we're going to get the money next year, but we don't know how much. It depends on how good we are or have done. They evaluate us every day to decide how much money we get."*
> *(Registry Specialist, RS9, International, Oct 2021)*

From all the experts' remarks, it is obvious that affiliating the registry to an academic or research institution would be beneficial in terms of increased opportunities for obtaining external funds. This is particularly important in the absence of national mandates on funding such activities. The experts listed some potential sources of the fund as governmental support, academic grants, and external or international funds.

Moreover, experts have linked the availability and stability of funds to the sustainability of the registry. Many of them mentioned that the registries that proved the successfulness and sustainability of operations over a prolonged time were the ones that have secured funding.

On the contrary, an expert involved in an international registry in one of the developing middle-income countries presented her experience with initially establishing the registry with no funds available. She stated:

> *"So, it will be difficult. I think the truth is that the actual registry, if it's a basic registry, funding doesn't matter, and in fact, we didn't get any funding for the basic registry. The only major costs were the setup, securing the domain name, setting up the websites, and then with the websites, we had to pay maintenance. So, those two tasks didn't cost us at the time up to $300." (Registry Specialist, RS3, International, Sep 2021)*

The specialist's quote revealed that although securing funding is challenging initially, establishing a registry could be done with minimum costs when starting with a few sites from the institution's network. However, funding will be required during the further steps of expansion.

On the other hand, experts have also illustrated other factors that affect the sustainability of the registry, including the availability of legitimate regulations or sort of law that enforce and facilitate the collection of data for healthcare benefit. An expert who is responsible for one of the most successful registries mentioned:

> *"So, we have spoken to numerous other countries ... the ones that have been the most sustainable long term have been the ones that have had legislation established" (Registry Specialist, RS4, International, Oct 2021)*

> *"I feel like that is key, so there's sustainability in terms of it being a law" (Registry Specialist, RS4, International, Oct 2021)*

It is obvious from the expert's quotes that the availability of laws and legislations that support the registry in terms of data collection enforcement is key to maintaining the sustainability of the registry.

Another factor that impacts sustainability is the compliance of healthcare providers in terms of collecting the data for the registry. In addition, the experts agreed that convincing patients to participate and share their data in the registry could greatly impact the registry sustainability and the prolonged as well as longitudinal data collection.

A clinical neurologist who works at one of the largest geriatric centers in Egypt expressed his opinion regarding registry sustainability. He stated:

> *"Sustainability will depend on two things, the target population or physicians that will be included, and they should be included in the selection of data, so they do not waste their time entering data that will not benefit them or the*

> *patient. The second thing is to convince the patients and physician and take their consent." (Clinical Neurologist, CN2, Cairo, Jan 2021)*

The expert's note shed light on the importance of considering the overload of work put on the shoulders of participating physicians. Designing a minimum dataset that includes the required items while not adding much load on the clinicians would help maintain their willingness to participate and hence sustain the registry data collection process.

Similarly, an international expert who was involved in the set-up of a current registry in one of the developing countries stated that:

> *"In terms of sustainability, I think, where we have had a challenge is that you have to prompt people to remind them because I think most people participating in this study, they get tired or fatigued after a year or year and a half." (Registry Specialist, RS3, International, Sep 2021)*

The expert's note confirmed the idea that encouraging the participating physicians is extremely important not to lose their interest and continue collecting their data.

All in all, the experts' remarks reveal some opportunities that can enhance the participation of both healthcare professionals and patients in the registry. Including the healthcare workers in the planning process, particularly the development of the minimum dataset and the data collection form, is essential to consider their convenience and effort (Theme 2.4). In addition, prompting them through regular reminders is also beneficial in encouraging them to collect new patient data. Moreover, depending on skilled personnel to acquire the patient concern is crucial to ensure their involvement and encouragement (Theme 3.1).

5.5. Legal and Ethical Considerations

5.5.1. Principles of Ethics and Regulations

There is no doubt that the basic principles and guidelines that control ethical processes in conducting research using human subjects will also apply to creating a registry to protect the participating individuals (*The Belmont Report | HHS.Gov*, n.d.). All experts agree that obeying the ethical considerations of imposing no harm on patients is fundamental.

A social researcher who works for one of the largest research centers in Egypt, responsible for many studies conducted on public health and aging, stated that:

> *"So first, you could obey with the ethical consideration of any research, not to harm the patient or the caregiver. Don't impose any kind of stress on the person. this is the basic." (Social Researcher, SR2, Cairo, Jan 2021)*

In terms of the regulations required for establishing a registry, many Egyptian experts raised the discussions on the required approvals that should be obtained prior to the initiation of the registry. They indicated that the process of getting ethical approvals is not always straightforward, especially when collecting nationwide data or using population-based surveys. Training permission from CAPMAS would be essential in the population-based studies, as mentioned earlier (Theme 2.1). In addition, the experts highlighted the fact that getting an IRB from the affiliated institution is also a fundamental preparatory activity prior to the initiation stage.

A social researcher who has experience in many public health studies explained, from her experience, the regulations that should be followed to conduct such a study. She stated:

> *"There are preparatory activities to implement the registry, implementation efforts, so first, obtain permissions to be able to strategize the project, it is not straightforward as many parties can be involved. Second, you conduct the ethical review prior to data collection. To collect data, in a field, you have to abide by two conditions 1) legal conditions to obtain CAPMAS field permits and 2) review process to establish ethical consideration." (Social Researcher, SR1, Cairo, Jan 2021)*

The expert's quote revealed that various preparatory activities are required prior to the initiation of the registry study. Obtaining CAPMAS approval as well as the institutional IRBs are the main steps. Yet, the CAPMAS approvals are only required for the epidemiological studies that target general participants from the country, not only patients. Collecting data from patients that visit medical centers would only require the IRB approval of the participating institution.

On the same hand, a clinical neurologist who used to work for a large geriatric hospital in Egypt mentioned:

> *"You will need to get permissions first from the university or institution you are collecting the data from, and they can ask you to get security approvals as well as all the papers for who you are and the purpose of collecting the data, ethical procedures, and regulations and so on" (Clinical Neurologist, CN4, Cairo, Sep 2021)*

It is clear from. The experts note that getting the required permissions is a critical step prior to initiating the registry to be able to collect the data of patients with no ethical considerations.

Similarly, international experts addressed the same point and explained their personal experiences. One of the experts indicated the importance of carefully following the regulations as an essential step for any registry in order to have the rightfulness to collect, share and publish the data. She stated:

> *"So, the first thing I think is the most important is regulation. Because the data that you're collecting, from whichever registry you set up, essentially, to publish it, you do have to get ethics approval for the process. So, that's one thing that's important. So, either insert whatever method is used in Egypt, whether it's each institution or there's a single national ethics process, you need to get approval, but that means that you have to establish what your initial methodology is going to be and so on, when you're putting together the proposal" (Registry Specialist, RS3, International, Sep 2021)*

It is clear from the expert's point of view that getting ethical approvals is mandatory for the process. However, to facilitate this process, the registry team should set a clear strategy or plan proposing the main purpose of the registry, the procedure, the methodology, and the anticipating outcomes to be able to easily get these permissions.

On the other hand, one international expert presented her experience regarding the difficulty of including the private sector in the registry due to the complex procedures. However, approvals from all the participating institutions as well as involved clinics and departments should be obtained. She stated:

> *"We didn't include private hospitals, we just use those university hospitals, and so all of them had to get permission, ethics approval from that institution. So first, you have to get national approval, so we went to the national ethics committee. Then on institutions, participating neurologists submitted the national approval to the institution to recruit patients from the institution's hospitals." (Registry Specialist, RS3, International, Sep 2021)*

The expert's note revealed that including the private sector hospitals from the early beginning would be a challenge due to the limitations of getting ethical approvals. Depending on the public and institutional hospitals to set up the registry would require the institutions' approvals that would be easily handled, especially if the ministry of health is a partner in the study.

5.5.2. Patient Consent

All experts agreed that collecting patient data will require obtaining patient consent. An opt-in or opt-out consent is essential to guarantee voluntary patient participation and ensure patients' ethical regulations and privacy.

An international specialist who works for one of the well-established registries explained his experience regarding the patients' consent. He stated:

> *"We need each professional in each hospital that correlates with us to request to the patient the informed consent to agree to be registered in an anonymous way, but an informed consent is necessary to introduce the latter from the patient." (Registry Specialist, RS6, International, October 2021)*

It is obvious from the expert's quote that obtaining patients' consent is necessary prior to collect their data. Introducing patients to the purpose of the study and informing them that their data will be anonymous is a way to help convince them to participate.

Another registry specialist added that getting the patient's consent might be challenging. He stated:

> *"I think the informed consent is one of the big issues; people come to the clinic then make sure to ask if they want to participate in research and if they accept you get a consent for participation for the assessment and for the follow up" (Registry Specialist, RS1, International, May 2021)*

The expert's note revealed that the patient has to accept the registration of his data in the registry and give consent for investigation and follow-up. The type of consent was also discussed by one of the international registry specialists who mentioned:

> *"We have to tell the person that now we have to register you and they can say no, they don't need to say yes or sign something, but they have to be informed both by paper and by telling them." (Registry Specialist, RS8, International, October 2021)*

The expert's opinion stated that both paper and oral consent are accepted; the most important thing is that the patient agrees to participate. In addition, experts mentioned the role of caregivers in signing the consent form in the case of severely demented patients, which indicates that the process of taking consent is essential. A clinical neurologist who used to work for one of the largest geriatric hospitals in Egypt stated:

> *“For patients, some of them will not be able to consent, so you will have to get the consent from the caregiver. I do not think that anyone would refuse, especially those who visit the public hospitals” (Clinical Neurologist, CN1, Cairo, Jan 2021)*

The expert’s note shed light on the idea that many dementia patients may not be able to consent. In this case, consent from their caregiver would be required.

The discussions with experts also shed light on the limitations that might appear due to patients’ consent. One international registry expert presented her experience mentioning that obtaining patient consent limits the activity of collecting data from previous patient records as it would require time and effort to contact all of them to obtain consent. She mentioned:

> *“Thinking about going back in time and kind of saying these people who historically have been on the registry or have had a diagnosis of dementia for, you know, a number of years, I don't think we will go back and try to contact all of those. I think we will just start from a certain point in time. Say from here on, we'll ask people about consent.” (Registry Specialist, RS2, International, May 2021)*

The expert’s quote shed light on the challenge that might appear when trying to include retrospective patients’ data available at hospitals in case consent was obtained. Yet, starting from a certain time point and getting patients’ consent prior to registering them would be the most suitable method.

However, some experts highlighted that the availability of a national or legal mandate to collect data for the benefit of the healthcare system is very beneficial as the registries that follow these jurisdictions are not required to get consent for data collection. Yet, they have to obey the principle of ethical regulations for data privacy, sharing and confidentiality.

An expert involved in one international registry expressed her point of view on how sharing data should be handled when having patients' consent. She stated:

> *"Something to think about is, are you going to have the data available for researchers to use? we're concentrating on the health service, but at some point, we will want to open up the data for research, and we're going to have to put in a consent process when we do that." (Registry Specialist, RS2, International, May 2021)*

The expert's note stated that sharing and using the data in the healthcare system would not require consent under these legal mandates. However, opening access to researchers would certainly require consent from patients prior to sharing their data.

Overall, many concerns are there regarding the importance of opt-in and opt-out patient consent in order to be included in the registry. Although most of the researchers expressed the importance of this step to guarantee the patients' rights, many experts argued that this process should not be necessary as this might hinder the process of data collection. In addition, a national mandate that states the mandatory collection of patients' data for benefit healthcare services should be established. The availability of legal laws that enforce and control the collection of data would greatly impact the registry and facilitate its progress (R. E. Gliklich et al., 2014b).

5.5.3. Need For Enforcement

Some Egyptian experts argued that establishing a national registry that includes data from all over the country would require a system of enforcement. A sort of national law that states the mandate of collecting data on health that will enforce all the sites in the country to participate and enter the data of their patients into the system. The legal authorization will tremendously facilitate the process of data collection in terms of obliging professionals to enter the data using the standardized data collection forms set by the registry.

A neuroscience researcher who works for one of the biggest research institutions in Egypt expressed his opinion regarding the need for enforcement. He stated:

> *"Part of that is basically, of course, communicating and enforcing and coming up with rigors ... I cannot go to every hospital in Egypt and tell them this is a platform I want you to use; who am I? And if you are going to put something in place, you need a system of monitoring and assessment. How do I know it is working? How do I know there is compliance? Which means you need to put in place also a system of enforcement" (Neuroscience Researcher, NR2, Cairo, January 2021)*

The expert's quote revealed that having a sort of law that supports the registry and enforces the data collection process would be required to be able to include all the centers on a national level. Otherwise, only the centers that have direct contact with the registry investigators would be willing to participate.

In the same regard, international experts explained their experiences with their established registries and how the data collection laws impacted the process. They mentioned:

> *"So now it is a law, and we have, as part of the law, the ability to access secondary data sources to be able to compile the registry, data from insurance companies, so any data that are collected for billing and for insurance purposes. So, we collect long-term care information ... It's our legislation that gives us the permission to do that, because sometimes you don't have that sort of permission because of confidentiality issues" (Registry Specialist, RS4, International, Oct 2021)*
>
> *"We're connected to legislation for data collection, it's an organization for quality registries. We have a real strict regulation, what we can do and what we cannot do" (Registry Specialist, RS8, International, Oct 2021)*

It is clear from the experts' notes that the legal and regulatory environment in the country has many implications for the process of registry development. There is a need for a national mandate that enforces the collection of patients' data and information for use in advancing healthcare services and procedures.

5.6. Challenges and Barriers

Experts identified several challenges that could face the process of establishing a national dementia registry in Egypt. However, the experts themselves., in many cases, were trying to present the available opportunities that could help overcome the challenges. Yet, many of the barriers need to be considered while planning the registry to eventually design the most suitable structure for our context.

5.6.1. Disease Perception

There is no doubt that stigma and stereotypes are significant complications of dementia due to the perception of people regarding the disease (Low & Purwaningrum, 2020). These perceptions significantly affect the well-being and quality of life of dementia patients and their families (Rewerska-Juśko & Rejdak, 2020; Swaffer, 2014). Therefore, many families tend to be protective of their patient relative, which hinders diagnosing and registering the patient.

Many experts indicated that peoples' perceptions of dementia are among the main obstacles in general advancing disease outcomes. Yet, collecting patients' data for a registry would be hindered due to the lack of awareness and the fear of social stigma.

An international expert who is involved in one of the recently established registries stated her experience regarding the peoples' perceptions. She said:

> *"People have very different opinions of others and people with dementia themselves and their families, they didn't want to be asked about consent, or they didn't want to be asked about putting information onto the registry when they were only receiving their diagnosis, because they said that's a very*

> *emotional time. They're trying to understand what the diagnosis means and so on" (Registry Specialist, RS2, International, May 2021)*

It is obvious from the expert's note that a diagnosis of dementia makes people a bit sensitive or worried about their case as the general perception about the disease is negative, which makes them emotional. Many patients refuse to be asked to participate in a study during this emotional time.

In addition, a neuroscience researcher who works for a large research institution in Egypt and who also has a long experience working in the USA expressed his opinion about the stigma associated with dementia. He stated:

> *"A lot of cultures are very protective about the population. Part of it is the pharma culture because if you're taking data about disorders, there is a certain stigma, so one wonders whether some cultures, not specifically in Egypt but in general, mental diseases are underreported, so in certain circles, culturally even in Egypt, if you have somebody who's a mental disorder you basically lock him away and don't wanna embarrass yourself" (Neuroscience Researcher, NR2, Cairo, January 2021)*

It is obvious from the expert's quote that the social stigma associated with dementia makes families tend to be protective of their patients. The fear of being stigmatized makes them hide the patient and refuse to share the data. Yet, this social stigma is not only associated with dementia but is usually associated with any mental disorder.

Moreover, a public health specialist added that the case of dementia stigma worsened after the COVID-19 pandemic. She mentioned:

> *"So now there is COVID, the people who have COVID fears to tell because they are stigmatized, so think of people who have dementia" (Public Health Researcher, PHR1, Cairo, Jan 2021)*

The expert's note revealed that the stigma associated with dementia could be very limiting, and that appeared after the COVID-19 pandemic. It was apparent that people with COVID-19 feared admitting that they were infected not to be stigmatized. Yet, the stigma of dementia is much worse.

A clinical expert elaborated that social stigmatization is a serious issue as it hinders the patients from seeking help unless they are severely affected. This leads to the late detection and diagnosis of many of the cases that are mostly severely deteriorated, which decreases the effectiveness of the used interventions. She stated:

> *"The issue of stigmatization is a very big issue, especially in dementia or in all the psychological diseases in general. The patient usually comes to us at a moderate to severe stage, and their family only brings him when they do not know how to deal with him. This is the fact that they do not come early on. No one comes early except the people who are very highly educated or those who have other conditions, and their consultant referred them to us ... So, we call it a memory clinic, not a dementia clinic, for example, so that we can decrease the stigmatization in a way" (Clinical Neurologist, CN1, Cairo, Jan 2021)*

The expert clearly indicated how the fear of stigma impacts when a patient is diagnosed unless the patient is highly educated or is referred by another consultant. She also mentioned that the clinicians try to reduce this stigma in all ways to encourage patients to visit the clinics, seek help, and get the needed care.

In addition, some experts stated the opportunities available to overcome the stigmatization issue when developing the registry. They mentioned:

> *"We recognize the stigma; we have the same issues here. So the way that works, so we show the patients that nothing that's posted online can identify them, so that way they're usually able to give their consent" (Registry Specialist, RS3, International, Sep 2021)*
>
> *"Definitely there is a stigma, but you know, those who left their homes and came to visit the clinic are not the ones who fear stigma, The stigmatized are*

> *the ones who hide in their homes, and no one knows anything about them" (Clinical Neurologist, CN1, Cairo, Jan 2021)*

It is clear from the experts' notes that informing and convincing patients that their data will remain anonymous and no one will be able to identify their personality is crucial to encourage them to accept to participate and sign the consent form. In addition, initially, depending on patients that are alr*eady diagnosed in hospital clinics are not probably going to face the problem of fear of stigmatization as the fact that the patients went to seek help indicates that they overcame this fear of stigma.*

5.6.2. Disease Diagnosis

Dementia is a syndrome that is usually hard to diagnose due to many factors. Most of the experts elucidated that this part of diagnosis is particularly challenging in dementia as usually diagnosing the disease is either late, inaccurate, or broad with no indication of the subtype.

Absence of Accurate and Early Diagnosis

All experts agreed that the absence of an accurate and early diagnosis of dementia is a major challenge. It is usually hard to reach the people as they only seek a diagnosis in the moderate or late stages of the disease. This leads to losing a very high proportion of potential patients as well as including data of only the severe cases, which will have implications on the outcomes of the registry.

A clinical neurologist who works at a geriatric hospital with also a long experience in the UK mentioned:

> *"The second thing is the absence of an accurate diagnosis. This makes us discover cases only when they are in late stages. That's because we don't have GPs, so the patient doesn't go to a specialist unless someone refers or*

> *diagnoses him. So, only 10% of the patients will come to the clinics, but we lost the other 90%" (Clinical Neurologist, CN3, Cairo, March 2021)*

It is obvious from the expert's note that most dementia patients do not get the proper diagnosis unless they are referred to a neurologist by another specialist. This problem is due to the lack of general practitioners in Egypt. So, no specialist discovers the symptoms unless the patient is severely affected; hence, they refer him to a neurologist.

In addition, one of the international registry specialists added that patients usually do not seek help unless they are severely affected, which also hinders the diagnosis until the late stages. She stated:

> *"It sounds like most people don't have dementia properly diagnosed in the later stages because they're only seeking the care if they need to care, you know." (Registry Specialist, RS4, International, Sep 2021)*

In addition, experts also highlighted the fact that a national registry to be representative should include all the patients with the disease. A clinical neurologist expressed her point of view regarding the unrepresented patients that do not visit public hospitals. She stated:

> *"The main challenge is reaching the patients. So, the patients only came when no one was able to deal with them, which means that their case is severe or deteriorated. Also, there are patients who visit private clinics; how will you include them in the registry? Then you have those who are at home, and no one knows about them." (Clinical Neurologist, CN1, Cairo, Jan 2021)*

It is obvious from the expert's quote that many dementia patients either are not diagnosed or visit private clinics, which makes the patients available in public hospitals, not representative. Likewise, another clinical neurologist added that nursing homes are also a target. He mentioned:

> *"The nursing homes do not have a psychiatrist or neurologist, but they have a good medical service, internists, and request neurologists when needed. So, it depends, some patients are diagnosed, but there is no system" (Clinical Neurologist, CN3, Cairo, March 2021)*

The expert's note revealed that nursing homes are also a target place for registry as many of the elderly living there might have dementia while not diagnosed as most of these homes do not have a specialized neurologist.

Overall, collecting data that is representative of all of the population is important. However, this is complicated in the case of dementia as most of the patients are either undetected at their homes or diagnosed at private clinics or nursing homes which are difficult to include in the beginning, as mentioned earlier (Theme 2.3).

On a similar note, international experts explained how this fact of dementia under detection a limiting factor for data collection is, especially when depending on medical records. Some of them suggested expanding the diagnostic process to all elderly patients in a participating site, including those who are visiting with other conditions. They mentioned:

> *"What is difficult in patients' records is the diagnosis. Dementia is under-detected or diagnosed, you get many people in the hospital come in, say respiratory or cardiac issues, but dementia has not been diagnosed or not in the record. This is one way to go, but you probably will have to have a way of verifying whether the people have actual dementia or not" (Registry Specialist, RS1, International, May 2021)*
>
> *"If you could even do some sort of assessment, a cognitive assessment on individuals that are a certain age, so maybe 60 and over. That might be a way to identify them a little bit more in the earlier stages, which is, you know, while cognitive impairment is not quite dimension, yet that might give you some more information, depending on your research questions" (Registry Specialist, RS2, International, May 2021)*

It is clear from the experts' quotes that generalizing the cognitive assessment to include all the patients above 60 could be a way of including patients who are undiagnosed. This approach can open the opportunity for detecting more patients in earlier stages. Yet, some sort of monitoring should be implied in this approach to verify the accuracy of diagnosis.

The concept of verifying the diagnosis was also raised to overcome the difficulty of correctly diagnosing the disease or its subtype. Experts from an international registry presented their experience, mentioning that depending on two or more different specialists to diagnose a case is useful in terms of case ascertainment. They stated:

> *"Dementia is a bit different. So, if you're doing a dementia registry, the level of cases attainment you probably have to consider multiple levels and so that, for instance, with this are you including all dementias. But they also have to indicate the diagnostic criteria for dementia, but also what's sub-type of dementia. So, one of the critiques we had for our dementia study was, I mean, for case ascertainment, you may have to have two or more people agree on the subtype of dementia by looking at the clinical data and radiological data. So, it's a bit more involving because if they say that they are registering for Alzheimer's, they have to say, Okay, how did they arrive at the time of diagnosis and so forth." (Registry Specialist, RS3, International, Sep 2021)*

> *"In a hospital, what you might have to do is to go, detect and diagnose people yourself because they may have no diagnosis for dementia, or they have dementia undiagnosed ... I do not think you can just accept the chart diagnosis, and to go to hospital and see all people that are over 60 or 65 that's a huge resource for you" (Registry Specialist, RS1, International, May 2021)*

Overall, the experts' notes reveal that to overcome the challenge of detecting and diagnosing dementia. Some standard procedures should be put in place to help the early detection of patients as well as standardized, verified diagnostic measures. Depending on two specialists for diagnosis could be a way for the ascertainment of diagnosis. In addition, assigning a specialist from the registry to review the diagnosis and the followed criteria could also be another approach for verifying the diagnosis.

Dementia Subtypes

In addition to the late, inaccurate detection, identifying the sub-type of the disease was a concern for many experts. Although many of them ascertained the importance of including the different forms of dementia while collecting the data, some experts disputed this idea and encouraged the use of a broader classification of the disease.

One of the international specialists involved in establishing a recent registry expressed her opinion on including dementia subtypes. She stated:

> *"The thing with dementia is that it seems very obvious until you start doing research ... So, so I think the greatest challenge offered is distinguishing all similar forms of dementia. And also, so sometimes it's not obvious." (Registry Specialist, RS3, International, Sep 2021)*

It is apparent from the expert's comment that distinguishing the dementia subtype is a challenge as it is not always obvious. In the same regard, a clinical neurologist who is responsible for a large geriatric hospital in Egypt and who also has research experience added:

> *"Including dementia subtypes would need more investigations by a specialized person. So, it might be easy for someone to tell that a person has dementia, but which type of dementia? This is a step further that would require more specialized persons. So, it could be a second stage which you will need to verify ... So, more or less, the broader the classification, the less you will need specialized persons because, after all, the highly specialized people in the area of old age are not too much" (Clinical Neurologist, CN4, Cairo, Sep 2021)*

It is clear from the expert's thoughts that indicating the exact form of dementia would require more effort and resources than a highly specialized professional. In addition, the detection of the subtype might still be unclear even when applying all the standard measures due to the complex nature of the disease. Hence, in the beginning, adopting a broader classification could be a more practical approach.

5.6.3. Issues of Data Sources

Diversity of Sources

Many experts agreed that the diversity of data sources might be a challenge for the data collection process, particularly in the case of Egypt. Experts discussed the problematic situation of dementia in the absence of the optimum role of primary care.

A government official who used to work for the ministry of health explained the challenge of diversity of specializations that should be included. He said:

> *"But it's very difficult, especially since most of the people with dementia go to Internists rather than going to Psychiatrists or Neurologists. They would go to private doctors. Because people are always afraid of visiting a psychiatrist…. Most of them would go to an Internist, and for you to initiate this, you have to include Internists, Psychiatrists, and Neurologists. It's very difficult." (Government Official, HP1, Cairo, January 2021)*

The expert's quote revealed that the situation in Egypt is challenging, especially in the absence of primary care medicine. Patients usually fear visiting a psychiatrist or a neurologist. When they suffer any symptoms, they usually visit an internist. Hence, the registry should include psychiatrists, neurologists, and internists in addition to the private clinics. Yet, this is very challenging, especially in the phase of initiation.

In addition, the diversity of the service providers is also a challenge. The government official added:

> *"It's very difficult because, in Egypt, we have different types of services. We have services in the ministry of health, services in the ministry of higher education in the university hospitals, the army hospitals, police hospitals, and the private sector ... This is the difficulty in the registry in Egypt." (Government Official, HP1, Cairo, January 2021)*

The expert's quote elaborated on the challenge that arises from the diversity in data sources as in Egypt, there are several healthcare service providers, including the public, university, army, and private hospitals, and each of them has a variety of cases that would be difficult to be included in the registry, especially in the beginning.

Moreover, a registry specialist who has experience working on elderly research studies in Egypt added:

> *"With you, the challenge in clinics is the distance, the distance between clinics outside Cairo and even Cairo is a huge city, so you just try" (Registry Specialist, RS1, International, May 2021)*

The expert's quote sheds light on the challenge that will arise due to the large distances between the governorates in Egypt. Cairo is a huge city, and collecting data from all over Cairo would be challenging.

Overall, from the experts' quotes, it is obvious that most of the patients usually visit private clinics of different specialties rather than visiting public memory clinics. In addition, the fact that Egyptian healthcare system comprises many different types of medical services, including the public, university, private hospitals, and clinics, in addition to the military and police hospitals. Each of these service providers is part of a different ministry which complicates the process of including data from all the representative sites. In addition, the large distances between the governorates might be a challenge for collecting data from outside Cairo.

Moreover, a clinical registry expert indicated that the inclusion of the private sector in order build the national registry would be challenging. A clinical neurologist explained his opinion as he said:

> *"The idea of being national is having some limitations that the private sector is not always easy to be included" (Clinical Neurologist, CN4, Cairo, Sep 2021)*

Taken together, the findings are consistent with the earlier discussions on the importance of determining a few accessible sites to start initiating the registry, then the rest of the data sources can be added in the next phases of the implementation process (Theme 2.4).

Improper Documentation

Many experts raised the discussion of the importance of data documentation as a significant limiting factor for collecting data from patients' records. The experts clarified the situation in the Egyptian health system as, in some cases, there is no regular recording of cases, while in most of the recorded cases, the documentation is incomplete. The Egyptian experts explained:

> *"So, the challenge in dementia is that what is documented is much less than what is already there" (Clinical Neurologist, CN1, Cairo, Jan 2021)*
>
> *"There is no proper documentation, either there are no records or incomplete records or records that are filled as a template with no specific or accurate data" (Geriatric NGO Consultant, GN1, Cairo, Jan 2021)*

The experts' quotes revealed that the improper documentation of cases might hinder the collection of data retrospectively from the available records. In most healthcare centers, either there are no available records, or the records are incomplete.

5.6.4. Challenges of Data Collection

Many experts explained their concerns regarding the difficulty of data collection processes. Some of them stressed the challenging process of interviewing dementia patients when recruiting patient cohorts. It usually ends up doing proxy interviews with the caregiver, which makes the process a bit complex. However, an aging researcher who is involved in many longitudinal studies on aging mentioned the open opportunity to build on the data that was already been collected in the study. He said:

> *"It's very hard to interview these demented people; in most cases, we end up doing a proxy interview. But in some sense, you could create a dementia registry by the data we have" (Aging Researcher, AR1, International, Sep 2021)*

Yet, this approach will require a more standardized evaluation of data to detect the diagnosed patients among the normally aging participants, then contact the patient or the caregiver to complete the required assessments. This idea is consistent with the fact that dementia registries are different from aging longitudinal studies as registries require the application of gold standard diagnostic measures in order to include patients in the registry, unlike longitudinal studies.

In addition, most Egyptian hospitals, particularly the public ones, use manual documentation forms, which make the data hard to retrieve. Clinical neurologists working in different Egyptian geriatric institutions added:

> *"The major problem is that the data we have are on papers in most of the medical institutions. Some have started to use electronic records now, but mostly we have paper records, and collecting the data from papers is much harder. Definitely, the use of technology will save a lot of time and efforts, but many places won't be able to deal with that" (Clinical Neurologist, CN3, Cairo, March 2021)*
>
> *"We have registered data, but in the form of paperwork, the problem of paperwork is that you cannot retrieve it." (Clinical Neurologist, CN2, Cairo, Jan 2021)*

It is obvious from the experts' quotes that retrieving data from the already existing paper records is also challenging. Trained and specialized personnel would be required to be able to identify the suitable diagnosis to be added to the registry.

Moreover, a data consultant raised the issue of storing data. She clarified the point from her experience with data collection efforts in public hospitals. She mentioned that this sort of big dataset requires large servers that are, in many cases, not available in hospitals. She stated

> *"The problem is where to store the data? That would need large servers"*
> *(Data Consultant, DC1, Cairo, Jan 2021)*

Overall, the data collection process would face many challenges depending on the technique used. Using multiple data collection methods is extremely beneficial for the registry's comprehensiveness and overcoming the barriers faced.

5.6.5. Communication Issues

Most experts considered communication a major challenge, especially when convincing patients, families, and healthcare professionals to participate in the registry. Some of them indicated that raising awareness regarding the importance of registries is crucial as the Egyptian healthcare professionals are not used to the concept. A geriatric training consultant who has experience working with neurology healthcare practitioners stated:

> *"It would be important to raise the issue of the registry first because we are not used to it in Egypt. People should be aware first to avoid the destruction of any available data" (Geriatric Training Consultant, GT1, Cairo, March 2021)*

The expert's quote sheds light on the importance of raising awareness of the benefits and functions of the registry so that the healthcare professionals get used to the term and be encouraged to participate.

In addition, a major concern regarding convincing clinicians to collect data is the fact that clinicians are usually very busy, and in order to collect the data, they should always be encouraged, convinced, and reminded. An expert who works for one of the well-established registries explained her experience regarding the encouragement of clinicians. She stated:

> *"Of course, to get the clinics to report, to take the time and type in everything ... when we implemented primary care, the data wasn't so good, all the time, so the clinics who were starting to use the reports, they do it well, but some clinics, they just typed in, and they are not reporting anymore, because they haven't seen the rewards." (Registry Specialist, RS8 International, Oct 2021)*

The expert's note stressed the idea that clinicians are always busy, and hence they need to see the rewards of this extra work to be encouraged and continue participating (Section 5.3.1).

In addition, an international expert raised the issue that implementing a pilot that adopts a minimal dataset could discourage many stakeholders from being involved, especially if the data they need is not captured. She stated:

> *"We know everybody isn't going to be happy, we know people are going to say oh, you also need to capture this and this. What we wanted to do is to kind of bring down expectations." (Registry Specialist, RS2 International, May 2021)*

The expert's note stressed the challenge that might arise when some data are not collected while they are of interest to specific stakeholders. Therefore, setting clear objectives of the primary outcomes to achieve would help lower the expectations from the early beginning.

On the other hand, convincing patients to participate and share their data is more problematic. One of the experts related that to the global trending issues of data leakage. He mentioned:

> *"So, the leakage of information that is widely seen nowadays in everything made constraints in all the data related perceptions" (Clinical Neurologist, CN1, Cairo, Jan 2021)*

The expert's note revealed that knowing that patients usually fear sharing their data, especially since the disease has many social implications for the patient. Therefore, clearly defining the policies regulating data confidentiality and informing the patients accordingly would be essential to convince them.

Other experts raised the issue of showing patients the benefits of being included in such a registry. The experts agreed that the concept of volunteering for science is not common in the Egyptian culture. A geriatric training consultant who works for an academy that trains neurologists and geriatric specialists mentioned:

> *"We do not have this idea of the process of collecting data and use them. So even the patients when you ask them, they are not used to that, so they will think what they will benefit out of that" (Geriatric Training Consultant, GT2, Cairo, March 2021)*

The expert's comment revealed that the Egyptian patients are not familiar with the concept of volunteering for research studies. Therefore, the experts stressed the value of creating human interaction with the patients and illustrating the purpose of the registry and its benefits for them.

A social researcher who works for one of the biggest research institutions in Egypt responsible for public health-related studies expressed her point of view. She stated:

> *"The problem is that in Egypt we do not have the idea of volunteering for science, but you can create interest ... it is very important to engage the people with you, you have to give them something like ownership of the registry" (Social Researcher, SR2, Cairo, Jan 2021)*

> *"The barriers, first of all, people who have dementia, what is the benefit for them if you told them I am doing this for research? For them, it might be more beneficial if you formulated as we want to know the prevalence, we need to know which conditions lead to this situation, we need to know how the burden is ... You have to formulate it in a more humane way ... You need something to attract people" (Social Researcher, SR2, Cairo, Jan 2021)*

The expert's quotes stressed the importance of engaging the patients with the purpose of the registry by informing them of the benefits that they will get when this registry is created. Informing them about the benefits of registry data and how that will help decrease the disease burden is one way to keep them engaged.

Furthermore, experts also pinpointed the communication issues with families and caregivers as well. An aging researcher who has experience working in one of the largest international aging studies expressed his opinion regarding engaging caregivers. His stated:

> *"I think they are much harder, and one thing is obvious if somebody is demented, you have to use a special survey because they won't answer. Also, they are protected by their caregivers or institutions, so in many cases, you can't have access to them." (Aging Researcher, AR1, International, Sep 2021)*
>
> *In addition, a social researcher who works in elderly studies also added:*
>
> *"I am sure that you won't get the data from the dementia person, you'll get them from the caregiver if the caregiver felt that you're keen on what they're going through they might be encouraged to help" (Social Researcher, SR2, Cairo, Jan 2021)*

The experts' quotes stressed the fact that most dementia patients will not be able to inform data, which makes the caregiver responsible for deciding whether to participate or not. Showing them the benefits that will affect the patients' as well as the caregivers' lives, would be particularly of benefit.

Nevertheless, the situation in nursing homes was shown to be more challenging. Convincing the families of these patients will require more communication efforts. A clinical neurologist who works at a large memory clinic in Egypt elaborated on the nursing home situation. She stated:

> *“This is not the case in the nursing homes, for example, so trying to get consent from the families of patients living in nursing homes would be much more difficult” (Clinical Neurologist, CN1, Cairo, Jan 2021)*

From the expert’s quote, it is obvious that getting consent from the families of patients who live in nursing homes is much more difficult as most of them do not want to get involved in something that might embarrass them, as mentioned earlier. Hence, including nursing homes in the registry would be a very advanced step.

On the other hand, experts expressed their agreement that the major opportunity regarding communication challenges is the sufficient training of the registry team. They stated that the skills of the person communicating with patients as well as the knowledge of the persons who do the data collection and entry would greatly impact the participation as well as the quality of data. Experts mentioned:

> *“Communication is a challenge, training the workforce that can actually communicate to people whose education may not be a college education. Why is this important? We assume that if you have the scientific or the medical or the pharmacy know-how, that you should be able to take another job of talking to somebody and educating him” (Neuroscience Researcher, NR2, Cairo, January 2021)*
>
> *“I think it's just if you train, so that's the other aspect if you train the other researchers if you have a forum where you have a meeting, and you train them, and you highlight all these issues, it's just a matter of communicating with the patients, and I believe, because many of them already have some rapport.” (Registry Specialist, RS3, International, Sep 2021)*
>
> *“You should respect the patient. But also, it depends on the skills of the person who is interviewing the patient or doing the consent form to convince them that really no one will know you, that is why you will need extensive capacity building” (Public Health Researcher, PHR1, Cairo, Jan 2021)*

The experts’ quotes shed light on the importance of giving sufficient training to the personnel who will collect the data from patients. Having a medical background does not necessarily mean that the person has the communication skills that enable him to collect data from patients. Hence, focusing on building the capacity of the registry workforce would be an essential step in ensuring the participation of patients.

In general, setting clear aims, objectives, and outcomes of the registry along with adequate training of the data collection personnel would greatly enhance the communication with patients, families, and healthcare professionals in order to convince them to participate in the process.

5.6.6. Follow-Ups and Drop-Outs

Many experts stated that longitudinal follow-ups and drop-out of patients are also a challenge. Including follow-up data in the registry is essential to enable the tracking of cases and evaluate their outcomes. However, the international experts indicated that following up with patients regularly on a yearly or six-month basis brings about many dropouts. An international expert who works in one of the well-established dementia registries stated:

> *"The hardest parts of a registry are to follow-up and the long term. You know the connection with those individuals" (Registry Specialist, RS4, International, Oct 2021)*

The experts clarified that the dropout is either due to the death of patients, especially since most of them have deteriorated conditions, that the patients did not visit the clinic for follow-ups, or because the clinic did not enter the follow-up data although the patient visited them. A registry specialist explained her experience with dropouts. She mentioned:

> *"It's dropouts. Not so many, but the problem is that the clinics don't type in every follower. About 50% get follow-up after one year. But the clinic doesn't enter the data; why is it. Or maybe they don't meet the people, and they don't*

> *get to the follow-up that they should have." (Registry Specialist, RS8 International, Oct 2021)*

In addition, experts also discussed the complications of living with others, including caregivers, which sometimes hinders the follow-up process. A registry specialist stated:

> *"I'm sure a lot of them aren't living on their own. Someone else's taking care of them at home and that kind of thing. And that just complicates matters, you know, on another level too because it's not as simple to follow up with individuals with dementia, as you know, say, someone has diabetes or something else you know. So, you would have to get. Their caregivers' information as well, to be able to follow up and see." (Registry Specialist, RS4, International, Oct 2021)*

The expert's quote stressed on the idea that getting the caregiver's information is also important, especially in dementia. Yet, this might complicate the process of follow-up.

Moreover, experts also mentioned that part of the dropouts is because of the death of patients, especially since most of the participating cases are already registered when the case is deteriorated, as mentioned earlier. One of the experts who worked on planning a recently established dementia registry explained her experience with dropouts. She mentioned:

> *"The only thing that I know has been a challenge, and this is just from working on other research studies and even trying to follow up with this with our registry population, is that depending on when they're diagnosed. A lot of them pass away" (Registry Specialist, RS2, International, May 2021)*

It is clear from the experts' quotes that the process of following up with patients is not easy despite being critical for the registry. More monitoring activities should be performed to encourage the healthcare professionals to do the follow-ups and enter the data for the benefit of the registry.

5.6.7. Complexity of Regulations

Regarding the regulations for establishing the registry in the Egyptian context, experts indicated many challenges that arise from the complexity of the processes. First, experts expressed their concerns regarding the complex legislative structure in Egypt, which requires many security permissions prior to collecting national data. Egyptian researchers stated:

> *"There are a lot of legislative structures, and when you think of starting this you'll find people who say that it's a national security issue because of the security of data. In reality, the national security issue is not to have this information" (Neuroscience Researcher, NR1, Cairo, January 2021)*
>
> *"Obtaining the IRB approval will not be a challenge as there are well-established IRB committees in the institutions. But the field permits face constraints in Egypt as sometimes the security refuses the field permits. However, there are mechanisms and modalities to facilitate obtaining the permits" (Social Researcher, SR1, Cairo, Jan 2021)*

The experts' comments shed light on the challenge that arises due to the complexity of regulations required for collecting data in Egypt. In some cases, collecting this kind of data is considered a national security issue as people fear releasing national data regarding population health. In other cases, the regulations required to get field permits to collect data are complicated, hindering the process.

Similarly, experts stated that accessing patients' records also require many approvals from the IRB committee, the institution, the department, and the clinic from which the data will be collected. In addition, the process gets more complicated when the person collecting the data is not affiliated with the hospital. A clinical neurologist who works in a large geriatric center in Egypt explained:

> *"To retrieve data from patient records that would definitely need a legitimate, ethical process so that you can access them. This gets much difficult for people from outside the hospital though." (Clinical Neurologist, CN2, Cairo, Jan 2021)*

The expert's note revealed that the regulations get more complicated when the researcher is from outside the institution. In this case, more approvals have to be taken in order to be able to collect the required data.

Overall, it can be concluded from the experts' notes that all these issues usually take time and effort that hinders the progress of registry establishment (Theme 5.1).

5.6.8. Limited Funding

The majority of the experts stressed the criticalness of the issue of funding availability in directing the whole registry establishment process. They elaborated that a national registry will not be feasible unless there is a huge fund that can secure its operation and maintenance. National experts suggested that raising the awareness of potential stakeholders, particularly decision-makers, on the importance and economic benefits of the registry can be beneficial in terms of attracting funds for the registry.

Another suggestion was to approach the NGOs interested in healthcare services to seek funds and collaboration. One of the social researchers who have experience in elderly studies stated:

> *"The problem is to do that, they have to be included as partners, and that will need a budget. I will strongly recommend that you approach one of the large NGOs because they are already collecting data, and they can apply for data collection instead of you." (Social Researcher, SR2, Cairo, Jan 2021)*

Moreover, an international expert indicated that a registry can still be established with limited funds if the clinicians and patients are willing to participate. He mentioned:

> *"All of that requires funding. Unless all these clinicians are willing to see people every month or year, and people are willing to go back there just for the researcher's assessment. People might want to do that just for receiving additional follow-up because it's an advantage if the doctor is willing to do it for you" (Registry Specialist, RS1, International, May 2021)*

It can be concluded from the expert’s note that the positivity that the clinicians and patients could feel towards the idea of the registry is a clear facilitator to the progress of the project. It would seem to be an opportunity to convince them of the benefits so that they are willing to participate and provide you with the data you need just to benefit from the outcomes.

Chapter Six: Conclusions and Recommendations

6.1. Conclusions

The need for real-world data in clinical practice, patient outcomes, and healthcare services effectiveness led to the emergence of disease registries as important tools to get valuable insights into the disease (Hoque et al., 2017). Registries collect standardized data on a large number of patients. There is a general agreement in the literature that disease registries are informative tools that support several healthcare-related aspects, including clinical practice, research, policy, and decision-making endeavors.

The increased challenges related to dementia care resulted in the development of dementia disease registries around the world. The well-established dementia registries around the world contributed to advancing our understanding of the disease and hence, will impact multiple disease outcomes. Therefore, there is a great need for a national registry for dementia in Egypt with accurate and comprehensive data on Egyptian patients. Given the current direction of the government agenda and the increased focus on aging problems as well as big data analysis, it would seem to be an appropriate time for initiating this kind of registry.

Experts' opinions inferred that the development of a national registry for dementia in Egypt is feasible, yet with some complications. In addition, the numerous benefits and functions of the registry would make the investment worthwhile. Although the process of developing a registry entails many steps that require support and collaborative assessment activities, learning from the successful lessons and guidelines of the international registries would assist in the planning and strategizing of the registry.

The study suggests that for the registry to start, an institution should take the lead and be the champion of the initiation process to avoid any complexity that might arise from the involvement of the government in this early stage. The initial pilot of the registry can start by collecting data from the clinics that are among the network of the leading researcher to ensure their participation until generating insightful results. The clear purpose and objectives of the registry should be defined in order to direct the planning and design. A research registry that collects clinical, demographic as well as laboratory tests of the patients is the most appropriate type for Egypt to encourage both clinicians and researchers to participate while providing data of interest to all stakeholders.

Potential stakeholders could be involved in the planning step to help accommodate their input and needs. Phasing the registry is crucial to test the functionality and effectiveness of the process. Prior to the start of data collection, a minimum data set should be developed by the registry administrator and the involved stakeholders to determine the data to be collected and provide the participating centers with a unified data collection sheet for the harmonization of results.

Expansion of data and coverage can be a second step after evaluating the success of the first phase to include more hospitals and sites to provide nationally representative data and insights. However, the availability of funds for the project should not be underestimated. Seeking funds from the government, academic grants, as well as international funding organizations, including the World Bank and the WHO, should occur in order to secure obtaining funds and sustain the process. A clear proposal containing the registry data operations, such as data inclusion, data collection, and data management, should be established to help obtain the required ethical approvals and permissions.

Overall, waiting for the strike of all the prerequisites of a registry, as mentioned in the guidelines, would hinder its development. Instead, the initiative is better to start depending on the available resources to give insights into the real situation, then be expanded subsequently.

6.2. Recommendations

This study brings together the recommendations and best practices for establishing a national disease registry for dementia in Egypt. The evidence we got through the discussions formulated the key steps that need to be followed in order to develop this kind of registry in Egypt. We also endorse the actions required in terms of policy and legislation to support the success and functionality of the registry once established (Figure 6).

The Registry Initiation:

1- The initiative should start from one institution that has a leading researcher who can bring together all the stakeholders and holds the responsibility of driving the discussions forward to set out a clear plan for the registry.

2- Including all the relevant stakeholders from the early beginning of the planning phase would significantly benefit the process. The early involvement would raise their feeling of ownership of the registry, facilitating the operation. The relevant stakeholders should be identified from all parties that might benefit from or be interested in using the registry data, including the government, medical caregivers, researchers, and patients' families.

The Registry Planning

3- Deciding on the registry type is a fundamental step of the planning process. The registry investigator, as well as the involved stakeholders, should work on analyzing the country's needs and prioritize the most needed outcomes to determine the registry objectives that would satisfy the needs carefully. Creating a registry that includes the patients' clinical and sociodemographic data, in addition to some research items, would be of great benefit to Egyptian society, especially in the case of dementia.

4- The diversity of data sources is considered an asset for the registry and the data collection process. Yet, deciding on the data sources used is an essential step during registry planning. Starting the registry with patients' cohort that is collected from the network of the leading institution would be an optimum step to guarantee the success of the registry. Once the process is initiated, other data sources can be included in the dataset.

5- Identifying the data elements to be covered by the dataset should be done by the involved stakeholders during the planning phase. Although collecting all socioeconomic, clinical, environmental, and policy data is appealing to stakeholders, considering the complexity of the process is crucial not to end up hindering the data collection process. Instead, stakeholders should, together with the registry investigators, should prioritize the data items they need the most to be able to create a minimum data set (MDS).

6- Defining the MDS used in data collection is critical as it should reflect the outcomes needed to achieve the registry purpose. In addition, using a standardized dataset to collect data across all the participating centers will enhance the effectiveness of the process. To define a minimum dataset that guarantees the functionality of the registry, the stakeholders should compare the other established registries to list the different items that are commonly used and then amend the list to suit the country's needs.

Eventually, creating a data collection form containing the selected elements would be essential to secure consistency across all data providers.

The Registry Operation

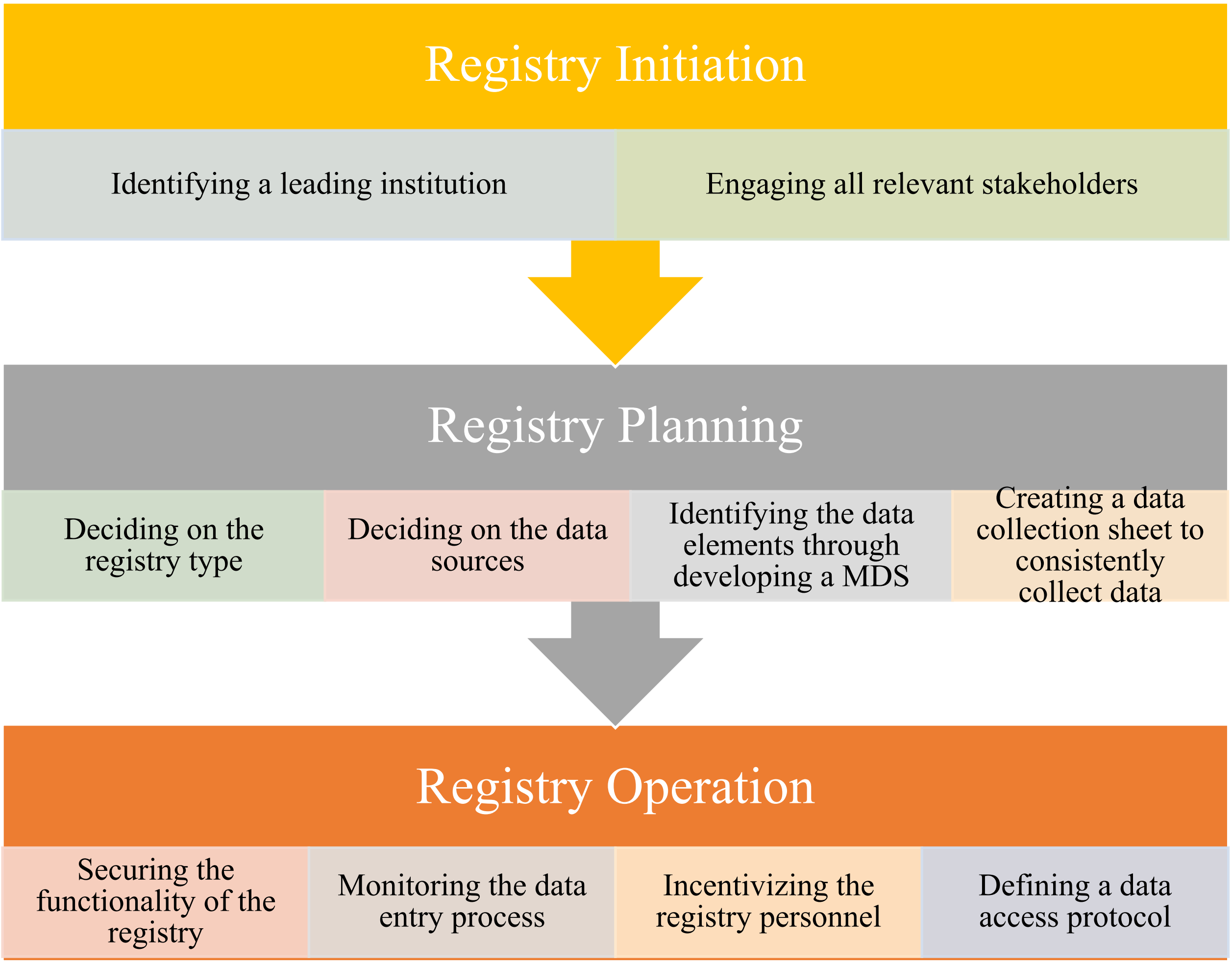
7- Securing the functionality of the registry and the effectiveness of its operation requires proper design and close monitoring and evaluation of the data collection and data management processes. The data collection should be done by trained personnel with a minimum medical background to guarantee the integrity of data. Collecting data directly from patients visiting the participating clinics would be an ideal way to collect data with minimal ethical requirements, especially during the pilot phase. Including retrospective data extracted from available records could be an advanced step when the registry is well-established.

8- The entry of data into the registry database is a fundamental step that should be monitored closely. Entering the data directly from the participating center to an online platform is the optimal setting. Yet, in the beginning, central manual data entry by the registry administrators could be a solution to decrease the complexity and overcome the lack of funding. The data collected by the different clinics will be sent to the central registry for an assigned person to enter into the database. This method will guarantee the consistency of data until a well-designed platform is established. Then, a system for entering the data directly by the clinics can be followed.

9- Providing some sort of incentives to the participating healthcare providers and well as data entry personnel would be required to facilitate their engagement and retain their participation. The incentives could be giving them access to the generated reports as well as giving them the opportunity to be included in the publication. Later, when the registry is stably funded, money can be used as an incentive.

10- Defining a protocol for data access is also essential to secure data confidentiality without refuting any ethical considerations. The best way is to develop an application process for users so that access would be granted based on their purpose. Yet not all the data items would be disclosed. Instead, more generalized reports or specific data sections would be better used to guarantee the privacy of patients and the confidentiality of data.

Figure 6: Proposed Steps for creating a registry



The Registry Implementation

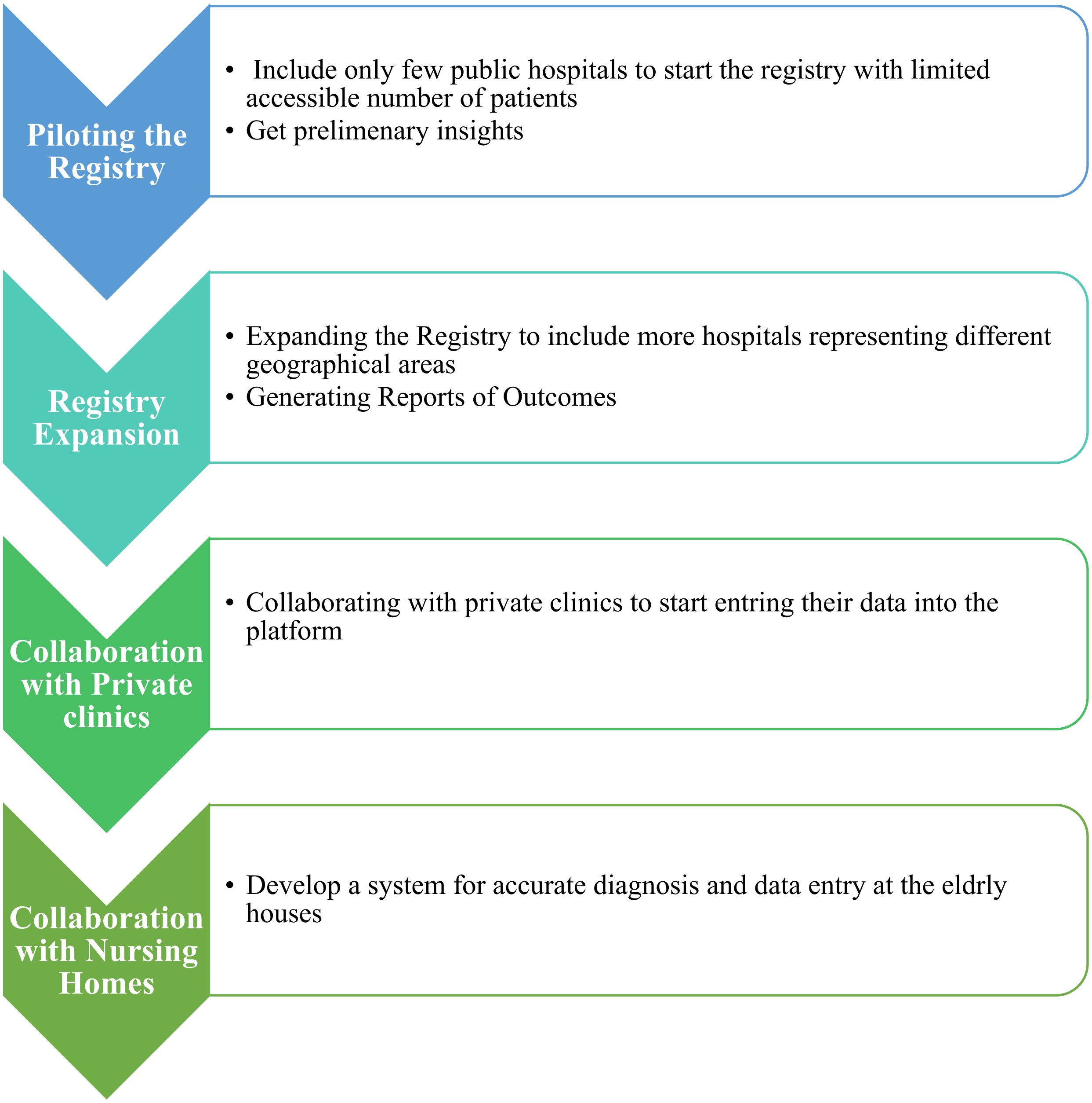
11- Implementing a national registry is a complex and expensive process. Phasing the registry to start with a small pilot will help evaluate the process, identifying what will work, and modifying the protocol accordingly is very beneficial. Implementing the first phase as a pilot by collecting data from a few centers, especially public or university hospitals that are among the network of the registry investigators, would be the most effective way to initiate the registry and get preliminary insights about the disease (Figure 7).

12- The ultimate goal should be to expand the dataset to cover the national level, so after evaluating the pilot’s success and amending any needs, the second phase should be implemented by including more hospitals from different geographical areas. At this phase, more comprehensive reports could be generated representing the prevalence of the disease across the country as well as the specific patients’ characteristics (Figure 7).

13- The third phase of the implementation process would be collaborating with the private sector to include the private clinics in the database. Including the private hospitals at this late step would be beneficial as the process would be well-established and functional by this stage. In addition, the registry outcomes generated during the second phase would help encourage the private healthcare providers to participate. Including the private sector would widen the coverage of the registry data making the outcomes more accurate and nationally representative (Figure 7).

14- The last phase of registry expansion would be including the patients living in nursing homes. This final step is a bit complex due to the lack of diagnosis and difficulty getting the patient’s or caregivers’ consent. Yet, as the registry gets more recognized in the country, developing an accurate system for diagnosing patients at the nursing homes would make it easier to include them in the database (Figure 7).

Figure 7: Proposed implementation strategy for a national registry in Egypt



Piloting the Registry

- Include only few public hospitals to start the registry with limited accessible number of patients
- Get prelimenary insights

Registry Expansion

- Expanding the Registry to include more hospitals representing different geographical areas
- Generating Reports of Outcomes

Collaboration with Private clinics

- Collaborating with private clinics to start entring their data into the platform

Collaboration with Nursing Homes

- Develop a system for accurate diagnosis and data entry at the eldrly houses

References

100 Million Healthy Lives Initiative. (n.d.).

'100 Million Seha' initiative saved lives of 2.2. Million Egyptians-SIS. (n.d.). Retrieved 5 September 2022, from https://www.sis.gov.eg/Story/154889?lang=en-us

AHCJ | Resources: Growing Older in America: The Health & Retirement Study. (n.d.). Retrieved 13 September 2020, from https://healthjournalism.org/resources-reports-details.php?id=28

Alasuutari, P., Bickman, L., Brannen, J., Elliott, J., Holland, J., & Thomson, R. (2012). Longitudinal and Panel Studies. In *The SAGE Handbook of Social Research Methods* (pp. 228–248). SAGE Publications Ltd. https://doi.org/10.4135/9781446212165.n14

Alonso-Gonzalez, R., Lopez-Guarch, C. J., Subirana-Domenech, M. T., Ruíz, J. M. O., González, I. O., Cubero, J. S., del Cerro, M. J., Salvador, M. L., dos Subira, L., Gallego, P., & Escribano-Subias, P. (2015). Pulmonary hypertension and congenital heart disease: An insight from the REHAP National Registry. *International Journal of Cardiology*, *184*(1), 717–723. https://doi.org/10.1016/J.IJCARD.2015.02.031

Amjad, H., Roth, D. L., Sheehan, O. C., Lyketsos, C. G., Wolff, J. L., & Samus, Q. M. (2018). Underdiagnosis of Dementia: an Observational Study of Patterns in Diagnosis and Awareness in US Older Adults. *Journal of General Internal Medicine*, *33*(7), 1131. https://doi.org/10.1007/S11606-018-4377-Y

Analysis of Dementia Risks among African Immigrants Compared with Caucasian Americans in Retirement | Health and Retirement Study. (n.d.). Retrieved 13 September 2020, from https://hrs.isr.umich.edu/publications/biblio/10561

Angrisani, M., Lee, J., & Meijer, E. (2020). The gender gap in education and late-life cognition: Evidence from multiple countries and birth cohorts. *Journal of the Economics of Ageing*, *16*, 100232. https://doi.org/10.1016/j.jeoa.2019.100232

Arnold School of Public Health. (2016). *2020 Annual Report outh Carolina Alzheimer's Disease Registry*.

Beekly, D. L., Ramos, E. M., van Belle, G., Deitrich, W., Clark, A. D., Jacka, M. E., & Kukull, W. A. (2004). The National Alzheimer's Coordinating Center (NACC) database: An Alzheimer disease database. *Alzheimer Disease and Associated Disorders*, *18*(4), 270–277.

Benach, J., Friel, S., Houweling, T., Labonte, R., Muntaner, C., Schrecker, T., & Simpson, S. (2010). a conceptual framework for action on the social determinants of health. *World Health Organization Geneva*.

Börsch-Supan, A., Brandt, M., Hunkler, C., Kneip, T., Korbmacher, J., Malter, F., Schaan, B., Stuck, S., & Zuber, S. (2013). Data resource profile: The survey of health, ageing and retirement in europe (share). *International Journal of Epidemiology*, *42*(4), 992–1001. https://doi.org/10.1093/ije/dyt088

Börsch-Supan, A., Czaplicki, C., Friedel, S., Herold, I., Korbmacher, J., & Mika, T. (2018). SHARE-RV: Linked Data to Study Aging in Germany. *Jahrbucher Fur Nationalokonomie Und Statistik*, *240*(1), 121–132. https://doi.org/10.1515/jbnst-2018-0034

Cáceres, J. A. G. (2015). Global comparisons for developing a national dementia registry in Cuba. *MEDICC Review*, *17*(1), 59–63. https://doi.org/10.37757/MR2015.V17.N1.12

Calvó-Perxas, L., Belchí, O., Turon-Estrada, A., van Eendenburg, C., Linares, M., Viñas, M., Manzano, A., Turró-Garriga, O., Vilalta-Franch, J., Garre-Olmo, J., Alemany, B., Coll, C., Cots, A., Hernández, M., Gich, J., López-Pousa, S., Lozano, M., Molins, A., Pericot-Nierga, I., … Soto, M. P. (2019). Incidence and characteristics of uncommon dementia subtypes: Results from 10 years of clinical surveillance by the Registry of Dementia of Girona. *Alzheimer's and Dementia*, *15*(7), 917–926. https://doi.org/10.1016/j.jalz.2019.03.017

Calvó-Perxas, L., López-Pousa, S., Turró-Garriga, O., de Eugenio, R., Linares, M., Fernández, M. D. M., Castellanos, M., Casas, I., Turón-Estrada, A., Casadevall, T., Vilalta-Franch, J., & Garre-Olmo, J. (2013). Pain treatment and its cost in old people with dementia: A descriptive analysis from the Registry of Dementias of Girona (ReDeGi). *International Journal of Neuroscience*, *123*(5), 339–346. https://doi.org/10.3109/00207454.2012.761216

Calvó-Perxas, L., Teresa Osuna, M., Gich, J., Eligio-Hernández, E., Linares, M., Viñas, M., Casas, I., Turró-Garriga, O., López-Pousa, S., & Garre-Olmo, J. (2012). Clinical and demographic characteristics of the cases of dementia diagnosed in the Health District of Girona throughout the period 2007-2010: Data from the Girona Dementia Registry (ReDeGi) | Características clínicas y demográfcas de los casos de demencia. *Revista de Neurologia*, *54*(7), 399–406.

Celidoni, M., Dal Bianco, C., & Weber, G. (2017). Retirement and cognitive decline. A longitudinal analysis using SHARE data. *Journal of Health Economics*, *56*, 113–125. https://doi.org/10.1016/j.jhealeco.2017.09.003

Cermakova, P., Nelson, M., Secnik, J., Garcia-Ptacek, S., Johnell, K., Fastbom, J., Kilander, L., Winblad, B., Eriksdotter, M., & Religa, D. (2017). Living Alone with Alzheimer's Disease: Data from SveDem, the Swedish Dementia Registry. *Journal of Alzheimer's Disease*, *58*(4), 1265–1272. https://doi.org/10.3233/JAD-170102

Comprehensive geriatric assessment - UpToDate. (n.d.). Retrieved 28 January 2022, from https://www.uptodate.com/contents/comprehensive-geriatric-assessment#H7

Conde-Sala, J. L., & Garre-Olmo, J. (2020). Early parental death and psychosocial risk factors for dementia: A case–control study in Europe. *International Journal of Geriatric Psychiatry*, *35*(9), 1051–1059. https://doi.org/10.1002/gps.5328

Cronin, H., O'Regan, C., Finucane, C., Kearney, P., & Kenny, R. A. (2013). Health and Aging: Development of The Irish Longitudinal Study on Ageing Health Assessment. *Journal of the American Geriatrics Society*, *61*(SUPPL2), S269–S278. https://doi.org/10.1111/jgs.12197

de Braekeleer, M., Cholette, A., Mathieu, J., Boily, C., Robitaille, Y., & Gauvreau, D. (1989). Familial factors in alzheimer's disease (IMAGE project): A case-control study in the saguenay-lac-st-jean region (Quebec, Canada). *European Neurology*, *29*, 2–8. https://doi.org/10.1159/000116473

Development Projects : Supporting Egypt's Universal Health Insurance System - P172426. (n.d.). Retrieved 5 September 2022, from https://projects.worldbank.org/en/projects-operations/project-detail/P172426

Donoghue, O., Feeney, J., O'Leary, N., & Kenny, R. A. (2018). Baseline Mobility is Not Associated with Decline in Cognitive Function in Healthy Community-Dwelling Older Adults: Findings From The Irish Longitudinal Study on Ageing (TILDA). *American Journal of Geriatric Psychiatry*, *26*(4), 438–448. https://doi.org/10.1016/j.jagp.2017.11.006

Dreyer, N. A., & Garner, S. (2009a). Registries for Robust Evidence. *JAMA*, *302*(7), 790–791. https://doi.org/10.1001/JAMA.2009.1092

Dreyer, N. A., & Garner, S. (2009b). Registries for robust evidence. *JAMA*, *302*(7), 790–791. https://doi.org/10.1001/JAMA.2009.1092

Egypt | Universal Health Coverage Partnership. (n.d.). Retrieved 5 September 2022, from https://www.uhcpartnership.net/country-profile/egypt/

Egypt's '100 Million Health' initiative has screened 20.8 mln women so far: Health ministry - Health - Egypt - Ahram Online. (n.d.). Retrieved 5 September 2022, from https://english.ahram.org.eg/News/443634.aspx

el Razek, Y. A., Sabry, W., Hendawy, H., Hegazy, D., Soultan, M., & el Banna, M. (2019). Prevalence and correlates of psychiatric morbidity in Egyptian sample of dementia patients' caregivers: a comparative descriptive study. *Middle East Current Psychiatry*, *26*(1), 1–11. https://doi.org/10.1186/S43045-019-0006-7/TABLES/6

el Tallawy, H. N. A., Farghaly, W. M. A., el Hamed, M. A., Badry, R., Usama, K., Shehata, G. A., Tohamy, A. M., Abdulghani, K. O., Ghanem, M. K., Sayed, M. A., Yousef, A. H., Hashem, H. S., & Rageh, T. A. (2019). Prevalence of Alzheimer dementia in upper Egypt (Desert areas). *Egyptian Journal of Neurology, Psychiatry and Neurosurgery*, *55*(1), 1–6. https://doi.org/10.1186/S41983-019-0074-Y/TABLES/5

el Tallawy, H. N. A., Farghaly, W. M. A., Rageh, T. A., Shehata, G. A., Badry, R., Metwally, N. A., el Moselhy, E. A., Hassan, M., Sayed, M. A., Waris, A. A., Hamed, Y., Shaaban, I., Hamed, M. A., & Kandil, M. R. (2013). Door-to-door survey of major neurological disorders (project) in Al Quseir City, Red Sea Governorate, Egypt. *Neuropsychiatric Disease and Treatment*, *9*, 767. https://doi.org/10.2147/NDT.S36956

el Tallawy, H. N. A., Farghaly, W. M. A., Rageh, T. A., Shehata, G. A., Metwaly, N. A., Elftoh, N. A., Hegazy, A. M., el Moselhy, E. A., Rayan, I., al Fawal, B. M. A., & Abd Elhamed, M. A. (2010). Epidemiology of Major Neurological Disorders Project in Al Kharga District, New Valley, Egypt. *Neuroepidemiology*, *35*(4), 291–297. https://doi.org/10.1159/000320240

el Tallawy, H. N., Farghly, W. M. A., Shehata, G. A., Rageh, T. A., Hakeem, N. A., Abo-Elfetoh, N., Hegazy, A. M., Rayan, I., & El-Moselhy, E. A. (2012). Prevalence of Dementia in Al

Kharga District, New Valley Governorate, Egypt. *Neuroepidemiology*, *38*(3), 130–137. https://doi.org/10.1159/000335655

el Tallawy, H. N., Farghly, W. M., Badry, R., Rageh, T. A., Shehata, G. A., Hakeem M, N. A., el Hamed, M. A., Sayd, M. A. M., Hamed, Y., & Kandil, M. R. (2014). Prevalence of dementia in Al-Quseir city, Red Sea Governorate, Egypt. *Clinical Interventions in Aging*, *9*, 9. https://doi.org/10.2147/CIA.S48325

Elo, S., & Kyngäs, H. (2008). The qualitative content analysis process. *Journal of Advanced Nursing*, *62*(1), 107–115. https://doi.org/10.1111/J.1365-2648.2007.04569.X

Elshahidi, M. H., Elhadidi, M. A., Sharaqi, A. A., Mostafa, A., & Elzhery, M. A. (2017). Prevalence of dementia in Egypt: a systematic review. *Neuropsychiatric Disease and Treatment*, *13*, 715–720. https://doi.org/10.2147/NDT.S127605

Elshehabi, N. I. (2013). *Multicenter Egyptian Registry of Coronary Catheter Procedures*. http://eulc.edu.eg/eulc_v5/Libraries/Thesis/BrowseThesisPages.aspx?fn=PublicDrawThesis&BibID=11678462

El-Tallawy, H., Farghaly, W., Metwally, N., Rageh, T., Shehata, G. A., Badry, R., Moselhy, E. el, Hassan, M., Sayed, M. M., Abdelwarith, A. A., Hamed, Y., Shaaban, I., Mohamed, T., el Hamed, M. A., & Kandil, M. R. (2013). Prevalence of neurological disorders in Al Quseir, Egypt: methodological aspects. *Neuropsychiatric Disease and Treatment*, *9*, 1295. https://doi.org/10.2147/NDT.S42392

Enache, D., Fereshtehnejad, S.-M., Kåreholt, I., Cermakova, P., Garcia-Ptacek, S., Johnell, K., Religa, D., Jelic, V., Winblad, B., Ballard, C., Fastbom, J., & Eriksdotter, M. (2016). Antidepressants and mortality risk in a dementia cohort: data from SveDem, the Swedish

Dementia Registry. *Acta Psychiatrica Scandinavica*, *134*(5), 430–440. https://doi.org/10.1111/acps.12630

Farouk, H., Shaker, A., El-Faramawy, A., Mahrous, A., Baghdady, Y., Adel, A., Soliman, H., Abdel-Meguid, M., Elasry, A.-A., & Sorour, K. (2015). Adult Congenital Heart Disease Registry at Cairo University. *World Journal for Pediatric and Congenital Heart Surgery*, *6*(1), 53–58. https://doi.org/10.1177/2150135114558067

Farrag, A.-K. F., Farwiz, H. M., Khedr, E. H., Mahfouz, R. M., & Omran, S. M. (1998). Prevalence of Alzheimer's Disease and Other Dementing Disorders: Assiut-Upper Egypt Study. *Dementia and Geriatric Cognitive Disorders*, *9*(6), 323–328. https://doi.org/10.1159/000017084

Fereshtehnejad, S. M., Damangir, S., Cermakova, P., Aarsland, D., Eriksdotter, M., & Religa, D. (2014). Comorbidity profile in dementia with Lewy bodies versus Alzheimer's disease: A linkage study between the Swedish dementia registry and the Swedish National Patient Registry. *Alzheimer's Research and Therapy*, *6*(5–8), 65. https://doi.org/10.1186/s13195-014-0065-2

Fereshtehnejad, S.-M., Johannsen, P., Waldemar, G., & Eriksdotter, M. (2015a). Dementia diagnosis, treatment, and care in specialist clinics in two scandinavian countries: A data comparison between the swedish dementia registry (SveDem) and the danish dementia registry. *Journal of Alzheimer's Disease*, *48*(1), 229–239. https://doi.org/10.3233/JAD-150144

Fereshtehnejad, S.-M., Johannsen, P., Waldemar, G., & Eriksdotter, M. (2015b). Dementia diagnosis, treatment, and care in specialist clinics in two scandinavian countries: A data comparison between the swedish dementia registry (SveDem) and the danish dementia registry. *Journal of Alzheimer's Disease*, *48*(1), 229–239. https://doi.org/10.3233/JAD-150144

Ferreira, R. G., Brandão, M. P., & Cardoso, M. F. (2020). An update of the profile of older adults with dementia in Europe: findings from SHARE. *Aging and Mental Health*, *24*(3), 374–381. https://doi.org/10.1080/13607863.2018.1531385

Fillenbaum, G. G., van Belle, G., Morris, J. C., Mohs, R. C., Mirra, S. S., Davis, P. C., Tariot, P. N., Silverman, J. M., Clark, C. M., Welsh-Bohmer, K. A., Welsh-Bohmer, K. A., & Heyman, A. (2008). Consortium to Establish a Registry for Alzheimer's Disease (CERAD): The first twenty years. *Alzheimer's and Dementia*, *4*(2), 96–109. https://doi.org/10.1016/j.jalz.2007.08.005

Fisher, G. G., & Ryan, L. H. (2018). Overview of the health and retirement study and introduction to the special issue. *Work, Aging and Retirement*, *4*(1), 1–9. https://doi.org/10.1093/workar/wax032

Foverskov, E., Glymour, M. M., Mortensen, E. L., Holm, A., Lange, T., & Lund, R. (2018). Education and Cognitive Aging: Accounting for Selection and Confounding in Linkage of Data from the Danish Registry and Survey of Health, Ageing and Retirement in Europe. *American Journal of Epidemiology*, *187*(11), 2423–2430. https://doi.org/10.1093/aje/kwy162

Frank, L. (2000). When an entire country is a cohort. *Science*, *287*(5462), 2398–2399. https://doi.org/10.1126/science.287.5462.2398

Gadallah, M. (n.d.). *Draft Country Profile on Ageing : Egyptian Case Study*. Retrieved 26 January 2022, from https://www.un.org/esa/socdev/ageing/documents/workshops/Vienna/egypt.pdf

Garcia-Ptacek, S., Dahlrup, B., Edlund, A.-K., Wijk, H., & Eriksdotter, M. (2019). The caregiving phenomenon and caregiver participation in dementia. *Scandinavian Journal of Caring Sciences*, *33*(2), 255–265. https://doi.org/10.1111/scs.12627

Garcia-Ptacek, S., Farahmand, B., Kareholt, I., Religa, D., Cuadrado, M. L., & Eriksdotter, M. (2014). Mortality risk after dementia diagnosis by dementia type and underlying factors: A cohort of 15,209 patients based on the swedish dementia registry. *Journal of Alzheimer's Disease*, *41*(2), 467–477. https://doi.org/10.3233/JAD-131856

García-Ptacek, S., Kåreholt, I., Farahmand, B., Cuadrado, M. L., Religa, D., & Eriksdotter, M. (2014). Body-mass index and mortality in incident dementia: A Cohort study on 11,398 patients from SveDem, the Swedish dementia registry. *Journal of the American Medical Directors Association*, *15*(6), 447.e1-447.e7. https://doi.org/10.1016/j.jamda.2014.03.001

Garre-Olmo, J., Garcia-Ptacek, S., Calvó-Perxas, L., Turró-Garriga, O., López-Pousa, S., & Eriksdotter, M. (2016). Diagnosis of Dementia in the Specialist Setting: A Comparison between the Swedish Dementia Registry (SveDem) and the Registry of Dementias of Girona (ReDeGi). *Journal of Alzheimer's Disease*, *53*(4), 1341–1351. https://doi.org/10.3233/JAD-160098

Gliklich, R. E., Dreyer, N. A., & Leavy, M. B. (2014a). Data Collection and Quality Assurance. In *Registries for Evaluating Patient Outcomes: A User's Guide* (3rd ed.). Agency for Healthcare Research and Quality (US). https://www.ncbi.nlm.nih.gov/books/NBK208601/

Gliklich, R. E., Dreyer, N. A., & Leavy, M. B. (2014b). *Informed Consent for Registries*. https://www.ncbi.nlm.nih.gov/books/NBK208622/

Gliklich, R. E., Dreyer, N. A., & Leavy, M. B. (2014c). Patient Registries. In *Registries for Evaluating Patient Outcomes: A User's Guide* (3rd ed.). Agency for Healthcare Research and Quality (US). https://www.ncbi.nlm.nih.gov/books/NBK208643/

Gliklich, R. E., Dreyer, N. A., & Leavy, M. B. (2014d). Planning a Registry. In *Registries for Evaluating Patient Outcomes: A User's Guide* (3rd ed.). Agency for Healthcare Research and Quality (US). https://www.ncbi.nlm.nih.gov/books/NBK208631/

Gliklich, R. E., Dreyer, N. A., & Leavy, M. B. (2014e). *Principles of Registry Ethics, Data Ownership, and Privacy*. https://www.ncbi.nlm.nih.gov/books/NBK208620/

Gliklich, R. E., Dreyer, N. A., & Leavy, M. B. (2014f). *Protecting Data: Confidentiality and Legal Concerns of Providers, Manufacturers, and Health Plans*. https://www.ncbi.nlm.nih.gov/books/NBK208608/

Gliklich, R. E., Dreyer, N. A., & Leavy, M. B. (2014g). Registry Design. In *Registries for Evaluating Patient Outcomes: A User's Guide* (3rd ed.). Agency for Healthcare Research and Quality (US). https://www.ncbi.nlm.nih.gov/books/NBK208632/

Gliklich, R. E., Michelle, B., Leavy, M. P. H., Daniel Levy, J., Karl, M. B. A., Daniel, P. M. P., Campion, M., & Taylor, M. B. A. T. (2012). *Research from the Developing Evidence to Inform Decisions about Effectiveness (DEcIDE) Network Effective Health Care Program Registry of Patient Registries (RoPR) Policies and Procedures*. https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/registry-of-patient-registries_research-2012-2_1.pdf

Gliklich, R., Leavy, M., & Dreyer, N. (2020). Data Sources for Registries . In *Registries for Evaluating Patient Outcomes: A User's Guide [* (4th ed.). Agency for Healthcare Research and Quality (US). https://www.ncbi.nlm.nih.gov/books/NBK562566/?report=reader

Green, C., & Zhang, S. (2016). Predicting the progression of Alzheimer's disease dementia: A multidomain health policy model. *Alzheimer's and Dementia*, *12*(7), 776–785. https://doi.org/10.1016/j.jalz.2016.01.011

Hassanein, S. (2014). *National Registry for Egyptian Pediatric Neuromuscular Diseases - Full Text View - ClinicalTrials.gov*. https://clinicaltrials.gov/ct2/show/NCT02124616

Heikal, S., Salama, M., Richard, Y., Moustafa, A., & Lawlor, B. (2022). The impact of disease registries on advancing knowledge and understanding of dementia globally. *Frontiers in Aging Neuroscience*. https://doi.org/10.3389/fnagi.2022.774005

Holmes, C. (1996). The Camberwell Dementia Case Register. *International Journal of Geriatric Psychiatry*, *11*(4), 369–375. https://doi.org/10.1002/(SICI)1099-1166(199604)11:4<369::AID-GPS429>3.0.CO;2-O

Hooper, L. (2017). *A national dementia registry for Ireland: A feasibility study*. https://drive.google.com/file/d/1bVZ-k1OcMhqxvpnDHdWF3nL0IaP5JCYD/view

Hopper, L., & Bowen, C. (2021). *Development of a Model for the National Dementia Registry*. https://www.dcu.ie/sites/default/files/inline-files/development-of-a-model-for-the-national-dementia-registry.pdf

Hopper, L., Hughes, S., Burke, T., & Irving, K. (2016). *A national dementia registry for Ireland: a feasibility analysis (accessible summary)*.

Hoque, D. M. E., Kumari, V., Hoque, M., Ruseckaite, R., Romero, L., & Evans, S. M. (2017). Impact of clinical registries on quality of patient care and clinical outcomes: A systematic review. *PLoS ONE*, *12*(9). https://doi.org/10.1371/JOURNAL.PONE.0183667

Hsieh, H. F., & Shannon, S. E. (2005). Three approaches to qualitative content analysis. *Qualitative Health Research*, *15*(9), 1277–1288. https://doi.org/10.1177/1049732305276687

Implementing the universal health insurance law of Egypt: what are the key issues on strategic purchasing and its governance arrangements? (n.d.). Retrieved 5 September 2022, from https://apps.who.int/iris/handle/10665/311781

Johannsen, P., Jørgensen, K., Kørner, A., Elmo, E. G., Lauesen, L. B., & Utzon, J. (2011). Development of a dementia assessment quality database. *Aging & Mental Health*, *15*(1), 40–46. https://doi.org/10.1080/13607863.2010.508769

Kaiser, A. (2013). A Review of Longitudinal Datasets on Ageing. *Journal of Population Ageing*, *6*(1–2), 5–27. https://doi.org/10.1007/s12062-013-9082-3

Kenny, R. A., Coen, R. F., Frewen, J., Donoghue, O. A., Cronin, H., & Savva, G. M. (2013). Normative values of cognitive and physical function in older adults: Findings from the Irish Longitudinal Study on Ageing. *Journal of the American Geriatrics Society*, *61*(SUPPL2). https://doi.org/10.1111/jgs.12195

Kerpershoek, L., de Vugt, M., Wolfs, C., Orrell, M., Woods, B., Jelley, H., Meyer, G., Bieber, A., Stephan, A., Selbæk, G., Michelet, M., Wimo, A., Handels, R., Irving, K., Hopper, L., Gonçalves-Pereira, M., Balsinha, C., Zanetti, O., Portolani, D., & Verhey, F. (2020). Is there equity in initial access to formal dementia care in Europe? The Andersen Model applied to the Actifcare cohort. *International Journal of Geriatric Psychiatry*, *35*(1), 45–52. https://doi.org/10.1002/GPS.5213

Khedr, E., Fawi, G., Abbas, M. A. A., Mohammed, T. A., El-Fetoh, N. A., al Attar, G., Noaman, M., & Zaki, A. F. (2015). Prevalence of Mild Cognitive Impairment and Dementia among the Elderly Population of Qena Governorate, Upper Egypt: A Community-Based Study. *Journal of Alzheimer's Disease*, *45*(1), 117–126. https://doi.org/10.3233/JAD-142655

Khedr, E. M., Abo El Fetoh, N., Khalifa, H., Ahmed, M. A., & A El Beh, K. M. (2012). Prevalence of Depression, Anxiety, Dementia and other Non Motor Features of a large Cohort of Egyptian Parkinson's Disease Patients. *Life Science Journal*, *9*(2), 1097–8135. http://www.lifesciencesite.comhttp://www.americanscience.orgeditor@americanscience.org 509http://www.lifesciencesite.com.76

Kim, E.-J., Park, K.-W., Lee, J.-H., Choi, S., Jeong, J. H., Yoon, S. J., Kim, B. C., Kwon, J. C., Ku, B. D., Kim, S. H., Choi, B.-O., & Na, D. L. (2014). Clinical and Neuropsychological Characteristics of a Nationwide Hospital-Based Registry of Frontotemporal Dementia Patients in Korea: A CREDOS-FTD Study. *Dementia and Geriatric Cognitive Disorders Extra*, *4*(2), 242–251. https://doi.org/10.1159/000360278

Krysinska, K., Sachdev, P., & Brodaty, H. (2016). *Dementia registries around the world: a review and recommendations*.

Krysinska, K., Sachdev, P. S., Breitner, J., Kivipelto, M., Kukull, W., & Brodaty, H. (2017a). Dementia registries around the globe and their applications: A systematic review. *Alzheimer's and Dementia*, *13*(9), 1031–1047. https://doi.org/10.1016/j.jalz.2017.04.005

Krysinska, K., Sachdev, P. S., Breitner, J., Kivipelto, M., Kukull, W., & Brodaty, H. (2017b). Dementia registries around the globe and their applications: A systematic review. *Alzheimer's and Dementia*, *13*(9), 1031–1047. https://doi.org/10.1016/j.jalz.2017.04.005

Krysinska, K., Sachdev, P. S., Breitner, J., Kivipelto, M., Kukull, W., & Brodaty, H. (2017c). Dementia registries around the globe and their applications: A systematic review. In *Alzheimer's and Dementia* (Vol. 13, Issue 9, pp. 1031–1047). Elsevier Inc. https://doi.org/10.1016/j.jalz.2017.04.005

Kuznetsova, L. (2020). COVID-19: The World Community Expects the World Health Organization to Play a Stronger Leadership and Coordination Role in Pandemics Control. *Frontiers in Public Health*, *8*, 470. https://doi.org/10.3389/fpubh.2020.00470

Lang, L., Clifford, A., Wei, L., Zhang, D., Leung, D., Augustine, G., Danat, I. M., Zhou, W., Copeland, J. R., Anstey, K. J., Chen, R., & Li, W. (2017). Prevalence and determinants of undetected dementia in the community: a systematic literature review and a meta-analysis. *Open*, *7*, 11146. https://doi.org/10.1136/bmjopen-2016

Langa, K. M., Larson, E. B., Crimmins, E. M., Faul, J. D., Levine, D. A., Kabeto, M. U., & Weir, D. R. (2017). A comparison of the prevalence of dementia in the United States in 2000 and 2012. *JAMA Internal Medicine*, *177*(1), 51–58. https://doi.org/10.1001/jamainternmed.2016.6807

Larsson, S., Lawyer, P., Garellick, G., Lindahl, B., & Lundström, M. (2012). Use of 13 disease registries in 5 countries demonstrates the potential to use outcome data to improve health care's value. *Health Affairs (Project Hope)*, *31*(1), 220–227. https://doi.org/10.1377/HLTHAFF.2011.0762

Leonard, E. W., Bu, R., & Brown, A. A. (n.d.). Best Practices for Establishing Georgia's Alzheimer's Disease Registry. *Science & Technology Minnesota Journal of Law*, *17*. Retrieved 26 January 2022, from https://scholarship.law.umn.edu/mjlsthttps://scholarship.law.umn.edu/mjlst/vol17/iss1/4

Low, L. F., & Purwaningrum, F. (2020). Negative stereotypes, fear and social distance: a systematic review of depictions of dementia in popular culture in the context of stigma. *BMC Geriatrics*, *20*(1), 1–16. https://doi.org/10.1186/S12877-020-01754-X/TABLES/1

Macera, C. A., Still, C. N., Brandes, D. A., Abramson, R. K., & Davis, D. R. (2016). The South Carolina Alzheimer's disease patient registry: A progress report: *Http://Dx.Doi.Org/10.1177/153331759100600108*, *6*(1), 35–38. https://doi.org/10.1177/153331759100600108

Mack, N., Woodsong, C., MacQueen, K. M., Guest, G., & Namey, E. (2005). Qualitative research methods : a data collector's field guide. In *Qualitative Research Methods: A Data Collector's Field Guide*. FLI;USAID.

Maguire, F. J., Killane, I., Creagh, A. P., Donoghue, O., Kenny, R. A., & Reilly, R. B. (2018). Baseline Association of Motoric Cognitive Risk Syndrome With Sustained Attention, Memory, and Global Cognition. *Journal of the American Medical Directors Association*, *19*(1), 53–58. https://doi.org/10.1016/j.jamda.2017.07.016

Marshall, C., & Rossman, G. B. (2015). *Designing Qualitative Research* (6th ed.). SAGE Publications, Inc.

Martín-García, S., Rodríguez-Blázquez, C., Martínez-López, I., Martínez-Martín, P., & Forjaz, M. J. (2013). Comorbidity, health status, and quality of life in institutionalized older people with and without dementia. *International Psychogeriatrics*, *25*(7), 1077–1084. https://doi.org/10.1017/S1041610213000458

Mayburd, A. L., & Baranova, A. (2019). Increased lifespan, decreased mortality, and delayed cognitive decline in osteoarthritis. *Scientific Reports*, *9*(1), 1–15. https://doi.org/10.1038/s41598-019-54867-8

McGarrigle, L., Irving, K., van Boxtel, M. P. J., & Boran, L. (2019). Cognitive Reserve Capacity: Exploring and Validating a Theoretical Model in Healthy Ageing. *Journal of the*

International Neuropsychological Society, *25*(6), 603–617. https://doi.org/10.1017/S1355617719000250

MIPAA. (2002). *Political Declaration and Madrid International Plan of Action on Ageing*. https://www.un.org/esa/socdev/documents/ageing/MIPAA/political-declaration-en.pdf

Myung, W., Park, J. H., Woo, S.-Y., Kim, S., Kim, S. H., Chung, J. W., Kang, H. S., Lim, S.-W., Choi, J., Na, D. L., Carroll, B. J., & Kim, D. K. (2017). Extrapyramidal signs and risk of progression from mild cognitive impairment to dementia: A clinical research center for dementia of South Korea study. *Psychiatry Investigation*, *14*(6), 754–761. https://doi.org/10.4306/pi.2017.14.6.754

NCRPE. (n.d.). *MCIT | Digital Transformation - ICT for Health*. 2018. Retrieved 15 April 2019, from http://www.mcit.gov.eg/Project_Updates/58/ICT_Infrastructure/ICT_for_Health

Newton, J., & Garner, S. (2002). *Disease Registers in England*.

NIA. (2013). *Publicly Available Databases for Aging-Related Secondary Analyses in the Behavioral and Social Sciences | National Institute on Aging*. https://www.nia.nih.gov/research/dbsr/publicly-available-databases-aging-related-secondary-analyses-behavioral-and-social

Nicaise, S., Palermiti, F., Abdul-Rahman, M., Alouane, L., Alouane, S., Ankri, J., Bartorelli, L., Castel Tallet, M. A., Ceccaldi, M., Desana, M.-O., do Rosario Zincke, M., Gelonch, A., Georges, J., Guetin, S., Gzil, F., Hirsch, E., Kissani, N., Kocaman, F., Kusan Jukic, M., … Zlobec, S. (2016). *Alzheimer and the Mediterranean report 2016 : overview – challenges – perspectives*. https://www.um.edu.mt/library/oar/handle/123456789/27737

NIH. (n.d.). *List of Registries | National Institutes of Health (NIH)*. Retrieved 14 April 2019, from https://www.nih.gov/health-information/nih-clinical-research-trials-you/list-registries

Odejimi, O., Tadros, G., & Sabry, N. (2020). Prevalence of Mental Disorders, Cognitive Impairment, and Dementia Among Older Adults in Egypt: Protocol for a Systematic Review. *JMIR Res Protoc 2020;9(7):E14637 Https://Www.Researchprotocols.Org/2020/7/E14637*, *9*(7), e14637. https://doi.org/10.2196/14637

Park, H. K., Na, D. L., Han, S. H., Kim, J. Y., Cheong, H. K., Kim, S. Y., Kim, S. Y., Hong, C. H., Kim, D. K., Ku, B. D., Moon, S. Y., Lee, J. Y., Shim, Y. S., Youn, Y. C., Kim, E. J., Kim, B. C., Park, K. H., Cha, K. R., Seo, S. W., & Lee, J. H. (2011). Clinical characteristics of a nationwide hospital-based registry of mild-to-moderate Alzheimer's disease patients in Korea: A credos (clinical research center for dementia of South Korea) study. *Journal of Korean Medical Science*, *26*(9), 1219–1226. https://doi.org/10.3346/jkms.2011.26.9.1219

Park, K. M., Sung, J. M., Kim, W. J., An, S. K., Namkoong, K., Lee, E., & Chang, H.-J. (2019). Population-based dementia prediction model using Korean public health examination data: A cohort study. *PLoS ONE*, *14*(2). https://doi.org/10.1371/journal.pone.0211957

Park, M., Sung, M., Kim, S. K., Kim, S., & Lee, D. Y. (2015). Multidimensional determinants of family caregiver burden in Alzheimer's disease. *International Psychogeriatrics*, *27*(8), 1355–1364. https://doi.org/10.1017/S1041610215000460

Power, J. E. M. H., Sjöberg, L., Kee, F., Kenny, R. A., & Lawlor, B. (2019). Comparisons of the discrepancy between loneliness and social isolation across Ireland and Sweden: findings from TILDA and SNAC-K. *Social Psychiatry and Psychiatric Epidemiology*, *54*(9), 1079–1088. https://doi.org/10.1007/s00127-019-01679-w

Punch, Keith. (2006). *Developing effective research proposals* (2nd ed.). SAGE.

Ransmayr, G., Hermann, P., Sallinger, K., Benke, T., Seiler, S., Dal-Bianco, P., Marksteiner, J., Defrancesco, M., Sanin, G., Struhal, W., Futschik, A., & Schmidt, R. (2018). Caregiving and caregiver burden in dementia home care: Results from the prospective dementia registry (PRODEM) of the Austrian Alzheimer Society. *Journal of Alzheimer's Disease*, *63*(1), 103–114. https://doi.org/10.3233/JAD-170657

Recommendations, 6. (2010). *Inside this Issue Brief: 1. Definition of a Disease Registry 2. Benefits of a Registry 2. Considerations 2. Electronic Health Records and a Registry 3. Iowa Legislative Health Care Coverage Commission-Disease Registry Recommendation 3. Example of a Disease Registry Data Report 4. Iowa Registries in Action*. http://www.legis.state.ia.us/lsadocs/IntReport/2010/IPAMV000.PDF.

Religa, D., Fereshtehnejad, S.-M., Cermakova, P., Edlund, A.-K., Garcia-Ptacek, S., Granqvist, N., Hallbäck, A., Kåwe, K., Farahmand, B., Kilander, L., Mattsson, U.-B., Nägga, K., Nordström, P., Wijk, H., Wimo, A., Winblad, B., & Eriksdotter, M. (2015). SveDem, the Swedish Dementia Registry – A Tool for Improving the Quality of Diagnostics, Treatment and Care of Dementia Patients in Clinical Practice. *PLOS ONE*, *10*(2), e0116538. https://doi.org/10.1371/journal.pone.0116538

Religa, D., Fereshtehnejad, S.-M., Cermakova, P., Edlund, A.-K., Garcia-Ptacek, S., Granqvist, N., Hallbäck, A., Kåwe, K., Farahmand, B., Kilander, L., Winblad, B., & Eriksdotter, M. (2015). SveDem, the Swedish Dementia Registry - A tool for improving the quality of diagnostics, treatment and care of dementia patients in clinical practice. *PLoS ONE*, *10*(2). https://doi.org/10.1371/journal.pone.0116538

Religa, D., Spångberg, K., Wimo, A., Edlund, A.-K., Winblad, B., & Eriksdotter-Jönhagen, M. (2012a). Dementia diagnosis differs in men and women and depends on age and dementia severity: Data from Svedem, the Swedish dementia quality registry. *Dementia and Geriatric Cognitive Disorders*, *33*(2–3), 90–95. https://doi.org/10.1159/000337038

Religa, D., Spångberg, K., Wimo, A., Edlund, A.-K., Winblad, B., & Eriksdotter-Jönhagen, M. (2012b). Dementia Diagnosis Differs in Men and Women and Depends on Age and Dementia Severity: Data from SveDem, the Swedish Dementia Quality Registry. *Dementia and Geriatric Cognitive Disorders*, *33*(2–3), 90–95. https://doi.org/10.1159/000337038

Rewerska-Juśko, M., & Rejdak, K. (2020). Social Stigma of People with Dementia. *Journal of Alzheimer's Disease : JAD*, *78*(4), 1339–1343. https://doi.org/10.3233/JAD-201004

Richesson, R., & Vehik, K. (2010). Patient registries: Utility, validity and inference. In *Advances in Experimental Medicine and Biology* (Vol. 686). https://doi.org/10.1007/978-90-481-9485-8_6

Rosén, C., Farahmand, B., Skillbäck, T., Nägga, K., Mattsson, N., Kilander, L., Religa, D., Wimo, A., Blennow, K., Winblad, B., Zetterberg, H., & Eriksdotter, M. (2015). Benchmarking biomarker-based criteria for Alzheimer's disease: Data from the Swedish Dementia Registry, SveDem. *Alzheimer's and Dementia*, *11*(12), 1470–1479. https://doi.org/10.1016/j.jalz.2015.04.007

Russ, T., Murianni, L., Icaza, G., Slachevsky, A., & Starr, J. (2016). Geographical Variation in Dementia Mortality in Italy, New Zealand, and Chile: The Impact of Latitude, Vitamin D, and Air Pollution. *Dementia and Geriatric Cognitive Disorders*, *42*(1–2), 31–41. https://doi.org/10.1159/000447449

Sabry, N., Tadros, G., & Odejimi, O. (2021). A systematic review of the prevalence of mental disorders, cognitive impairment and dementia amongst older adults populace in Egypt. *BJPsych Open*, *7*(S1), S286–S286. https://doi.org/10.1192/BJO.2021.760

Salama, M., & Roe, L. (2020). *Towards a Longitudinal Study of Egyptian Healthy Aging | Global Brain Health Institute*. https://www.gbhi.org/news-publications/towards-longitudinal-study-egyptian-healthy-aging

Salem, G., Said, R. M., Amin, S. I., Elserafy, T. S. E. S., & Awadallah, M. B. (2020). Prevalence, types and different predictors of Dementia ,s diseases among people, community based study, , Egypt. *The Egyptian Family Medicine Journal*, *4*(2), 64–79. https://doi.org/10.21608/EFMJ.2020.20933.1005

Seiler, S., Schmidt, H., Lechner, A., Benke, T., Sanin, G., Ransmayr, G., Lehner, R., Dal-Bianco, P., Santer, P., Linortner, P., Bancher, C., & Schmidt, R. (2012). Driving Cessation and Dementia: Results of the Prospective Registry on Dementia in Austria (PRODEM). *PLoS ONE*, *7*(12). https://doi.org/10.1371/journal.pone.0052710

Silverman, D. (2016). *Qualitative research* (4th ed.). SAGE.

Solomon, D. J., Henry, R. C., Hogan, J. G., van Amburg, G. H., & Taylor, J. (1991). Evaluation and implementation of public health registries. *Public Health Reports*, *106*(2), 142. /pmc/articles/PMC1580226/?report=abstract

Sonnega, A., Faul, J. D., Ofstedal, M. B., Langa, K. M., Phillips, J. W. R., & Weir, D. R. (2014). Cohort profile: The Health and Retirement Study (HRS). *International Journal of Epidemiology*, *43*(2), 576–585. https://doi.org/10.1093/ije/dyu067

Sorbi, S., Hort, J., Erkinjuntti, T., Fladby, T., Gainotti, G., Gurvit, H., Nacmias, B., Pasquier, F., Popescu, B. O., Rektorova, I., Religa, D., Rusina, R., Rossor, M., Schmidt, R., Stefanova, E., Warren, J. D., Scheltens, P., & EFNS Scientist Panel on Dementia and Cognitive Neurology. (2012). EFNS-ENS Guidelines on the diagnosis and management of disorders associated with dementia. *European Journal of Neurology*, *19*(9), 1159–1179. https://doi.org/10.1111/j.1468-1331.2012.03784.x

Stokes, A. C., Weiss, J., Lundberg, D. J., Xie, W., Kim, J. K., Preston, S. H., & Crimmins, E. M. (2020). *Estimates of the Association of Dementia With US Mortality Levels Using Linked Survey and Mortality Records*. *02118*, 1–8. https://doi.org/10.1001/jamaneurol.2020.2831

Swaffer, K. (2014). Dementia: Stigma, Language, and Dementia-friendly. *Dementia*, *13*(6), 709–716. https://doi.org/10.1177/1471301214548143

Terracciano, A., Stephan, Y., Luchetti, M., Albanese, E., & Sutin, A. R. (2017). Personality traits and risk of cognitive impairment and dementia. *Journal of Psychiatric Research*, *89*, 22–27. https://doi.org/10.1016/j.jpsychires.2017.01.011

The Belmont Report | HHS.gov. (n.d.). Retrieved 29 January 2022, from https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html

The Irish Longitudinal Study on Ageing (TILDA) - Trinity College Dublin. (n.d.). Retrieved 8 September 2020, from https://tilda.tcd.ie/

Turró-Garriga, O., Fernández-Adarve, M. del M., & Monreal-Bosch, P. (2021). Needs Detection for Carers of Family Members with Dementia. *Healthcare 2022, Vol. 10, Page 45*, *10*(1), 45. https://doi.org/10.3390/HEALTHCARE10010045

Vaughan, R. M., Coen, R. F., Kenny, R. A., & Lawlor, B. A. (2016). Preservation of the semantic verbal fluency advantage in a large population-based sample: normative data from the TILDA study. *Journal of the International Neuropsychological Society*, *22*(5), 570–576. https://doi.org/10.1017/S1355617716000291

Weiner, M. W., Nosheny, R., Camacho, M., Truran-Sacrey, D., Mackin, R. S., Flenniken, D., Ulbricht, A., Insel, P., Finley, S., Fockler, J., & Veitch, D. (2018). The Brain Health Registry:

An internet-based platform for recruitment, assessment, and longitudinal monitoring of participants for neuroscience studies. *Alzheimer's & Dementia : The Journal of the Alzheimer's Association*, *14*(8), 1063–1076. https://doi.org/10.1016/j.jalz.2018.02.021

West Virginia Alzheimer's Disease Registry. (n.d.). Retrieved 26 January 2022, from https://wvadr.hsc.wvu.edu/

Whelan, B. J., & Savva, G. M. (2013). Design and Methodology of The Irish Longitudinal Study on Ageing. *Journal of the American Geriatrics Society*, *61*(SUPPL2), S265–S268. https://doi.org/10.1111/jgs.12199

WHO. (2012a). *Dementia a public health priority*. https://apps.who.int/iris/bitstream/handle/10665/75263/9789241564458_eng.pdf;jsessionid=91F60603FF10908D2230F876DE20819C?sequence=1

WHO. (2012b). WHO | Neurological Disorders: Public Health Challenges. *WHO*. https://www.who.int/mental_health/neurology/neurodiso/en/

WHO. (2012c). *World Health Organization | Alzheimer's Disease International*. 2012. https://www.alz.co.uk/world-health-organization

WHO. (2015). WHO | Thematic briefs for the First WHO Ministerial Conference on Global Action Against Dementia, 16-17 March 2015. *WHO*. https://www.who.int/mental_health/neurology/dementia/thematic_briefs_dementia/en/

WHO. (2017). WHO | Global action plan on the public health response to dementia 2017 - 2025. *WHO*.

WHO. (2018). WHO | Towards a dementia plan: a WHO guide. *WHO*.

WHO | Programme Budget Web Portal. (n.d.). Retrieved 4 September 2022, from https://open.who.int/2018-19/country/EGY

Wilkins, S., Best, R. L., & Evans, S. M. (2015). Need for a roadmap for development of a coordinated national registry programme. *Internal Medicine Journal*, *45*(11), 1189–1192. https://doi.org/10.1111/imj.12898

Wimo, A., Religa, D., Edlund, A.-K., Winblad, B., Eriksdotter, M., & Spångberg, K. (2013). Costs of diagnosing dementia: Results from SveDem, the Swedish Dementia registry. *International Journal of Geriatric Psychiatry*, *28*(10), 1039–1044. https://doi.org/10.1002/gps.3925

Winblad, B., Amouyel, P., Andrieu, S., Ballard, C., Brayne, C., Brodaty, H., Cedazo-Minguez, A., Dubois, B., Edvardsson, D., Feldman, H., Wimo, A., & Zetterberg, H. (2016). Defeating Alzheimer's disease and other dementias: A priority for European science and society. *The Lancet Neurology*, *15*(5), 455–532. https://doi.org/10.1016/S1474-4422(16)00062-4

Wu, J. J., Wang, H. X., Yao, W., Yan, Z., & Pei, J. J. (2020). Late-life depression and the risk of dementia in 14 countries: a 10-year follow-up study from the Survey of Health, Ageing and Retirement in Europe. *Journal of Affective Disorders*, *274*, 671–677. https://doi.org/10.1016/j.jad.2020.05.059

Zaitoun, A. M., Ma, A.-A., Sarhan, moun M., Selim, A. M., & Mousa, G. R. (2008). Epidemiological Study of Dementia after Retirement. *Egypt J. Neurol. Psychiat. Neurosurg*, *45*(1), 65–74.

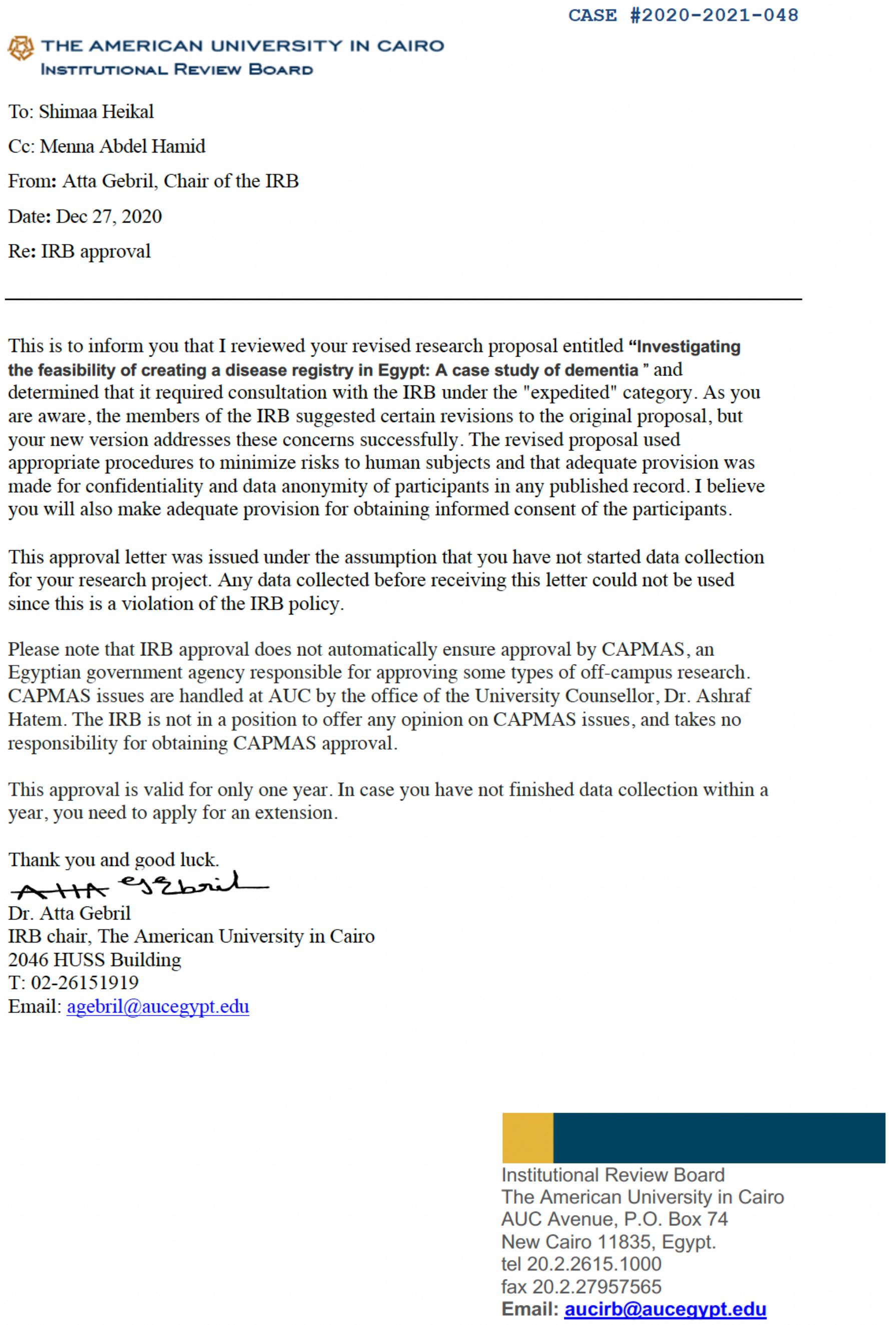
Zaletel, M., & Kralj, M. (2015). *Methodological guidelines and recommendations for efficient and rational governance of patient registries*. https://ec.europa.eu/health/system/files/2016-11/patient_registries_guidelines_en_0.pdf

Zeeneldin, A. A., & Taha, F. M. (2016). The Egyptian clinical trials' registry profile: Analysis of three trial registries (International Clinical Trials Registry Platform, Pan-African Clinical

Trials Registry and clinicaltrials.gov). *Journal of Advanced Research*, *7*(1), 37–45. https://doi.org/10.1016/j.jare.2015.01.003

Zhu, Y., Chen, Y., Crimmins, E. M., & Zissimopoulos, J. M. (2020). Sex, Race, and Age Differences in Prevalence of Dementia in Medicare Claims and Survey Data. *The Journals of Gerontology: Series B*. https://doi.org/10.1093/geronb/gbaa083

Annex 1: IRB Approval



CASE #2020-2021-048

THE AMERICAN UNIVERSITY IN CAIRO
INSTITUTIONAL REVIEW BOARD

To: Shimaa Heikal

Cc: Menna Abdel Hamid

From: Atta Gebril, Chair of the IRB

Date: Dec 27, 2020

Re: IRB approval

This is to inform you that I reviewed your revised research proposal entitled **"Investigating the feasibility of creating a disease registry in Egypt: A case study of dementia "** and determined that it required consultation with the IRB under the "expedited" category. As you are aware, the members of the IRB suggested certain revisions to the original proposal, but your new version addresses these concerns successfully. The revised proposal used appropriate procedures to minimize risks to human subjects and that adequate provision was made for confidentiality and data anonymity of participants in any published record. I believe you will also make adequate provision for obtaining informed consent of the participants.

This approval letter was issued under the assumption that you have not started data collection for your research project. Any data collected before receiving this letter could not be used since this is a violation of the IRB policy.

Please note that IRB approval does not automatically ensure approval by CAPMAS, an Egyptian government agency responsible for approving some types of off-campus research. CAPMAS issues are handled at AUC by the office of the University Counsellor, Dr. Ashraf Hatem. The IRB is not in a position to offer any opinion on CAPMAS issues, and takes no responsibility for obtaining CAPMAS approval.

This approval is valid for only one year. In case you have not finished data collection within a year, you need to apply for an extension.

Thank you and good luck.

Atta Gebril

Dr. Atta Gebril
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Annex 2: Interview Guide

Investigating the feasibility of creating a disease registry in Egypt: A case study of dementia

1- Personal experience of registries

- What does registry mean? What's the importance of a registry?
- What type of registry would be more valuable to be created as the first step in a country?
- From your experience, what are the best ways to plan a dementia registry?

2- Challenges for piloting this project:

- What challenges would be faced throughout the process?

3- Data consideration

- From your experience, what data should be included in the registry?
- What will be the most appropriate data collection method? (Hired volunteers, clinic-based, online, etc.…)

4- Data ownership and governance

- Who should own the data or be authorized to access the data?
- Who should collect the data for better management?

5- Ethical considerations

- What steps should be donetakenavoid any ethicalconsiderationsn or decrease patient stigmatization?

Annex 3: Consent Form

THE AMERICAN UNIVERSITY IN CAIRO
INSTITUTIONAL REVIEW BOARD

Documentation of Informed Consent for Participation in Research Study

Project Title: Investigating the feasibility of creating a disease registry in Egypt: A case study of dementia
Principal Investigator: Shimaa Heikal - -----------

You are being asked to participate in a research study. The purpose of the research is to explore the feasibility of creating a dementia disease registry in Egypt by evaluating the knowledge of experts, their perspectives regarding this issue and ,the legal, financial, ethical, and technical issues that may arise. The findings may be published. The expected duration of your participation is five months starting January 2021 till May 2021.

The procedures of the research will be as follows; you will be asked to answer some questions during an interview, and a follow up meeting can be done if needed.

There will not be any risks or discomforts associated with this research. You will have the right to skip any question if you want. There will not be benefits to you from this research as well.

The information you provide for the purposes of this research is confidential. Only the principal investigator will have access to the informant data, and no personal information will be included in the research.

Questions about the research and any related issue should be directed to the principal investigator, Shimaa Heikal, at -----------

Participation in this study is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue participation at any time without penalty.

Signature ________________________________
Printed Name ________________________________
Date ________________________________