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National Collaborative Surveillance Measures in Diabetic Care: Addressing Avoidable Blindness

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Chapter 1 Introduction

Background, Problem and Purpose

The purpose of this project is to provide recommendations for a national web-based open-access registry system. This project will discuss ways in which a national registry could impact eye disease prevalence, incidence, progression, and functional and anatomic outcomes. It will also discuss the impact that such a national system will have on patient and provider engagement, data availability, follow-up care and long-patient monitoring across specialties.

Across the United States, it is estimated that there are millions of data points collected on a yearly basis (IRIS, 2019). However, the literature suggests that there are enormous gaps in disease monitoring, data accessibility, system interoperability and long-term patient follow-up care. According to the National Academies of Sciences Engineering and Medicine (NASEM), "A systematic and ongoing collection of relevant data about risk factors, determinants of visual health, care practices, and related health outcomes associated with eye health and visual impairment is lacking. Currently, information is drawn from an array of surveys, EHRs, and administrative claims data, but it is difficult to triangulate information from these sources because of inconsistencies in definitions, measures, and other problems inherent in data collection activities that are discordant or developed independently." (National Academies of Sciences, Engineering, and Medicine, 2016).

The recommendations outlined in this project are not suggesting that current data systems do not add value in patient care settings for those suffering eye disease but is instead promoting an upgrade to current data collection and dissemination processes on a national scale. The long-term goal of this technology, therefore, is to reverse the continuous rise in disease prevalence and subsequent disease complications over the next 10 years.

The International Agency for the Prevention of Blindness (IAPB) stated that the most effective programs for impacting eye disease prevalence will take a holistic approach and will include patient education, behavioral changes, and disease management strategies in addition to annual vision exams.

This will be accomplished by establishing a National Eye Surveillance (NES) system which will incorporate the following components:

Data In

On-Going Structured Data Collection - will provide continuous data uploads across providers without the need for individual data mining and analysis teams. After the initial time commitment required by participants, national standardization measures will allow large amounts of information to be captured by NES without a large time commitment by stakeholders.

Data Out

The Patient User Interface - will promote and improve patient engagement, education and encourage follow-up care including yearly eye examinations. The graphic interface, which can be accessed both in the office and at home, will chart current treatment plans and long-term eye health regimes.

The Provider User Interface - will provide real-time data for both in-office patients at the time of treatment, in addition to real-time access to national treatment outcomes data. The provider user interface will also provide automated follow-up reporting, reducing patients who are lost to follow-up.

Multi-Care Team User Interface - will allow access to patient information across all specialties in a patients' care team, providing a holistic approach to care management.

Open-Access User Interface - will allow de-identified information to be shared for educational institutions and foundations who serve this population indirectly. This would provide users with national disease prevalence data (beyond current Medicare data collection), which will aid in the development of enhanced eye disease initiatives and strategies.

Report User Interface - will provide both pre-set and customizable reports to serve the needs of various stakeholders. This would include research initiatives for eye diseases to inform treatment innovation.

The development and implementation of this new technology will incorporate key stakeholder participation at each step (this will promote buy-in), in order to reduce the current siloed

approach which retards public health goals and initiatives. A national eye surveillance system will better serve the public health need.

Although there are hundreds of eye diseases suffered by individuals throughout the United States, this project will establish the need for this system through the lens of vision-threatening eye disease sufferers among the diabetic community.

Diabetes - Global Prospective

In 2016, the World Health Organization (WHO) estimated that there were approximately 422 million people with diabetes worldwide. In the same year, 1.6 million people died from diabetes or a diabetes-related illness. While there are extensive complications associated with diabetes, some of the most serious include: stroke, heart attack, kidney failure, loss of limbs and blindness (IAPB, 2016). Unfortunately, as the prevalence of diabetes rises so, too, does the prevalence of these complications. It is estimated that by the year 2040, the number of people with diabetes will reach 642 million (Fred Hollows Foundation, 2019).

Diabetic retinopathy (DR) is a progressive eye disease that occurs in patients who have diabetes. Diabetic patients who suffer from prolonged and or uncontrolled high blood sugar may also experience eye damage. When normal blood vessels in the retina degrade in patients with DR, new and abnormal blood vessels often develop in their place; these blood vessels may leak and scar causing cloudy, blurry vision, advancing to partial or total blindness (Boyd, 2019).

In a twenty-year meta-analysis study (1990-2010), it was cited that as of 2010 there were 3.7 million people who were visually impaired due to diabetic retinopathy (DR). The study was designed to determine the Global Burden of Disease which showed a 27% increase in the incidence of blindness and a 64% increase in the incidence of visual impairment due to DR. While this study noted the challenges and inconsistencies of disease reporting practices in some countries, the data clearly indicated a sharp rise in disease prevalence, which held substantial socioeconomic burden (Flaxman, 2017).

This is particularly concerning because 80% of those affected by this disease are living in poverty. This means that in countries where there are already limited resources and the burden of disease

continues to rise, it further broadens the economic strain currently experienced by both low- and middle-income countries (Hollows, 2019).

According to the Centers for Disease Control and Prevention (CDC), in the U.S. there were over 30 million people suffering from Type 2 diabetes in 2017, with over 84 million adults with pre-diabetes. Compounding this problem, there are 1.5 million who are diagnosed with diabetes each year (CDC, 2019).

Diabetic Retinopathy

Among the 422 million people reported by the WHO with diabetes, approximately 1 in 3 have some form of diabetic retinopathy, defined as a diabetes complication that affects eyes. It is caused by damage to the blood vessels of the light-sensitive tissue at the back of the eye (retina). (Mayo 2018). Importantly, 1 in 10 people will develop a vision threatening form of the disease. Diabetic Retinopathy is one of the leading causes of vision loss in working adults in the world (IAPB, 2016).

Individuals with diabetes frequently have multiple co-morbidities and it is often difficult to determine singular causes of disease advancement. Some potential factors which influence DR rates include urbanization, consumption of less nutritious foods, obesity, access to care, education levels and socioeconomic factors (IAPB, 2016).

Moreover, among patients diagnosed with diabetic retinopathy in the United States, the actual number of patients with severe stages of the disease, such as the vision threatening stage, remains unclear due to the wide variances in data collection practices across data resources. Frequently, patients are asymptomatic until after sight-threatening disease advancement has occurred (IAPB, 2016).

Chapter 2 Methods

Introduction

In order to stay within the scope of this project, only U.S. data sources were selected for inclusion in the proposed registry system. The information that was gained, however, from the analysis of

those international systems has been incorporated, as it provides valuable information of the current structure and function of existing national registry systems for eye disease.

In the United States, there are numerous individual data registries which capture diabetes and eye disease information, but it has been suggested that disease surveillance systems be improved to better meet the current and future needs of stakeholders (O'Connor, 2011).

In order to establish a plan for the development of a national system to better meets those needs, the following procedures were taken:

Description of Procedures

The process for this project included the exploration and development of the following components:

- Insights from Retina Professionals
- System Requirements
- Review of Data Source Types and Current Registries (U.S. and Abroad)
    - National Disease Registries Surveillance Systems (Abroad)
    - Medical Claim Systems (U.S.)
    - Organization-Sponsored Registries (U.S. and Abroad)
    - Insurance Claims Data (Global)
- Plan Development
- High Level-Implementation & Risk Mitigation Strategy

Interviews with Ophthalmic Professionals (U.S.)

In the Retina Research department of Mid-Atlantic Retina in Philadelphia, the practice has conducted numerous studies which look at the care and treatment of retina diseases, including sight-threatening retinal diseases such as glaucoma, macular degeneration and diabetic retinopathy. This team included physicians, surgeons, and research fellows who conduct clinical trials and extract and analyze data from large data sets on a daily basis.

For this project, two research fellows were asked to share their insight into the challenges they have faced in obtaining data for diabetic retinopathy and other retinal diseases. Their feedback includes:

1. A common shortfall of retinal disease data observed were in gaps in long-term follow-up information. The initial care and treatment of patients were found to be captured, along with demographic, diagnoses and surgery data. Long-term follow-up data, however, were found to be inconsistently reported. Some of the gaps in follow-up were attributed to patients failing to return for visits as part of their treatment plan. Long-term data was important in analyzing disease outcomes, treatment response and complications of retinal diseases.
2. The location of pathology in the retina was a data element, described by practitioners in not one but in multiple ways. Disease reporting varied greatly, such that the location of eye disease might be described by the quadrant of the eye, while others may use clock hours, while still others may not describe a location at all.
3. A data element which is frequently missing from patient records is one which captures how long symptoms of eye disease had been experienced by the patient.
4. In US data studies, socio-economic factors were rarely captured, however, race was consistently reported.
5. Access to some registries was difficult to obtain, and access to the IRIS data sets were found to be inaccessible, if a practice was not eligible to participate with Medicare.

Next Steps

The insights gained from this feedback led me to seek out more information to address the following questions:

- What are the challenges faced in closing gaps in follow-up care?
- Can an open-access system be created to affect data flow among stakeholders in order to provide timely reporting if they are not Medicare stakeholders?
- What should the system requirements be in order to provide the highest level of inclusion of stakeholders?

In order prepare for the implementation component of this improved system, several components were evaluated. Much like the CDC and the National Notifiable Diseases Surveillance System (NNDSS) which helps in public health monitoring, control, and prevention of about 120 diseases, a selection of primary components needed to be established. The NNDSS for example, consists of three core functions: data collection, analysis and data sharing. These functions were then further sub-divided for legislation: data standards, stakeholders and partnerships among the levels of government (CDC NNDSS, 2019)

Establishment of System Requirements

From a review of the NNDSS and other surveillance systems, there were basic components which were repeated across multiple sources. This proposal recommends the inclusion of four core elements: Structure, Function, Quality and Support features.

Figure 1.

Four (4) Elements of a Comprehensive Surveillance System (This chart represents selected components from the National Disease Registries 2019).

Surveillance Structure:	**Surveillance Support:**
Legislative Compliance	Resources
Implementation and Stakeholders	Guidelines
Partnerships	Regulation Authorities and Control
Interoperability	Evaluation and Feedback
Surveillance Function:	**Surveillance Quality:**
Establishment of Disease Trends	Data Element Selection Standards
Disparate Group Monitoring (Future)	Short Turn-Around of Data Return
Long-Term Outcome Reporting	Inclusiveness
	Data Validation

Due to the monetary limitations, as they would exist with the implementation of any national system, it is important to note that some elements from Fig. 1, may not be fully functional at the time of initial launch of this new system, but all of the elements will be part of its' long-term data plan.

The 4 elements above formed the basic structure by which each data source type and registry was reviewed. These elements were used to effectively evaluate the strengths and weaknesses of each registry assessed, although the variability of the data types made this a challenge.

Instruments

The tools used to collect information during this project include the following:

Figure 2

Name of Instruments	Description
Interviews	Informal discussions were conducted with Retina Research Fellows at Mid Atlantic Retina at Wills Eye Hospitals
Literature Review	Research was conducted using the Emory library, Google and Google scholar. Keyword searches included some of the following terms: diabetes, diabetic retinopathy, data registries, diabetes collaborative, Geographic Information System (GIS) and diabetes, the CDC, diabetes and disparate groups, and diabetes and WHO.

Name of Instruments	Description
Data System Applications Review	This included review of the structure and operation of the registry system, who it was sponsored by and how long had it been in operation
Data Collection Form Review	Review of the forms being used by healthcare providers was conducted. Some collection forms included data elements such as demographics, disease history, medications, lab results and surgical events.
Published Data Source Reports	Reports were reviewed as issued which outlined their progress, shortfalls, and future outlook.
Registry Data Search	Data searches were conducted on Open-Access registries to help to better understand what data output/return could be achieved by their system, how information was housed and general accessibility, (where access was available).
Project Plan Development	Stakeholder evaluation, development of information flow, database design, platform consideration, maintenance requirements, implementation & risk mitigation. Explore limitations and future expansion opportunities.

Description of Current Registry Data Sources

There are many sources of information that were found to be in operation during the development of this thesis, and the inclusion of each is beyond the scope of this project. Of the information found, those sources which appeared to be most representative of the diabetic retinopathy disease population were selected for further evaluation.

Before specific data resources could be selected for further analysis, a review of materials and reports was conducted on numerous organizations. This review process enabled better familiarity of various data systems which included organizations such as the American Diabetes Association, the NIH National Eye Institute, and the Pinnacle Registry. The Centers for Disease Control and Prevention (CDC), in their continuous efforts to fight diabetes, has developed a

Diabetes Atlas System and a U.S. Diabetes Surveillance System, which are two tools that capture statistical data on national, state and county patient trends. (CDC-Diabetes Atlas). This open-access system did not contain clinical data but provided insights into data collection strategies for prevalence estimates of diabetes disease patterns as it relates to specific complications. (CDC 2019). After reviewing several data types, the following questions were then developed to analyze data sources for inclusion into the national system:

Key Questions

Data In:

- Who are the participants providing the patient information?
- What were the specific diseases and disease complications collected?
- How long had the source been in existence?
- What data elements were being collected? (what is excluded)
- What was the format standards of the information being collected? (i.e. coded data, image data, free text)
- What is the general geographic area of collection?
- What was the stated goal for collection of the information?
- Who are the sponsors of the data systems? (societies, pharmaceuticals, government organizations, private companies)

Data Out:

- Did any source share information to other data sources (or were future plans for interoperability noted)?
- What information was consistently included in the collection process, and what information was found to be incomplete or missing?
- How frequently was reporting provided, particularly to the healthcare providers and or the general public?
- Were long-term disease outcomes available to data source participants?
- Did reporting include multi-disciplinary care teams or did the source only include one type of healthcare professionals?

The approach for this project was to incorporate the data from existing U.S. stakeholders in order to facilitate data integration of multiple individual data systems. The data sources and registries selected provided valuable insights into current availability and uses of disease data. Insights and analysis were included from the following sources:

- National Disease Registries Surveillance Systems (Abroad)
  - Fighting Retinal Blindness- Saving Sight Registries
  - National Eye Database (NED)- Malaysia
- Medical Claims Systems (U.S.)
- Organization-Sponsored Registries (U.S. and Abroad)
  - American Academy of Ophthalmology Intelligent Research in Sight (AAO's IRIS Registry)
  - Diabetes Collaborative Registry
- Insurance Claims Data (Global)
  - Visual Service Plan Insurance (VSP)

National Disease Registries Surveillance Systems (Abroad)

Fighting Retinal Blindness Registry (FRBR) is one of four registries which comprise the Save Sight Registries in Australia. This set of Registries represents the first to house ten years of patient information for various eye diseases. Although this platform serves primarily Australians, the project has a strong presence in New Zealand, Singapore and a few countries in Europe, such as Switzerland, the Netherlands, the UK, Spain, France and Austria (Saving Sight Institute, 2019).

The multi-system approach of the Save Sight Registries serves as the umbrella under which four disease registries are housed. This structure allows multiple diseases to be addressed individually, while retaining the capacity for interoperability across eight other nations (Saving Sight Institute, 2019).

National Eye Database (NED) is a Malaysian system that houses two patient registries and three surveillance registries, including a Diabetic Eye Registry.

The data collection is organized as a cohort study, and it is supported by the Ministry of Health. The data are primarily collected from healthcare providers from the public sector. In addition to the information provided by healthcare providers, the Ministry of Health also collects monthly census data as part of this system (NED-About NED, 2019).

Claims Data Resources (U.S.)

Medicare Claims Data - This data set includes patient information from claims and billing data from hospitals for both in-patient and out-patient services, home health care, skilled nursing homes and Part D data (this represents prescription drug coverage for its members). Visual health information is included in each of these billing sources (SGIM, 2019).

Organization-Sponsored Registries - (U.S. and Global)

The American Academy of Ophthalmology Intelligent Research in Sight (AAO's IRIS Registry) - is the only society-sponsored registry in the country and housed data for over 14 million patients, over the past 3 years. This large registry participates in and is centered around electronic health records and the Merit-Based Incentive Payments (MIPs) program, which provided bonus payments through the Centers for Medicare and Medicaid Services to healthcare providers nation-wide. This registry is not an open-access system, however it does award research grants, allowing access to their data system (Park II, 2017).

Insurance Claims Data - (Global)

Visual Service Plan (VSP) contains data derived from insurance claims and is the largest vision insurer in the nation. VSP collects information for both routine vision care and vision corrections; data that are not routinely captured in other registry sources (VEHSS-VSP Global, 2019)

Chapter 3 IMPLEMENTATION

Introduction

The results of the analysis of current registry systems were derived from both international and US databases. This approach was critical since there were many lessoned to be learned from the data collection systems currently synthesizing large amounts of information.

Implementation Background

Although there are many regions around the globe which do not have formal electronic data collection, there are still many database systems which have been collecting diabetes data, and more specifically eye disease data for many years.

Due to the scope of this project, only 2 were selected for exploration. The two systems were selected based on the availability of information on the system and evaluated by how many Key Questions (see Figure 3) could be answered successfully by this resource.

Fighting Retinal Blindness Registry– Strengths & Limitations (Australia)

The Save Sight Registries houses 5 individual registries to include retinal, corneal, glaucoma, tumor and uveal blindness. The FRB project includes data for four conditions which include neovascular age-related macular degeneration (nAMD or "wet" AMD), Choroidal neovascularization (CNV) meaning conditions other than wet AMD, retinal vein occlusion and diabetic retinopathy (Saving Sight Institute, 2019).

This system is both a web-based database and interface platform which serves four groups: patients, clinicians, the general population and health systems. FRB has been endorsed by the International Consortium for Health Outcomes Measurement (ICHOM) as a preferred tool to collect data (Saving Sight Institute, 2019).

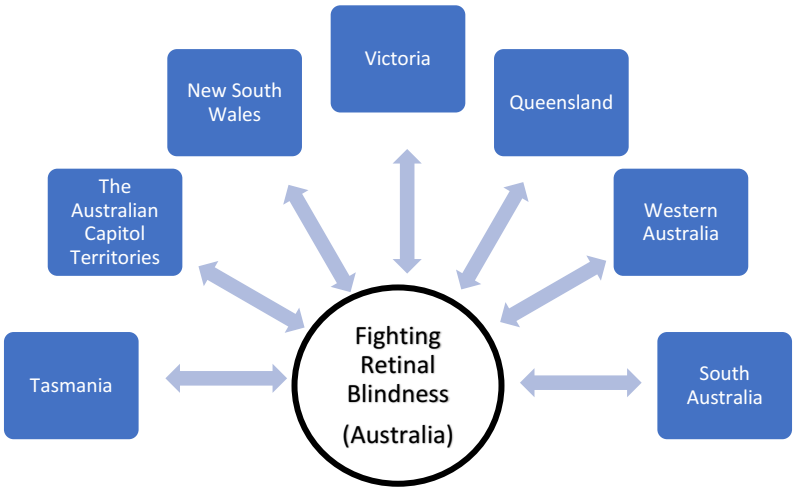
ICHOM is a consortium which has been recognized internationally for their work in the establishment of global data standards with a particular focus on Patient Outcome

measures and more recently setting the standard for Diabetes at World Diabetes Day in 2018 (ICHOM, 2019).

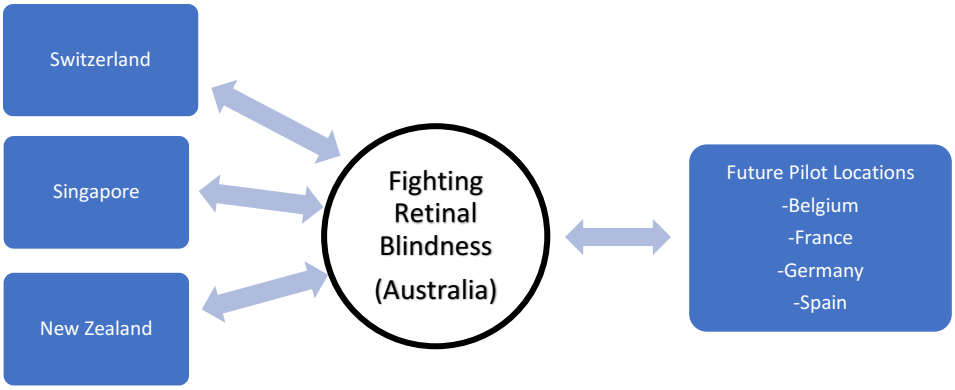
FRB currently includes seven regions of Australia, three international participants and four pilot regions which are still in the trial phase. This system incorporates all four essential elements of a surveillance system as shown in Figure 1.

Surveillance *Structure* components are demonstrated by the inclusion of multiple participants, such as clinicians, patients, health systems and the population. Partnerships have been established in multiple regions, with plans for additional expansion. The *Function* components would include data analysis functionality of disease trends and long-term outcome reporting (both data sets and real-time interface). The *Support* features would include guidelines as resources as provided to all participants which include tools to help track disease trends and outcomes. The *Quality* component would include standardization of data elements which allows interoperability across regions and countries. The system also offers fast data input and subsequent short turn-around times on data output. Another quality component would be in its inclusion of health entities in both the public and private sector.

Figure 5 - National Participants included in FRB Registry (Saving Sight Institute, 2019)

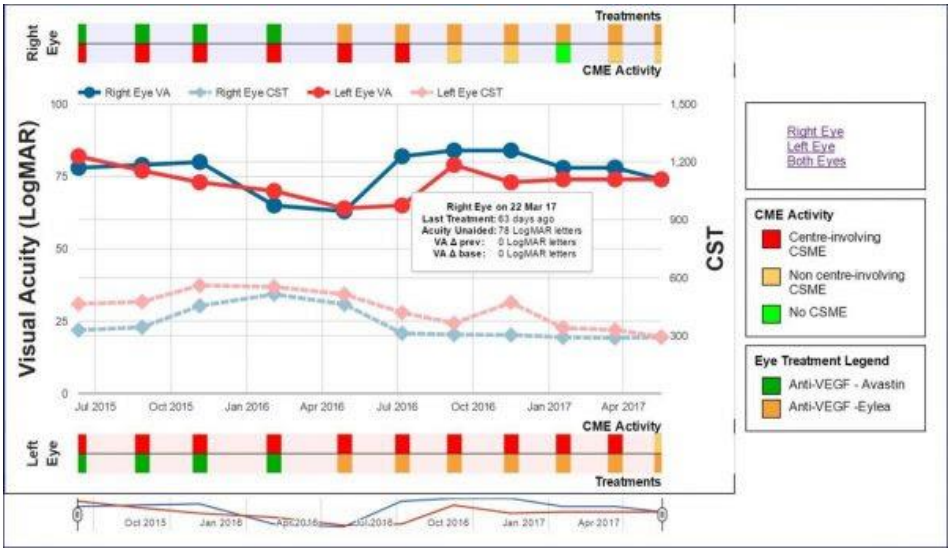


International Participants included in FRB Registry



The following diagram (Fig. 6) shows a patient's course of treatment as generated by the FRB registry system. This chart maps a medication regimen and compared it against the results of visual acuity testing for 2 years. One of the strengths of this system is that it allows both clinicians and patients to track disease progression.

Figure 6



http://savesightregistries.org/clinicians/#graph

Outstanding questions that were not readily available would include the following:

How is this system funded (Non-profit- privately funded?)

How are the under-served and under-insured incorporated?

How many people are included in the database, thus far?

What kind of time investment did it require to get each participant incorporated into the system?

National Eye Database (NED) - Strengths & Limitations Malaysia

The NED system in Malaysia was chosen for evaluation, because much like the FRB registry, it had many of the components of the 4 Essential Elements of a comprehensive surveillance system. Information was sourced from their website and journal articles, which provided insights into the strengths and shortfalls of the system (NED-About NED, 2019).

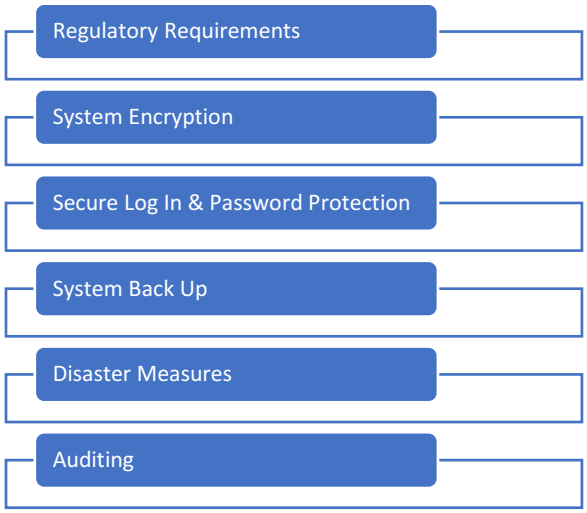
The NED database system was established in 2007 and collects prospective data on patients who are seen for the first time. This means that anyone who was already under-going routine eye exams, was excluded. The purpose of this registry was to assess the magnitude of DR through those who had never been diagnosed or treated and provided recommendations for improved clinical practices (Goh, 2017).

In a population-based study of NED data which included 19 hospitals, an inner city clinic and a U.S. VA medical center, it was found that of 10,586 diabetics who had been seen for the first time at a Ministry of Health (MOH) eye care facility, 15% of those patients had eye-threatening disease (Goh, 2007). It is important to note that this study stated that patients who utilize MOH facilities tend to be in poorer health.

In evaluation of this system, they included multiple stakeholder involvement such as patients, clinic physicians, and hospital collaborations. Any eye care provider in Malaysia who conducts vision screenings can take part in the registry. This inherently promoted partnerships across various regions.

This system appeared to place particular emphasis on data security. These measures become important in maintaining HIPAA compliance while system access continues to expand to more users.

Figure 7 7 *Support* components included in the NED registry system:

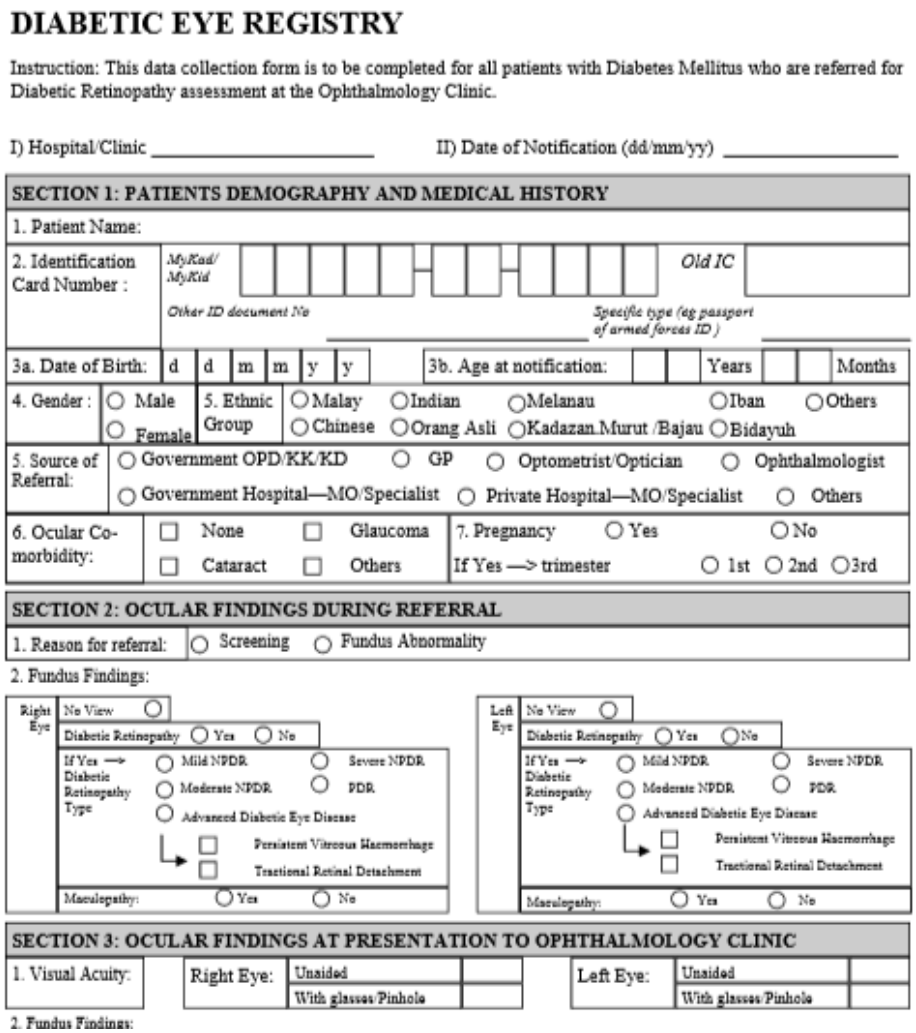


The NED system allows each practice which participates in this site the ability to manage their own data and edits. The process begins with a standard collection tool (see Figure 8) and this affords each site a quick turn-around for data output.

It is unclear of how standards of the system are maintained and if the participating sites are allowed to make edits, although a manual is provided to each site. The resources available did not provide much detail on which data elements were afforded variances from practice to practice.

The NED Data Collection Instrument includes many of the common elements included in other collection instruments, as it captures demographics, general eye data and stages of DR. However, it did not include eye surgical history or medications prescribed which would aid in capturing long-term treatment outcomes data.

Figure 8 NED Data Collection Instrument (NED, 2019)



DIABETIC EYE REGISTRY

Instruction: This data collection form is to be completed for all patients with Diabetes Mellitus who are referred for Diabetic Retinopathy assessment at the Ophthalmology Clinic.

I) Hospital/Clinic _____ II) Date of Notification (dd/mm/yy) _____

SECTION 1: PATIENTS DEMOGRAPHY AND MEDICAL HISTORY

1. Patient Name:

2. Identification Card Number : *My/Kad/ My/Kid* | *Old IC*

Other ID document No _____ *Specific type (eg passport of armed forces ID)* _____

3a. Date of Birth: d d m m y y | 3b. Age at notification: Years Months

4. Gender : ○ Male ○ Female | 5. Ethnic Group ○ Malay ○ Indian ○ Melanau ○ Iban ○ Others ○ Chinese ○ Orang Asli ○ Kadazan Murut /Bajau ○ Bidayuh

5. Source of Referral: ○ Government OPD/KK/KD ○ GP ○ Optometrist/Optician ○ Ophthalmologist ○ Government Hospital—MO/Specialist ○ Private Hospital—MO/Specialist ○ Others

6. Ocular Co-morbidity: ☐ None ☐ Glaucoma ☐ Cataract ☐ Others | 7. Pregnancy ○ Yes ○ No If Yes —> trimester ○ 1st ○ 2nd ○ 3rd

SECTION 2: OCULAR FINDINGS DURING REFERRAL

1. Reason for referral: ○ Screening ○ Fundus Abnormality

2. Fundus Findings:

Right Eye: No View ○ | Diabetic Retinopathy ○ Yes ○ No | If Yes —> Diabetic Retinopathy Type: ○ Mild NPDR ○ Severe NPDR ○ Moderate NPDR ○ PDR ○ Advanced Diabetic Eye Disease ☐ Persistent Vitreous Haemorrhage ☐ Tractional Retinal Detachment | Maculopathy: ○ Yes ○ No

Left Eye: No View ○ | Diabetic Retinopathy ○ Yes ○ No | If Yes —> Diabetic Retinopathy Type: ○ Mild NPDR ○ Severe NPDR ○ Moderate NPDR ○ PDR ○ Advanced Diabetic Eye Disease ☐ Persistent Vitreous Haemorrhage ☐ Tractional Retinal Detachment | Maculopathy: ○ Yes ○ No

SECTION 3: OCULAR FINDINGS AT PRESENTATION TO OPHTHALMOLOGY CLINIC

1. Visual Acuity: Right Eye: Unaided / With glasses/Pinhole | Left Eye: Unaided / With glasses/Pinhole

2. Fundus Findings:

U.S Data Sources- Insights for National Surveillance System

Medicare Claims Data - Strengths & Limitations

When data collection began, in what was then called clinical information systems, in the late 1960s and 70s, providers were allowed to develop their own system of collection. It was not until the 80s that legislative leaders began to question the need for greater standardization (AMA Journal, 2011). Changes in data collection practices were slow going and 2o years later there were still major stumbling blocks in effective data collection. In 2009 as part of President Obama's American Recovery and Reinvestment Act, a national system of EHR or Health Information Technology Act (HITECH) was proposed due to drastic inadequacies which included frequent system crashes, data security, response times, and inadequacies of inter-specialty communications. The HITECH provided higher payments to providers who met current meaningful use criteria for EHR system. It is important to note, however, that meaningful use requirements apply only to those individuals who are covered by government insurance.

Beyond the government sector, there are numerous standardizations needed, for example, in there were multiple sources which housed ophthalmic disease data points, under the umbrella of diabetes, while other national sources focused only on diseases of the eye.

As recent as February of 2019, CMS has set out to address this challenge by proposing greater secure standards for provider data, therefore it appears that there will be more potential changes to come (CMS, 2019).

The Centers for Medicare & Medicaid Services (CMS) has long been plaque with the issues of interoperability, with data being collected in silos (SGIM, 2019).

Data flows in one direction. Medicare does not share data with providers, and once collected is owned by CMS. This means that reporting capacity is very limited to providers and healthcare facilities. Gaining access to datasets is expensive to obtain and often requires biostatisticians in order to mine data in order to format it for use. Medicare Claims Data represents a valuable tool in data collections, but it must be noted, this data represents approximately 50 million people or 16% of the U.S. population, all of which are over 65 years of age. Despite this limitation, the data housed by Medicare is robust (SGIM, 2019).

Medicare Claims houses information in the following patient file types:

- ✓ Inpatient
- ✓ Outpatient
- ✓ Skilled Nursing Facility
- ✓ Hospice
- ✓ Home Health
- ✓ Carrier
- ✓ Durable Medical Equipment
- ✓ Base Master Beneficiary Summary file (MBSF)
- ✓ Chronic Conditions (MBSF) File
- ✓ Part D Event Data
- ✓ Part D (Characteristics including Drug, Pharmacy, Prescriber and Plan)

In order to capture data for participants under the age of 65 inclusive of a national population with eye disease, other resources would need to be incorporated to achieve a comprehensive dataset.

IRIS Database - Strengths & Limitations

The IRIS Database is unique in that currently it is the only registry collection system in the U.S which collects and houses eye data for over 200 practices which accept Medicare payments. For IRIS registry participants, data collection through the integration of the AAO's electronic health system, there is very little time commitment required in order to provide continuous data collection. IRIS's EHR system is hosted on a server at each the practice and the practices' data is provided to clinicians allowing them to track the treatment outcomes of their patients (AAO, 2019).

The data collection process for the IRIS registry is handled by FIGMD, which is the platform being used for systems integration. This provider has performed successful collection for over fifty (50) different electronic health record systems, but it is important to note that FIGMD did not have the capacity to integrate with four (4) of the largest electronic health records vendors, which includes any hospitals which use EPIC, Meditech, Cerner or the McKesson system (Singh, 2015).

The Plan Implementation Purpose & Objectives

By adopting a new electronic health information system on a national level, we are able to address public health issues that were left previously unresolved. Some of the major issues that the new NES system will solve center around better patient care as a primary objective. The secondary objective is to provide better real-time data flow to healthcare providers to optimize treatment plans.

The NES system will achieve this by supporting stakeholder participation, information flow, data standards, database reporting considerations, and maintenance requirements for system implementation.

Stakeholders

The stakeholders of this national eye registry could be defined as anyone who would be affected by the implementation of such a system. The stakeholders in the NES system will include entities across six different categories.

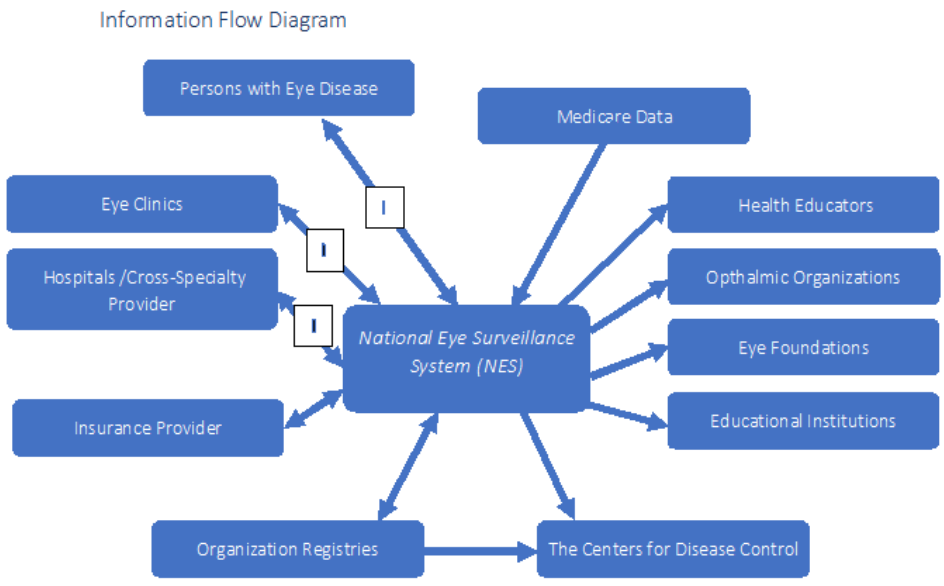
Categories	Stakeholder Groups
Individuals	• Persons with Diabetes and or Eye Disease • Caregivers and Family Members • Health Educators
Health care Providers	• Eye Clinics • Hospitals • Other Specialty Providers • National Professional Organizations
Industry Representative	• Insurance Companies • Pharmaceutical Companies
Professional Organizations (local and national)	• Ophthalmic Organizations • Diabetes Organizations • Retina Foundations
Government (local and national)	• U.S. State Boards of Medicine & Policy Makers • The National Institute of Health (NIH) • Centers for Medicare and Medicaid
Public Health Departments	• The Centers for Disease Control and Prevention (CDC)

Database Design & Information Flow

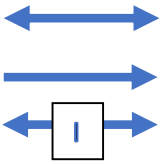
In accordance with HIPAA regulations identifiable information will only be shared with entities who obtain patient consent, and de-identified patient data will be shared across all stakeholders. Data will flow through the following mediums:

- Patient & Provider User Interface Access (Visual Interface) - This medium will be modeled after the Saving Sights Registries shown in Figure 6. This will allow patients and providers to see long-term progress in a user-friendly format. Access can be shared with multiple providers within a patients' care team, providing easy access to information, and enabling data sharing across healthcare providers.
- Open-access reports - This will allow quick access to national data without the need to submit formal data requests. This will enable data sharing without membership requirements and can be used by all stakeholders.
- Data set requests - This will allow customized reports to be requested for a nominal fee for specialized data requests.

The Information Flow Diagram below shows the high-level exchanges among health and non-healthcare entities. It is important to note that not all entities will provide uploads of data into the surveillance system, for example the Centers for Disease Control and Prevention (CDC) as they are not a healthcare provider. Medicare data is collected through claims data and will be shared with NES, although Medicare may not have a relationship with continual data exchange as with hospitals and eye clinics.



Key to Arrows



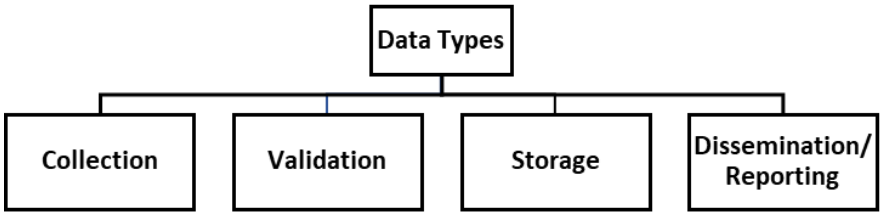
Data flows in both directions among these entities.

Data flows in one direction.

National Surveillance System shares Identifiable Visual Data with entity

Data Element Standards

The data standards for the newly developed NES system were developed during the evaluation of existing registries, medical and insurance claim systems. Figure 3 below shows the four categories for which each data type will be used.



In order to meet the needs of these four data functions across the various participants who will be adding information to NES, this information must be HL7 compliant and be standardized into one of the following formats or national classifications.

ICD 9 and or ICD 10 (International Classification of Diseases) - to capture Diagnosis Categories
CPT codes (Current Procedural Technology) - to capture Procedure Codes for Eye Exams, Patient Visits, Home Visits

System Requirements High-Level Technological Considerations

Platform Choice

The system recommendation for this project would center around a virtual private cloud-based data platform which has the scalability to accommodate the large system requirements of the NES system. By providing private cloud services, this will better ensure the security of patient data while also providing cloud-based continuous delivery. This will result in a shorter turn-around time on the return of usage data. Additionally, the platform will need the capability of integration with other providers such as Microsoft, Amazon Web Server and Linux, which will allow faster up-start for various data participants.

Maintenance and Security

The NES system would require the following components in order to house sensitive and private health information and to comply with HIPAA regulations. The following list includes six high-level considerations for data security of the NES system.

1. Create & Maintain Evidence Checklist (This allows auditors to validate compliance with regulations by keeping track of artifacts.)
2. Perform Regular Security Patch Installation & Recording of Patch Procedures
3. Create & Maintain Logging Checklists (This ensure monitoring of who is accessing data of the system.)
4. Create & Maintain Encryption Lists (This measure logs all system encryption measures that are employed.)
5. Establish at least two-factor authentication for system users.
6. Ensure release and compliance of version upgrades across users.

CHAPTER 4 – Discussion

The recommendation of the NES system for eye diseases in the U.S., designed to respond to the inadequacies of current data systems, aims to provide comprehensive eye disease data and address the continuous rise in eye disease and its complications.

In a recent data plan written by the National Opinion Research Center (NORC) at the University of Chicago, in conjunction with a cooperative agreement with the Centers for Disease Control and Prevention (CDC), they proposed the development of a national surveillance system (CDC-VEHSS, 2019). The objective of the proposal was limited to the establishment of eye disease prevalence rates.

The aim of the NES system is to provide a system which would establish eye disease prevalence, increase data availability among patients and providers, create interoperability among patient care teams, and enable increased long-term follow-up initiatives on a national level. This solution aims to improve patient outcomes and provides the healthcare community with greater access to national data which can be used in real-time in the treatment of their patients. The open access data framework will also enhance the efforts of those agencies, organizations and institutions who are working to eradicate eye disease complications through outreach, research, and education.

An area for future expansion of the proposed NES system would be to incorporate tools to better address disparate groups (Chow, 2012). Although there have been many advancements in care and treatment options, there have been many inequities found in studies of disease estimates and the resulting DR burden. For example, African-Americans are twice as likely as non-Hispanic Whites to die from diabetes and Latinos are 70% more likely to be diagnosed with diabetes compared to non-Latino Caucasians (ADA, 2019).

REFERENCES

American Optometric Association (2019). Diabetic Retinopathy. American Optometric Association, *EHR*, Retrieved from https://www.aao.org/iris-registry/ehr-systems

American Diabetes Association. (2019). *Advocacy priorities*, Retrieved from http://www.diabetes.org/advocacy/advocacy-priorities/

American Diabetes Association. (2017).*Health Disparities*, Retrieved from http://www.diabetes.org/advocacy/advocacy-priorities/health-disparities.html

American Optometric Association (2019). *Diabetic Retinopathy*. Retrieved from https://www.aoa.org/patients-and-public/eye-and-vision-problems/glossary-of-eye-and-vision-conditions/diabetic-retinopathy#1

Atherton, MD Jim. (2011). *Virtual Mentor*. American Medical Association Journal of Ethics, History of medicine: Development of the electronic health record. Volume 13, Number 3: 186-189

Boyd, Kierstan. American Academy of Ophthalmology (2019). *What Is Diabetic Retinopathy?* Retrieved from https://www.aao.org/eye-health/diseases/what-is-diabetic-retinopathy

Center for Innovation in Research (CIRT). (2019). Analyzing Qualitative Data. Retrieved from https://cirt.gcu.edu/research/developmentresources/research_ready/qualitative/analyzing_data

Centers for Disease Control and Prevention (CDC). (2019). *Diabetes Atlas*. Retrieved from https://gis.cdc.gov/grasp/diabetes/DiabetesAtlas.html#

Centers for Disease Control and Prevention (CDC). (2019) National Notifiable Diseases Surveillance System (NNDSS). Retrieved from https://wwwn.cdc.gov/nndss/

Centers for Disease Control and Prevention (CDC). (2019). *Vision and eye health surveillance system (EHSS): Project Description*. Retrieved from https://www.cdc.gov/visionhealth/vehss/project/index.html

Centers for Disease Control and Prevention (CDC). (2019). *Vision and eye health surveillance system (VEHSS): VSP Global*. Retrieved from https://www.cdc.gov/visionhealth/vehss/data/claims/vsp.html

Chow, E. A., Foster, H., Gonzalez, V., & McIver, L. (2012). The disparate impact of diabetes on racial/ethnic minority populations. 30(3), 130-133. doi:10.2337/diaclin.30.3.130 %J Clinical Diabetes

Fred Hollows Foundation. (2019). Diabetic Retinopathy, Retrieved from https://www.hollows.org/au/eye-health/diabetic-retinopathy

Flaxman, S. R., Bourne, R. R. A., Resnikoff, S., Ackland, P., Braithwaite, T., Cicinelli, M. V., Vision Loss Expert Group of the Global Burden of Disease, S. (2017). *Global causes of blindness and distance vision impairment 1990-2020: a systematic review and meta-analysis.* Lancet Glob Health, 5(12), e1221-e1234. doi:10.1016/S2214-109X(17)30393-5

Gillies MC, Walton R, Liong J, Arnold JJ, McAllister I, Morlet N, Hunyor A, Guymer R, Keeffe J, Essex R, Herrera-Bond A, Glastonbury B, Simpson JM, Barthelmes D. (2014). *Efficient capture of high quality data on outcomes of treatment for macular diseases: the fight: Retinal Blindness! Project.* Retina, 34(1): 188–195.

Goh, PP., H Elias, N NorFariza, I Mariam, on behalf of the National Eye Database Steering Committee. (2008) *National Eye Database – A Web Based Surveillance System.* Med J Malaysia, Volume:63, Supplement C: Sept pages: 20-23. Located at https://www.acrm.org.my/ned/documents/journals/MJM_63 C _20_23_National Eye Database E2...

ICHOM. (2019). *ICHOM Diabetes Standard Set Released On World Diabetes Day 2018.* Retrieved from https://www.ichom.org/news/ichom-diabetes-standard-set-released-on-world-diabetes-day-2018/

International Agency for the Prevention of Blindness (IAPB). (2016). What is avoidable blindness-Diabetic Retinopathy. Retrieved from https://www.iapb.org/knowledge/what-is-avoidable-blindness/diabetic-retinopathy/

Lee, R., Wong, T. Y., & Sabanayagam, C. (2015). *Epidemiology of diabetic retinopathy, diabetic macular edema and related vision loss.* Eye and vision (London, England), 2, 17. doi:10.1186/s40662-015-0026-2

Mayo Clinic. (2019) Diabetic Retinopathy. Retrieved from https://www.mayoclinic.org/diseases-conditions/diabetic-retinopathy/symptoms-causes/syc-20371611

Mues, K. E., Liede, A., Liu, J., Wetmore, J. B., Zaha, R., Bradbury, B. D., … Gilbertson, D. T. (2017). Use of the Medicare database in epidemiologic and health services research: a valuable source of real-world evidence on the older and disabled populations in the US. Clinical epidemiology, 9, 267–277. doi:10.2147/CLEP.S105613

National Academies of Sciences, Engineering, and Medicine. (2016). *Making eye health a population health imperative: Vision for tomorrow*. Washington, DC: The National Academies Press. doi: 10.17226/23471.

National Eye Database (NED). (2019). *About NED*. Retrieved from http://www.acrm.org.my/ned/about.html

National Eye Database (NED). (2019). *Downloads*. Retrieved from http://www.acrm.org.my/ned/download.html

National Eye Database (NED). (2019). *National Eye Database (NED).* Retrieved from http://www.acrm.org.my/ned/index.htm

Nguyen, V., Daien, V., Guymer, R. H., McAllister, I. L., Morlet, N., Barthelmes, D., & Gillies, M. C. (2018). Clinical and social characteristics associated with reduced visual acuity at presentation in Australian patients with neovascular age-related macular degeneration: a prospective study from a long-term observational data set. The Fight Retinal Blindness! Project. 46(3), 266-274. doi:10.1111/ceo.13038

O'Connor, P. J., Bodkin, N. L., Fradkin, J., Glasgow, R. E., Greenfield, S., Gregg, E., … Wysham, C. H. (2011). *Diabetes performance measures: current status and future directions*. Diabetes care, 34(7), 1651–1659. doi:10.2337/dc11-0735

Parke II, D. W., Lum, F., & Rich, W. L. J. D. O. (2017). *The IRIS® registry*. 114(1), 1-6. doi:10.1007/s00347-016-0265-1

Rawson, Sarah. Yourlifesolution.com. (2012). Who are the stakeholders in the healthcare industry? Retreived from http://yourlifesolution.com/howtosavemoney/who-are-the-stakeholders-in-the-healthcare-industry/

Rhodes, L. A., Huisingh, C. E., McGwin, G., Jr, Mennemeyer, S. T., Bregantini, M., Patel, N., … Owsley, C. (2016). Eye care quality and accessibility improvement in the community (EQUALITY): impact of an eye health education program on patient knowledge about glaucoma and attitudes about eye care. Patient related outcome measures, 7, 37–48. doi:10.2147/PROM.S98686

Saving Sight Institute. (2019). *Fighting Retinal Blindness*. http://www.savesightinstitute.org.au/research-units/save-sight-registries/fight-retinal-blindness/

Save Sight Registries. (2019). *Clinicians*. Retrieved from http://savesightregistries.org/clinicians/

Save Sight Registries. (2019). *Research Output*. Retrieved from http://savesightregistries.org/research-outputs

Singh MD, Rishi P. (2015) *IRIS springs into action*, Retinal Physician, Volume: 12, Issue: Jan / Feb page(s): 53-55, Retrieved from https://www.retinalphysician.com/issues/2015/jan-feb/iris-springs-into-action

Society of General Internal Medicine (SGIM). (2019). Medicare claims data. Retrieved from https://www.sgim.org/communities/research/dataset-compendium/medicare-claims-data#

Stakeholdermap.com. (2019). Source: examples of stakeholders in healthcare. Retrieved from https://www.stakeholdermap.com/examples-stakeholders-healthcare.html#health

United States Department of Health and Human Service (U.S. H.H.S.) Office of Minority Health. (2019) *Diabetes and African Americans*. Retrieved from https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=18

Ventura A.A.C.M., Dadgostar H., Taban M. (2014) *Diabetic Retinopathy*. In: Bandeira F., Gharib H., Golbert A., Griz L., Faria M. (eds) Endocrinology and Diabetes. Springer, New York, NY

World Health Organization (WHO). (2019). *Public health surveillance*. Retrieved from https://www.who.int/immunization/monitoring_surveillance/burden/vpd/en/

World Health Organization (WHO)- *What is a good surveillance plan*. (2019). Retrieved from https://www.who.int/tb/advisory_bodies/impact_measurement_taskforce/meetings/ie_oct09_surveillance_components.pdf

Zheng, Y., He, M., & Congdon, N. (2012). *The worldwide epidemic of diabetic retinopathy*. Indian Journal of Ophthalmology, *60*(5), 428-31. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3491270/