Primary Healthcare-based Diabetes Registry in Puducherry: Design and Methods

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Abstract

Background: Diabetes registries monitor the population prevalence and incidence of diabetes, monitor diabetes control program, provide information of quality of care to health service providers, and provide a sampling frame for interventional studies. This study documents the process of establishing a prospective diabetes registry in a primary health-care setting in Puducherry. Methods: This is a facility-based prospective registry conducted in six randomly selected urban health centers in Puducherry, with enrollment of all known patients with diabetes attending chronic disease clinics. Administrative approvals were obtained from Government Health Services. Manuals for training of medical officers, health-care workers, and case report forms were developed. Diabetes registry was prepared using Epi Info software. Results: In the first phase, demographic characteristics, risk factors, complications, coexisting chronic conditions, lifestyle and medical management, and clinical outcomes were recorded. Around 2177 patients with diabetes have been registered in six Primary Health Centres out of a total of 2948 participants seeking care from chronic disease clinic. Registration coverage ranges from 61% to 105% in these centers. Conclusion: This study has documented methodological details, and learning experiences gained while developing a diabetes registry at the primary health care level and the scope for upscaling to a Management Information System for Diabetes and a State-wide Registry. Improvement in patient care through needs assessment and quality assurance in service delivery is an important theme envisioned by this registry.

Keywords: Diabetes, methods, primary health centers, registry

Introduction

India leads the world with the largest number of patients with diabetes earning the dubious distinction of being termed the “diabetes capital of the world.” According to the Diabetes Atlas 2015 published by the International Diabetes Federation, the number of people with diabetes in India is currently around 69.2 million and is expected to rise to 123.5 million by 2040.[1] Although there are large regional variations in the prevalence of diabetes, it has more than quadrupled in the past 20 years from <1%–3% to 10%–15% in urban and 3%–5% in rural areas.[2]

Diabetes registries can be used as an important epidemiological tool: to monitor the prevalence and incidence of diabetes, provide a sampling frame for epidemiologic and clinical studies, provide information to health service providers and planners on risk factors and complications, and assist in the overall monitoring of diabetes control program.[3] Diabetes registries are used in many countries for population management of diabetes, outcomes management, and development of Clinician Decision Support System, for example, National Diabetes Register (NDR) in Sweden,[4] New York glycated hemoglobin (HbA1c) registry,[5] and Singapore diabetes registry.[6] Hospital-based diabetes registries have been established in developing countries such as Thailand[7] and Malaysia.[8]

In India, the first diabetes registry was set up in Goa as a public–private partnership, with the aim of population-based disease management.[9] It is essential for similar registry in all states to implement and monitor activities under the National Program.
for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases, and Stroke. To make the registry sustainable and replicable, it is necessary to implement it within the existing system of primary health care. A community-based cohort study showed the incidence of diabetes in rural Puducherry to be 21.5 for 1000 person-year follow-up. In this context, a pilot project was set up to establish a diabetes registry in the primary health care setting of Puducherry. Here, we share the design and implementation of the registry and propose a Management Information System for Diabetes Registry in Puducherry.

**METHODS**

**Study setting and participants**

Union Territory of Puducherry has one of the best health care delivery services in the country. Primary health care is delivered through a network of 27 primary health centers (12 urban and 15 rural) and 52 subcenters, besides 8 hospitals. Patients with diabetes registered in the chronic disease clinics run at PHCs receive free insulin injections and oral hypoglycemic drugs along with regular blood sugar monitoring.

This was a facility-based prospective registry study done at six randomly selected PHCs in urban Puducherry district. Patients with a diagnosis of diabetes mellitus (DM), enrolled in chronic disease clinics at the selected PHCs were the participants. All known patients with diabetes, both Type I and II, receiving treatment from primary health-care facilities were included in the registry.

The project was approved by the Institute Scientific Advisory Committee and Ethics Committee and registered with the Clinical Trials Registry of India (REF/2012/04/003467). Administrative approvals were obtained from Puducherry Government Health Services. Research assistant was recruited to assist in data collection, data management, and final compilation of the registry. Manuals for training of medical officers and health-care workers on data collection and details on diabetes, risk factors, complications, and lifestyle modifications were prepared and issued to all the PHCs.

The study was planned in two phases: development of diabetes registry and development of management information system for diabetes [Figure 1]. Case report forms (CRFs) were developed for collecting information required for the diabetes registry in terms of demographic characteristics, risk factors, complications, coexisting chronic conditions, lifestyle and medical management, and clinical outcomes – Phase I. The data elements captured in CRFs for the Registry are shown in Figure 2. The follow-up card for obtaining data for Registry maintenance was also prepared – Phase II.

The research assistant underwent intensive training on all aspects of the study – interview techniques, data recording, anthropometry, data entry, communication skills, organization of health systems, functioning of PHC, etc. Training of medical officers and health workers from the selected PHCs was done through a sensitization workshop, in coordination with the State Government Health services. The process of creating a diabetes registry and implications for patient care were discussed. Logistics were planned out, and roles and responsibilities were identified during the workshop. A pilot study was carried out in urban health center of a tertiary care institute. Around 350 patients with diabetes were registered. The CRFs were modified, and data entry format in Epi Info [Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia (USA)] was finalized.

**RESULTS**

**Development of diabetes registry - Phase I**

**Setting up the diabetes registration counter**

The registration counter was set up in an accessible area of the PHC. Banners intimating the process, timings, and requirements were put up, and notices were issued to patients with diabetes indicating the same. Registration was scheduled for 5 days a week on fixed timing, for a period of 1–2 months. Health workers facilitated the distribution of registration cards and created awareness and sufficient publicity for registration among the patients.

**Registration of patients with diabetes at this counter**

During the chronic diseases clinics, all patients with diabetes were approached and explained the purpose of this registry. Patients with a diagnosis of DM, enrolled in chronic disease clinics at these PHCs, were enlisted in the registry. Consent from the participants for use of clinical data was sought after they are explained about the registry and its purpose. A unique id number was created for each patient based on PHC code (3 digits), presence of comorbidity (DM or diabetic and hypertensive [DH]), and patient identification (3 digits).

| PHC code | DM or DH | 001 TO 999 patient id |
|----------|----------|-----------------------|

Details on their demographic characteristics, information on diabetes and coexisting chronic conditions, and clinical outcomes were recorded.

**Quality control measures**

Review of activities done at these PHCs was done on a periodic basis. Data collected from each center were reviewed every week for completeness and accuracy. Incomplete information

**Figure 1: Design of the diabetes registry project**
Data elements captured for the diabetes registry and source of data

| CATEGORY                  | DATA ELEMENTS | SOURCE           |
|---------------------------|---------------|------------------|
| Demographic elements      | Pt. ID, Name, sex, address, telephone number, economic status | Patient interview |
| Disease details           | Duration, co-morbid Illness | Patient interview |
| Risk factors              | Family history, Tobacco use, Alcohol use | Patient interview |
| Complications             | Retinopathy, Neuropathy, Nephropathy, CVDI, Foot status | Patient records  |
| Anthropometry and BP      | Weight, Height, BMI, Waist, circ, Hip circ | Physical examination |
| Laboratory investigations | Fasting, PP BS, Hba1c, Lipid Profile, Serum Creatinine, Urine Albumina, ECG | Patient records  |
| Treatment history         | Oral hypoglycemic agents, insulin regimen, others | Patient records  |
| Service utilization       | Outpatient visits | Diabetes registry |
| Patient compliance        | Compliance to physical activity, dietary modification and medication | Diabetes registry |
| Follow up details         | Glycemic control: Blood pressure | Diabetes registry |
| Foot care                 | Date and results of most recent foot examination | Diabetes registry |
| Investigations            | Date and results of retinal examination, and other biochemical tests | Diabetes registry |

**Figure 2**: Data elements captured for the diabetes registry and source of data

and incongruence of data detected were given as feedback during subsequent visits. The medical officer in charge also assisted in quality control by verifying a proportion of randomly chosen participants.

**Data entry and compilation of diabetes register**

All data collected were stored electronically on Epi Info version 7. Discussions were held with a few health workers and medical officers before finalizing the register. This was done to maintain brevity without compromising on data quality and utility of register at the clinics. Data in the compiled registry can be categorized as (1) demographics, (2) risk factors, (3) disease and treatment details, (4) glycemic control, and (5) microvascular end-organ disease data.

Around 2177 patients with diabetes have been registered in six PHCs, out of a total of 2948 participants. The registration coverage ranges from 61% to almost 105% in these centers. Six patients had Type 1 DM; 332 patients received insulin from the PHCs. On an average, the research assistant spent nearly 10–15 min per patient to review all the details in the patient notebook, conduct interview regarding risk factors and treatment-seeking behavior, and perform anthropometry. Time taken to complete the registration process at each PHC was variable and depended mainly on the number of clinic days and efficiency of the existing system (ranging from 6 to 12 weeks at each center); completion of registry took around 14 months.

**Development of management information system for diabetes management - Phase 2**

Second phase involves setting up a management information system based on monthly reporting of a number of patients with diabetes, glycemic control, referrals, and compliance to treatment from all these centers. This requires the use of register by the staff-in-charge of the clinics on a regular basis for monitoring patient care and follow-up. The proposed flow of information from the PHCs to the nodal office (in the Directorate of Public Health) would constitute the management information system for diabetes. Based on the registry compiled, patient level indicators in terms of a number of patients who achieved glycemic control, compliance to treatment, existing level of complications, proportion of patients screened for complications in the past year, etc., could be analyzed.

Based on monthly reporting of activities, process and outcome measures can be designed to monitor the services provided. The target for a process indicator for each patient would be availability of investigation reports during the stipulated interval (1 year). Process targets such as proportion of patients with HbA1c, low-density lipoprotein (LDL), microalbuminuria, or foot examination done in the past 1 year would be designed. Outcome targets could be set based on desired clinical outcomes, for example, proportion of patients with glycemic control, LDL <130 mg/dl, and blood pressure <130/80 mm Hg.

**Discussion**

Any delivery system seeking to manage their patients with diabetes using a disease management program that is internally integrated within their primary care delivery system must develop a registry for diabetes as an essential element of the program. While setting up a population-based register, we need to notify the public health authorities, publicize the registry, establish arrangements for access to data, data security, and accountability (in terms of reporting and feedback).

Efforts to achieve improved outcomes for diabetes require an organized population-based approach to diabetes management using all of the components of the chronic illness care model that identifies the six essential elements of a health-care system - the community, the health system, self-management support, delivery system design, decision support, and clinical information systems. The UK, Australia, New Zealand, and Canada have taken the lead in adopting models of chronic care.

Health information technologies such as electronic health records and registers can be considered as an input or building block of health systems. There is a great potential of these interventions in facilitating decision-making both at the individual and community level.

The Swedish NDR was initiated in 1996 with 41,000 patients as a tool for local quality control and benchmarking against the national treatment aims. One aim of the NDR was that all patients with diabetes in Sweden should ideally be reported yearly, based on registered annual data from actual patient visits in primary health care. Another aim was to provide local centers with data regarding the quality indicators of diabetes care, also making a comparison possible with the national or regional NDR data. NDR is probably among the largest NDRs in the
world, with repeated annual surveys. Nearly 40% of all patients with diabetes in Sweden in 2005 were registered in the NDR.\textsuperscript{[13]}

A web-based interactive GIS system, Saudi National Diabetes Registry, was designed to serve as an electronic medical file for patients with diabetes retrieving data from medical files by trained registrars. A total of 84,942 patients were registered from 2000 to 2012, growing by 10% annually.\textsuperscript{[14]} The Singapore diabetes registry was built to enhance the continuity of care for patients with diabetes and facilitate greater efficiency in outcome measurement. The chronic disease management system provides reports of clinical outcomes in a systematic and efficient manner for quality improvement and evidenced-based population management. These include process indicators consisting of the rates of HbA1c, LDL-cholesterol (LDL-c), and nephropathy tests, and intermediate outcome indicators of the proportion of patients with poor HbA1c (>9%) and optimal LDL-c (<2.6 mmol/L) control.\textsuperscript{[8]} The Malaysian diabetes registry was set up in 2008 with the objective of creating an accessible diabetes information system, open for health clinics and hospitals, and to provide data for public health action. It covers 22,055 patients with diabetes.\textsuperscript{[9]}

In India, the first diabetes registry was set up in Goa as a public–private partnership, with the aim of population-based disease management. A state-wide campaign over 4 years has screened and revealed about 44,000 patients with diabetes in the state.\textsuperscript{[10]} This registry would help the State health services in regular monitoring, identify people at risk of diabetic complications, and aid in reducing the gap between evidence-based recommendations and clinical outcomes. Similar innovative initiatives under the Changing Diabetes Barometer of Novo Nordisk Education Foundation have targeted states such as Bihar and Gujarat. A total of 12,140 subjects were screened at five primary health centers in Gujarat found 13.1% diabetic and 11.3% prediabetes population.\textsuperscript{[15]}

Diabetes registry involves collecting and sharing of quality data, analyzing for variations, identifying current practices, comparing with existing guidelines for care, giving feedback, and providing learning opportunities for the health systems. At the patient level, this registry can facilitate needs assessment for specialist services, recall facility for complications screening, and aid in reducing the gap between evidence-based recommendations for care and clinical outcomes. At the health systems level, this can facilitate integration with other services (such as ophthalmology and podiatry). The registry can be used as a tool for the assessment of quality of care through system inputs (number of clinic visits and investigations), process measures (eye screening and foot status), and clinical outcomes (glycemic control, micro and macrovascular complications). This can also provide useful information to health service providers and planners on risk factors and complications, and hence the data can be utilized for the planning of preventive services and better resource management [Figure 3]. This could help change behaviors, enhance the quality of care, increase the value of the resources spent, and thus contributing toward a virtuous improvement cycle.

**Conclusion**

This study has documented the methodological details, and the learning experiences gained while developing a diabetes registry at the primary health care level and the scope for upscaling to a Management Information System for Diabetes and a State-wide Registry.

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**Conflicts of interest**

There are no conflicts of interest.

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