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The 3C Study: Coverage cost and care of type 1 diabetes in China—Study design and implementation

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ABSTRACT

Aim: To describe coverage, cost and care of type 1 diabetes (T1D) in 2 regions of China – Beijing and Shantou – including:

Estimating the numbers of people with T1D diabetes.
Estimating the economic burden of T1D and financial barriers to care.
Identifying scale of necessary government investment to improve health care coverage.
Defining the burden of disease based on clinical outcomes.
Describing the education and care experience of people with T1D with comparison to selected clinical practice guidelines.
Describing the information processes associated with diabetes care and education.

Methods: This is a mixed-methods descriptive study with three arms – coverage, cost and care. It is taking place in 4 tertiary hospitals, 3 secondary hospitals and 4 primary health facilities in Beijing, and 2 tertiary hospitals, 2 secondary hospitals and 2 primary health centres in Shantou, China. Two additional hospitals are involved in the coverage arm of the study. T1D participants are recruited from a 3-year list generated by each hospital and from those attending the outpatient clinic or admitted to the inpatient ward. Participants also include health care professionals and government officials. To determine coverage of care, a list of people with T1D is being developed including information on diagnosis, age, sex and vital status. The age and sex distribution will be compared with the expected distribution.

To estimate the economic burden of T1D three groups of costs will be calculated – direct medical costs, direct non-medical costs and indirect costs from different perspectives of analysis (patients and their families, health system, insurer and societal perspective). The data are being collected from people with T1D (patient–parents face-to-face interviews), hospital billing departments, medical records and government officials using a combined ''top-down, bottom-up'' approach developed to validate the data. Quality of life is assessed using the EQ-5D tool and burden of disease is measured based on clinical outcomes and complications. Standard care will be defined, costed and compared to the cost of current care identified within the study to determine the investment required to improve outcomes.

The third arm includes three components – health policy, clinical care and education, and information management. Face-to-face, semi-structured interviews are conducted with people with T1D (for those <15 years of age parents are interviewed), health care

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professionals, senior hospital management and government officials. The core Summary of Diabetes Self-Care Activities Measure plus an additional 6 questions from the revised SDSCA scale are used to assess patient self-care. A medical records audit tool is used to assess care [7]. Clinical outcomes and self-care activities will be analysed for associations with care and education. Information management and care processes will be described using the Standard for Integration Definition for Function Modelling (IDEF0) [8].

Progress to date: At the time of writing (early October) the 3-year case list includes 1269 people with type 1 diabetes from Beijing and 481 people for Shantou, a total of 1750. In addition, two hundred and twenty people with T1D or their parents participated in face-to-face interviews in Beijing and 183 in Shantou, a total of 403.

Practical preliminary conclusions: Key implementation considerations were identified early in the project. Project success is dependent on strong local partnerships with local opinion leaders and key officials. It is important that a physician is the first point of contact to build the case list and recruit participants. July, August and January are peak months for recruiting school-age children in the Children's Hospital as this is school vacation period when they are more likely to attend clinics.

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1. Background

As the economy in China strengthens, the government and opinion leaders are increasing their focus on healthcare and creating opportunities for change. Data drives policy decisions and investment, however very little data exists on type 1 diabetes (T1D) in China. The incidence of T1D in children age 0–14 years is estimated at 0.5 per 100,000 [1]. Evidence suggests that approximately 41% are diagnosed after admission for symptoms of diabetic ketoacidosis [2], and access to insulin and specialized care varies based on medical insurance possession, income and place of residence. The direct and indirect costs of current care for people with T1D and the investment required to improve care is not known.

This article describes a collaboration between the International Diabetes Federation and the Chinese Diabetes Society designed to improve clinical outcomes for people with T1D.

2. Aim

To describe coverage, cost and care of T1D in 2 regions of China – Beijing and Shantou.

3. Study Design

The study will invite all patients with T1D to participate in the study up to a maximum of 1000 participants. Patients will be invited sequentially; there will be no random selection. The recruitment of study participants with T1D will be open to all who attend the selected facilities and no maximum limit will be set.

Although it is recognized that children spend a significant amount of time in school, this study will not examine how diabetes is managed in the school setting.

3.1. Coverage

Objective

To estimate the numbers of people with T1D.

Methods

Coverage of care for people with T1D and the consequences of gaps in coverage will be examined by comparing their age and sex distribution with those who do not have T1D. This will be done by establishing basic demographic details of people with T1D attending major health facilities in Beijing and Shantou and patients registered over the previous 3 years.

Existing medical records, either electronic or manual, have been used to create a simple spreadsheet at each facility with basic identifiers for each person. A questionnaire collects additional information on national ID, insurance ID, date of birth, year of diagnosis with T1D, county of birth, and current county of residence, and year of migration, if appropriate, to the study region. The date of birth, year of diagnosis and county of birth are used to create a unique ID which will be used to identify people who attend more than one health facility within the study.

Patients with T1D attending the health facilities during the study period are recorded in the register and invited to participate in the other parts of the study.

A large proportion of those who are registered with the tertiary health facilities and who are likely to attend the clinic at some time in the year were expected to do so in the months of July and August. Now that this period is over, efforts are being made to contact all T1D recorded in the hospital systems within the previous three years, using contact information in the medical records. Up to three attempts are made to determine the status of each person with T1D. Status is recorded as: alive (and current county of residence), deceased, unknown.

The list of patients with their current vital status will be used to create a population structure of people with T1D. Population modelling will be used to examine the total effect of differential mortality patterns and to see if there is a critical age at which mortality increases.

3.2. Cost

Objective

To determine the economic burden of T1D in China and the burden of disease based on clinical outcomes including:

1. Defining the economic burden of T1D in Beijing and Shantou and the financial barriers to access care.
2. Identifying the affordability and financial gap in assuring good quality standard care for people with T1D and to define the government investment required to improve outcomes for people with T1D.
3. Evaluating quality of life in people with T1D.
4. Assessing the disease burden of people with T1D using level of blood pressure, HbA1c, lipid profile and diabetes complications.

Methods

Three groups of costs will be identified (from the patients and their families, health system, insurer and broad societal perspectives):

1. Direct medical costs (hospital and ambulatory care, diagnostic tests, medicines, blood glucose monitoring).
2. Direct non-medical costs (such as costs of transportation for obtaining health care, costs of home care giving).
3. Indirect costs (value of lost production due to morbidity and mortality caused by T1D).

The measurement of the costs of T1D applies a combined ''bottom-up, top-down'' approach, developed to identify and validate data from all available sources. Data reported by patients or their parents (for those under the age of 15) during the face-to-face personal interviews is supplemented with information from hospital billing departments and audits of patients' medical records (''bottom-up'' approach). Data from Government officials and routine statistics on health services will also be used (''top-down'' approach).

The Government officials' interviews are intended to identify existing local policies for access to care, describe the insurance schemes in the study regions and identify their reimbursement and costs-containment rules.

Barriers to care for people with T1D. Financial barriers to standard care within existing reimbursement schemes will be elicited based on the interviews of people with T1D, hospital administrators and opinion leaders.

Financial gap between the costs of standard care and actual care for people with T1D. Standard care will be defined based on the T1D clinical practice guideline [3,4] and compared to the costs of existing practice of T1D care. The study is focussed on valuing costs of standard care for T1D people without diabetes complications. The magnitude of necessary government investment to secure improvements in health care coverage in order to achieve good quality standard care will be calculated.

Quality of life of people with T1D. It is agreed that enhancing quality of life (QOL) and well-being is as important as metabolic control and prevention of complications [5].

Quality of life of persons with T1D will be assessed by a standardised instrument, EQ-5D™. This provides a simple descriptive profile and a single index value for health status [6]. The study uses the EQ-5D 3 level version (EQ-5D-3L) of the tool – implemented in year 1990.[1]

The levels of QoL of people with well controlled T1D in the study will be compared with people with less well controlled diabetes.

3.3. *Diabetes care – health policy, clinical care and education, and information management*

The third arm, diabetes care, includes three components – health policy, clinical care and education, and information management.

Objective

To describe the education and care experience of a person with T1D and the information processes that support care including:

1. Describing the health policies influencing care for T1D.
2. Describing the education and care experience of people with T1D and analysing associations with clinical outcomes.
3. Comparing actual care to clinical recommendations as described in clinical practice guidelines and standards of practice.
4. Modelling the clinico-administrative processes.
5. Describing the perceptions of opinion leaders on the feasibility of a national diabetes registry.

Methods

Health policy. Supporting health policy is the first component of the third arm. Data is being collected on health policy using structured interviews of government officials and senior hospital administrators to identify policies relevant to diabetes care, the influence of policies on care and the priority given to T1D on government and hospital agendas.

Clinical care and education. Clinical care and education are interdependent and together they form the second component of the third arm. Data is being gathered from three levels of the health delivery system – primary, secondary and tertiary – using structured interviews and a medical record audit tool. People with T1D and/or their parents if they are under 15 years of age, physicians, nurses, dietitians, and department directors respond to a structured interview conducted by a specially trained investigator. The interviews and medical record audits are used to identify and/or describe the method of diagnosis, education received, prevention of complications, incidence of acute complications, clinical outcomes, glycaemic control, medications, psychosocial support, role of health professionals and access to care. Blood is drawn to determine A1c and lipid profile if lab values are unavailable or dated more than 3 months from date of interview. The self-care activities of people with T1D are measured using the 11 core items of the Self-Care Activities Measure plus 9 additional items from the revised SDSCA scale [7].

[1] The permission for use of paper version of the instrument (both English and Chinese version) without restriction has been obtained from the EuroQol Group Executive Office (Marten Meesweg 107, 3068 AV Rotterdam, The Netherlands. Tel.: +31 884400190).

The Chinese Diabetes Society selected the ISPAD Guidelines and the ADA Guidelines as a locally recognized benchmark for care. These clinical practice guidelines along with the IDF Standards for Diabetes Education were used to develop the questionnaires and the medical record audit and will be the benchmark for care and education in the analysis phase of the project. The data collected will be analysed to describe the care and education provided, compare it to selected guidelines for practice, and identify associations between clinical outcomes and self-care; and clinical care and education.

The organization of care is assessed with a 17-item questionnaire on services provided at each level of the system. Directors of Endocrinology or Internal Medicine in tertiary and secondary facilities and the lead physician in primary care centres complete the questionnaire. Their responses will be used to describe services provided and the perception of services provided at primary, secondary and tertiary levels of care.

Information management. Information management, the third component, is sub-divided into two sections. One explores the aim and feasibility of a diabetes registry and the other describes patient information management in a hospital outpatient setting. The diabetes registry is recognized by local opinion leaders as an essential source of data to improve care for people with diabetes. Government officials and hospital senior managers are asked one question on the desired aim of a diabetes registry and five questions on the feasibility of implementing a national registry in one to two years including perceived barriers and enablers of success. Qualitative analysis will be used to determine the common aim and to identify potential barriers and enablers to support planning for a diabetes registry.

Health care professionals, people with T1D, staff from the records department and staff from the finance department are given unstructured interviews to describe the clinico-administrative processes of the T1D outpatient clinic. This data will be used to develop a model of care and information using the Standard for Integration Definition for Function Modelling (IDEF0) [8]. Patient information management in the outpatient clinic of two tertiary hospitals are used as an indicator of the clinic-administrative processes in other sites.

Health policy, clinical care and education and information management make up the three components of the third arm, diabetes care. The approach is based on current guidelines for T1D and the evidence which supports an interdisciplinary, multisystem approach to diabetes care.

4. Progress to date of article submission

The 3-year case list includes 1269 people with T1D from Beijing and 481 people for Shantou, a total of 1750. Two hundred and twenty people with T1D or their parents have at the time of writing participated in face-to-face interviews in Beijing and 183 in Shantou, a total of 403.

5. Practical preliminary conclusions

Key implementation considerations were identified early in the project. Project success is dependent on strong local partnerships with local opinion leaders and officials. It is important that a physician is the first point of contact to build the case list and recruit participants. July, August and January are peak months for recruiting school-age children in the Children's Hospital as this is school vacation period when children traditionally visit specialist clinics in large numbers.

6. International Diabetes Federation and the Chinese Diabetes Society

The International Diabetes Federation (IDF) has over 220 member associations representing over 160 countries and territories. The Chinese Diabetes Society is an active member of IDF. The 3C Study is a strong example of how close collaboration between the two organizations can achieve significant advancements for people with diabetes.

Conflict of Interest

One of the four authors declares a conflict of interest. Linong Ji has received lecture and consulting fees from Sanofi.

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