Key Case

Tuberculosis: An Inter-sectoral Disease-Management Approach

By Jeff Edelson, Jean Wilson, et al.

The Canadian healthcare system is continually forced to balance its legislated traditions of universal access, transportability, public funding and administration with contemporary demands for fiscal solvency, dramatic (and sometimes costly) therapeutic advances, efficient and integrated function, and significant changes in the population served.

Disease management (DM) programs have been embraced by US healthcare providers, health systems, institutions and the pharmaceutical industry. An outgrowth of increasing trends towards managed care, DM programs target groups of individuals with similar health needs. The basic principle of DM is to approach the health problems of such a defined population at a system level, aligning the system's resources with the population's health needs. Ideally this approach optimizes the flows of patients, providers, health information and financial resources. Although few programs have been rigorously evaluated, DM initiatives promise to deliver improvements in (disease-specific) healthcare quality and reduced costs of care.

On a worldwide basis, tuberculosis is the most common serious, infectious disease. Despite the availability of excellent powerful anti-tuberculous chemotherapy, and well-developed guidelines for their use, tuberculosis care in Canada remains suboptimal, characterized by a resurgence of disease and the emergence of organisms resistant to multiple drugs. Since many of the areas for improvement of tuberculosis care reside at the level of the care delivery process within the organizations that care for tuberculosis patients, and of the linkages between these organizations, it seems appropriate to explore the concept of a disease-management program for the treatment of tuberculosis.

> **"The difficulty lies not in the new ideas but in escaping from the old ones."**
>
> Lord Keynes

TB 1998: Burden of Illness

Once considered a disease of the past, tuberculosis has resurfaced as one of the most challenging communicable diseases of this decade. The World Health Organization (WHO) identified a 20 percent increase in the global notification rates for tuberculosis (Raviglione et al. 1995) between 1984 and 1991, and has declared tuberculosis a global health emergency (WHO 1993). There are at present some 8 million new cases and three million deaths per year worldwide, with projected increases to 12 million cases and over 4 million deaths by the year 2005 (Dolin et al. 1994; CDC 1993b:961–4) The largest mortality and morbidity burden occurs in developing countries such as Africa and Asia, while developed countries have experienced significantly lower rates thanks to improved sanitation, living conditions and public health programs (Kochi 1994; WHO 1995).

The Canadian experience has been characterized by steady decreases in tuberculosis rates between 1953 and 1985, although rates appear to have stabilized over the last decade (Rieder et al. 1989; Health Canada 1992; Statistics Canada 1992). By contrast, tuberculosis rates In the United States increased by 20 percent between 1985 and 1992 (CDC 1993: 696 – 704). Factors contributing to the resurgence of tuberculosis in North America include the parallel epidemic of HIV and changes in immigration patterns. Immigrants appear to maintain rates of infection and development of disease similar to those in their countries of origin. In addition, immigration appears per se to represent an additional TB risk factor. In Ontario 80 percent of new cases of active pulmonary tuberculosis arise in individuals who acquired their infection in their country of origin (Brudney and Dobkin 1991; Kerbel 1997).

Despite the availability of excellent and improving diagnos-

tic techniques, effective chemotherapy programs that are capable of curing the disease in over 95 percent of patients treated and, in many provinces, provision of medication and clinical services at no cost to the patient, current therapy for tuberculosis remains suboptimal. Non-completion rates in urban clinics are on the order of 30 percent, and rates of drug-resistant disease (itself an index of poor care) are increasing (Statistics Canada 1998; Naus 1997; Chaulk et al. 1998).

In Toronto, the traditional service-delivery system for tuberculosis is both fragmented and episodic. Individuals with tuberculosis have distinct and complex health needs. Tuberculosis frequently occurs in the context of poor nutrition, inadequate housing, recent immigration and poor access to traditional sources of healthcare. Such individuals may require complex multilevel care from a broad range of professionals and agencies. Unfortunately, it is unusual for such organizations to coordinate their delivery of services. These "disconnects" result in suboptimal outcomes for both clients and organizations.

The traditional roles of the public-health and acute-care sectors illustrate these issues. In the City of Toronto, the public health department is mandated to provide prevention and control programs for tuberculosis, while clinical care is provided by an amalgam of independent practitioners, hospitals, clinics and long-term-care facilities. Although each constituency shares the goal of providing excellent care to individuals with tuberculosis, there is no fundamental agreement about how to achieve this end. In addition, there is no continuity in treatment aims, healthcare outcomes, budgetary priorities, disease surveillance, data collection or dissemination of information. Movement of patients between sites of care within this "non-network" is not accompanied by similar movement of resources or of information. Within individual programs, variation from standard guidelines (such as Canadian Tuberculosis Standards of Care) fuels this ad hoc and inconsistent approach to care delivery. Such an environment seems ideal for development of a disease-management approach to tuberculosis.

What is Disease Management?

Disease management encompasses a set of interlinked interventions, the purpose of which is to align the health needs of a population with the resources of a delivery system. The population served by a DM program is defined administratively as individuals with a given disease or health state who are usually receiving services from a defined healthcare system. A key element of a DM program is the effort to systematically evaluate and address the health needs of an aggregate of patients across a delivery system. By addressing the processes of healthcare on a longitudinal basis, DM permits "holistic" approaches to dealing with diseases that cross a continuum of acuity of care (e.g. ,primary, secondary and tertiary) or other intersectoral boundaries (e.g., acute care to chronic care) (Hunter and Fairfield 1997). Key components of successful DM programs include clinical-practice guidelines, which lead development of a model of care delivery. Clinical information systems that identify, stratify and facilitate care of individuals with a given disease state, and development of information and learning tools for both patients and provider program participants are also key components (Epstein and Sherwood 1996).

Disease-management approaches generally target conditions that are either common and or expensive to treat. A first requisite for a DM program is agreement regarding what represents optimal care of the condition. This may take the form of clinical-practice guidelines, consensus statements or a shared vision of best practices. In addition, there should be objective evidence that providing optimal care improves clinical, health-status and organizational outcomes and ideally reduces the total costs of care (Chaulk and Spies-Pope 1997).

Interest in DM programs in the Canadian public sector is attenuated by the lack of availability of the significant resources required for program development and lack of professional and organizational familiarity with such enterprises. The minimum degree of integration of the healthcare-delivery system that is required to develop DM initiatives is not clear. Additional challenges are posed by the high degree of dynamism in the present Canadian public-sector environment, the relatively primitive state of clinical-information systems, the dominance of fee-for-service professional compensation, and the lack of true operational linkages between horizontal and vertical elements in the evolving healthcare system. Even in regions characterized by high degrees of managed care, it is perhaps surprising that DM programs are relatively uncommon in the public sector.

DM for Tuberculosis?

One might argue that tuberculosis is an ideal condition for disease-management efforts because of its public-health importance, the existence of effective treatment interventions, substantial room for improvement in current care delivery, the knowledge that good treatment is more effective than ineffective treatment, and the exceedingly high costs of treatment failure. TB is a disease in which the relationship between suboptimal care, poor outcome and increased costs is direct and significant. The costs of managing cases where initial treatment has failed, with resultant refractory disease and drug-resistant organisms, is staggering (Iserman et al. 1993). Tuberculosis is also characterized by the availability of clinical-practice guidelines of reasonable quality, and a public-health mandate and enabling legislation (in some provinces) supporting TB control programs. Information systems in the public-health arena may be more advanced than those in the acute-care sector. In addition, tuberculosis providers and practitioners may be more willing to explore alternative models of care delivery.

Clinical Practice Guidelines

Clinical-practice guidelines (CPGs) have been available for the treatment of tuberculosis for almost two decades (American

Thoracic Society 1980, 1994; Canada Health and Welfare 1993). These guidelines fulfil many of the characteristics of well-constructed guidelines, such as validity, clinical applicability, flexibility and clarity (Heffner et al. 1997). The process by which guidelines are developed is important in their application, and should be explicitly described.

It is important to recognize that the development of CPGs appears to be a necessary but not sufficient step, since guidelines alone appear to be relatively ineffective in influencing provider behaviours (Arik et al. 1998; RamphalNaley 1996). It has been emphasized that the guidelines be used as neither a floor nor a ceiling for treatment decisions. Ideally, they represent a point of reference for individualized decision-making, not a series of rigid rules for blanket application (Eddy 1990).

Information Systems

A second key enabler for disease-management programs is the availability of information systems that allow identification and stratification of individuals with a given disease state. In the context of Canadian tuberculosis programs, this task is facilitated somewhat by public-health legislation that mandates the reporting and notifying of individuals with tuberculosis. Although present public-health information systems are largely oriented towards archival-type epidemiologic reporting rather than real-time clinical management, present-day disease-specific databases provide an ideal platform for development of the next generation of systems that will support clinical management in real time. The City of Toronto Public Health Department developed a case-management tool that both provides central data gathering for epidemiological purposes and offers on-line assistance for fieldworkers in support of direct patient-management activities. Maintaining the connectivity of various information systems between sites and sectors of care remains a significant operational challenge.

Models of Care Delivery

Several features of the public-health environment may facilitate evolution of new care-delivery models for the treatment of tuberculosis. First, many providers in the public-health sector are compensated by means of sessional or salaried mechanisms, removing the fee-for-service pressures, which in some circumstances appear to favour fragmentation of care. Second, providers working in tuberculosis control programs frequently have experience and enthusiasm for working as members of multidisciplinary clinical teams. Directly observed therapy (DOT), for the supervised administration of anti-tuberculous medications, and nursing case management have both emerged as effective tools with demonstrated utility in tuberculosis control programs (Chaulk and Spies-Pope 1997). Finally, the public-health orientation of many TB control programs encourages a big-picture approach to clinical issues, with attention to population health outcomes as a reflection of current clinical practices. Thus, individual providers and participating organizations may enter into intersectoral program development with a more flexible mindset, organizational experience with alternative delivery models and enthusiasm for working in a cross-functional environment.

An Inter-sectoral Disease-Management Approach for Tuberculosis in Toronto

Recognizing the opportunities for improvements in the care of individual's with tuberculosis in the City of Toronto, St. Michael's Hospital, the City of Toronto Public Health Department, West Park Hospital and Street Health began developing an intersectoral approach to tuberculosis disease management. The development effort received two years of initial funding from the Change Foundation in November 1997.

Intersectoral partners

The participating organizations represent the spectrum of care for individuals with tuberculosis. St. Michael's Hospital, a large teaching hospital in Toronto's inner core provides acute in-patient and ambulatory tuberculosis services. These include a weekly hospital-based tuberculosis clinic staffed by a multidisciplinary group of healthcare professionals who have a strong knowledge base in assessment, diagnosis, treatment and follow-up of tuberculosis. St. Michael's Hospital is well known for its commitment to care of vulnerable patients in the inner city. West Park Hospital provides long-term specialized care for patients with active pulmonary tuberculosis. In addition, a tuberculosis clinic offers consultative and follow-up services. The staff at this facility are renowned for their knowledge and care of complex cases such as multi-drug-resistant tuberculosis and HIV co-infection. The City of Toronto Public Health Department is responsible for epidemiological and public-health activities as defined by the Public Health Act. In addition to ensuring that all cases of active tuberculosis have access to appropriate clinical care, the department is also responsible for prevention and control measures. The Direct Observed Therapy program provides nursing support to selected tuberculosis patients in order to ensure completion of therapy. Street Health is a grass-roots organization that provides community-based healthcare services. Established in 1986, the organization provides physical-and mental-health services, education, advocacy and support services to the homeless, poor and socially marginalized populations. The staff conduct daily walk-in clinics, that service a growing number of homeless individuals in the downtown core. The organization has also been an effective social advocate on behalf of its clients.

Program Description

The basic strategy of this project is to develop and evaluate an

intersectoral disease-management program for individuals with tuberculosis in the City of Toronto. The project's primary analytical approach is a pre/post comparison of changes in clinical, health-status, economic and organizational outcomes between current (status quo) therapy and the new DM model. A second level of analysis will be to examine whether specific patient characteristics are associated with specific outcomes.

After defining the outcomes to be measured and the evaluative tools that will be used, and as a prelude to rational program design, the team began a series of stakeholder and key-informant interviews (see below). The program-design phase of the project began in the spring of 1998, with implementation anticipated in early 1999.

The aspiration of the DM program is to improve clinical, economic and organizational outcomes through the development of a common disease registry, standardized clinical-practice guidelines, a longitudinal care-delivery model, with enhanced provider and patient education. The initiative's success depends on an intersectoral, interagency collaboration for program design, development and implementation.

Team Composition

The investigative team includes scientists with expertise in clinical respirology, health-services research, health economics, public health, epidemiology, nursing and care process design, and health-outcomes measurement. A research coordinator, with expertise in nursing practice models and epidemiology was recruited to facilitate program development, design and implementation. The operational team includes clinicians and managers from the sponsoring organizations who have interest and involvement in the project as it evolves. Two postgraduate health-sciences students have participated in and contributed to the project as part of their educational experiences.

Stakeholder Consultation

Stakeholder focus groups began in the winter of 1997. The purpose of these groups was to obtain information and suggestions surrounding the challenges presented by the traditional tuberculosis care-delivery system. This information would subsequently inform a more effective and efficient disease-management program design. Separate focus groups were held for both providers and tuberculosis patients.

The multidisciplinary provider focus group was well attended (nine participants) and rendered a detailed and helpful needs assessment. The focus group identified several challenges, including the need for more efficient dissemination of tuberculosis information and educational material to providers and patients, the need to utilize healthcare personnel more efficiently in the hospital, public health and community sectors, the need to standardize and coordinate clinical guidelines and care-delivery processes, the need to improve follow-up and movement of patients between sites of care, and the need to improve several internal organizational-process gaps. This focus group also provided specific operational suggestions that will be incorporated into program design. The participants agreed to serve on an advisory panel to provide feedback on program design and operation as it evolves.

The patient focus group was not well attended. It was surmised that the group format and hospital venue may have been negative factors in this outcome. However, the group also felt that in order to design a highly patient-centred disease-management program, it was important to persist in pursuing the "patient's voice." A more personal interviewing approach, using a brief, structured interview technique, conducted in a venue comfortable for the patient, will be conducted in 15 to 20 individual interviews.

Outcome Measures

The group has identified clinical, health-status, economic and organizational outcomes that will be measured during the implementation of the new DM care delivery model. Clinical outcomes will include traditional clinical outcomes, functional status and a number of process-of-care variables operationalized from TB care guidelines. In addition, laboratory indicators such as microbiological conformation of diagnosis and cure, incidence of relapse and rates of multi-drug resistance will be monitored. Process-of-care outcomes such as patient and provider adherence to the standardized clinical guidelines and patient completion of drug therapy will be measured. Retrospective data is available from chart reviews and a database template previously developed in the TB clinic at St. Michael's Hospital. Disease-specific health status and quality of life will be measured prospectively using validated instruments. It is acknowledged that retrospective data for health status will not be available. Organizational outcomes will include indicators for healthcare-service utilization. Finally, economic outcomes evaluation will focus on the direct and indirect costs of disease as well as potential costs of treatment failure. Both a societal and provider perspective will be used for analysis. A multiple-regression model will be used to determine whether Tuberculosis Disease Management strategy is a cost-effective approach as compared to the present (traditional) delivery system.

Dissemination

The collaborative team has a strong commitment to sharing their experience with this innovative DM approach to tuberculosis care delivery and disease control. It is hoped that in doing so through peer-review journals, invited presentations and conferences, other tuberculosis programs will find the DM program design useful in their settings.

Challenges

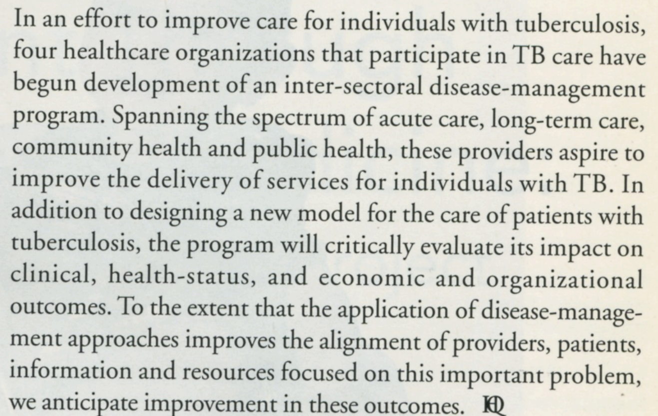
Since its inception the team has recognized several challenges to program development and design. These include a substantial dynamism among the participating research team and

institutions, predictable difficulty in maintaining communication and coordination between participants, and some specific challenges relating to information systems.

Although not unanticipated, two of the project participants have begun overarching changes in their organizational structure. The City of Toronto Public Health Department has been amalgamated into the "Mega" City restructuring effort. This has resulted in short-term changes to organizational structure and personnel. The ultimate impact of these changes on budget, focus and mandate are not clear. It is anticipated that tuberculosis-control efforts will remain a priority program of the restructured department. In addition, at the direction of Ontario's Health Services Restructuring Commission, St. Michael's Hospital has begun a corporate and physical merger with the Wellesley Central Hospital. Although the commitment of the organization, staff and physicians to its Inner City Health Program and the tuberculosis program remain strong, the merger has resulted in staffing, budget and facility changes that may impact the program's development and operation. Two of the investigators have had career changes that may also affect the composition and function of the research team. Although the present environment may be characterized as turbulent, this diminishes neither the rationale nor timeliness for developing the tuberculosis DM program.

A project of this scope requires an excellent health-information system for its successful operation. Although several systems are in place at participating organizations, they are limited by connectivity, data security and confidentiality issues. The team has identified development of a project database, using the architecture of an existing case-management tool, as a strategy for short-term development.

Conclusion



In an effort to improve care for individuals with tuberculosis, four healthcare organizations that participate in TB care have begun development of an inter-sectoral disease-management program. Spanning the spectrum of acute care, long-term care, community health and public health, these providers aspire to improve the delivery of services for individuals with TB. In addition to designing a new model for the care of patients with tuberculosis, the program will critically evaluate its impact on clinical, health-status, and economic and organizational outcomes. To the extent that the application of disease-management approaches improves the alignment of providers, patients, information and resources focused on this important problem, we anticipate improvement in these outcomes. HQ

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