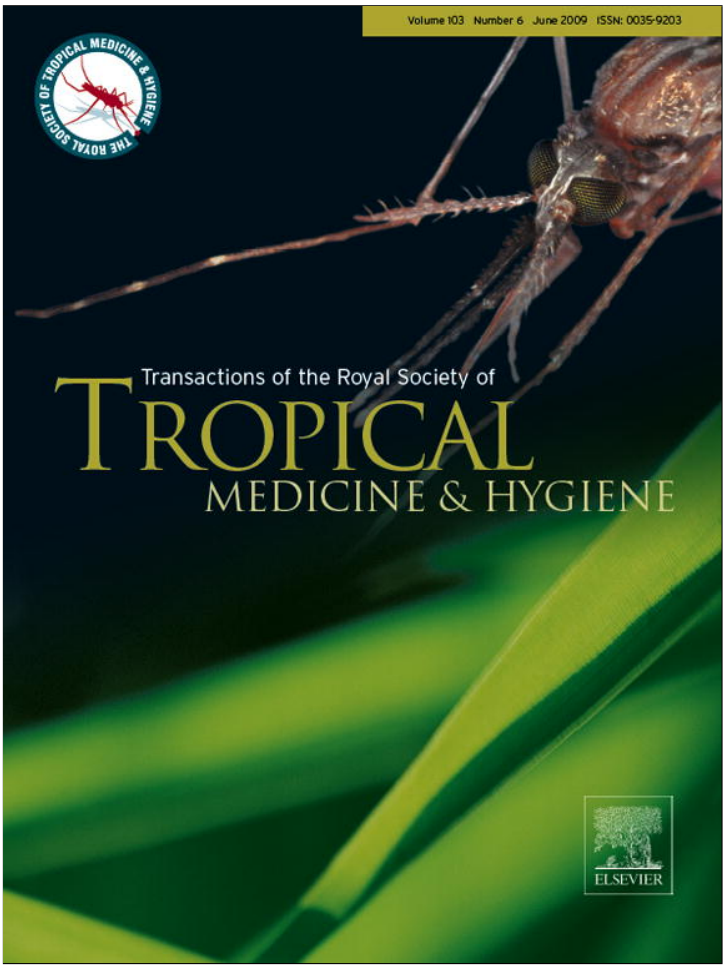

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REVIEW

The vital signs of chronic disease management

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Summary The vital signs of pulse rate, blood pressure, temperature and respiratory rate are the 'nub' of individual patient management. At the programmatic level, vital signs could also be used to monitor the burden and treatment outcome of chronic disease. Case detection and treatment outcome constitute the vital signs of tuberculosis control within the WHO's 'DOTS' framework, and similar vital signs could be adapted and used for management of chronic diseases. The numbers of new patients started on therapy in each month or quarter (new incident cases) are sensitive indicators for programme performance and access to services. Using similar reporting cycles, treatment outcomes for all patients can be assessed, the vital signs being: alive and retained on therapy at the respective facility; died; stopped therapy; lost to follow-up; and transferred out to another facility. Retention on treatment constitutes the prevalent number of cases, the burden of disease, and this provides important strategic information for rational drug forecasting and logistic planning. If case numbers and outcomes of chronic diseases were measured reliably and consistently as part of an integrated programmatic approach, this would strengthen the ability of resource-poor countries to monitor and assess their response to these growing epidemics.

1. Vital signs in clinical medicine

As every clinician and nurse knows, the measurement, recording and reporting of clinical vital signs is an integral part of individual patient management. These vital signs are pulse rate, blood pressure, temperature and respiratory rate. Healthy adults have a similar range of baseline vital

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signs that allows for individual variation. These signs change in illness and, to the experienced health worker, provide an immediate sense of underlying pathology. For example, a high fever, fast pulse rate and low blood pressure indicate possible septic shock, whilst a slow pulse rate and high blood pressure indicate possible raised intracranial pressure. Once a diagnosis is made and treatment instituted, the vital signs are monitored on patient treatment cards and regularly entered into progress charts and patient case files. Provided they are correctly measured and adequately recorded, they serve as a crucial tool to determine response to therapy.

In well resourced countries, monitoring of vital signs may be supplemented with more sophisticated monitoring of central venous pressure, pulmonary wedge pressure and so on, but in any setting the basic vital signs remain the 'nub' of clinical management.

2. Programmatic management of chronic disease in resource-poor settings

The prevalence and incidence of non-communicable diseases such as hypertension, diabetes mellitus, cardiovascular disease, obstructive airways disease and asthma grow inexorably each year and increasingly affect patients and communities in resource-poor settings.[1] For example, in 2007 diabetes mellitus was estimated to affect 246 million people globally, with 6 million new cases and 3.5 million deaths: 70% of this burden was in developing countries, particularly in Southeast Asia and the Western Pacific.[2] Similar numbers pertain to asthma: 300 million patients estimated to be living with the disease and 250 000 deaths annually, with the majority in developing countries.[3] These patients usually need chronic, life-time care and treatment, but in most resource-poor countries, outside of a few centres of excellence, this is simply not provided and there are no systems to monitor patient numbers or outcomes.

3. Vital signs of chronic disease management

Based on pioneering work by the International Union against Tuberculosis and Lung Disease, the 'DOTS' framework for tuberculosis (TB) control was developed by the WHO to expand, deliver and monitor TB treatment to millions of patients throughout the world.[4] Case detection and treatment outcome constitute the vital signs of TB control within this framework. Since the initiation of DOTS programmes in 1995, remarkable progress has been made and, through a simple recording and reporting system on case numbers and treatment outcomes, progress towards meeting case detection and treatment success targets have been monitored annually at national and global levels.[5]

In a previous publication, we have described how the DOTS paradigm could be adapted for the management of non-communicable diseases, focusing on political commitment, case finding, standardised treatment, standardised monitoring, evaluation and drug quantification.[6] We have also explained how this model could be implemented and scaled up in a phased approach at the country level. Since then, we have further developed our thoughts on the monitoring component of this model. In this current paper, we put forward what we believe are the vital signs of chronic infectious and non-infectious disease management and explain in detail the rationale and interpretation of these signs. The vital signs comprise case numbers and treatment outcomes, which, if measured reliably and consistently in all patients and as an integral part of a programmatic approach, would enormously strengthen the ability of resource-poor countries to monitor and assess their response to the growing epidemics of chronic diseases.

The number of registered cases can be subdivided into the number of new patients started on therapy in each quarter of a year (new incident cases) and the cumulative number ever started on therapy. The number of new registrations is one of the 'vital signs' and is a sensitive indicator for programme performance. If estimates for disease incidence are available, the number of new registrations can be used to monitor access to services. Using the same quarterly reporting cycle, treatment outcomes for all patients ever registered can be assessed, with the vital signs being: alive and retained on therapy at the respective facility; died; stopped therapy; lost to follow-up; and formally transferred out to another facility. Those alive and on treatment can be subdivided, according to type of disease, into those who have improved, remained stable or become worse: such a system has been used for patients with asthma.[7] For the ascertainment of retention in care, chronologically completed treatment cards or electronic patient data systems are needed that are updated at every follow-up visit. To interpret the vital signs correctly, treatment outcomes must be clearly defined and applied consistently.

Death may be ascertained proactively by a relative or friend providing information to the personnel at the clinic, or it may be discovered by the clinic team as part of active tracing of patients who failed to attend their appointment. Similarly, patients who have stopped therapy may inform the clinic, but it is more likely that this information will be discovered through active tracing. Thus, the definition of lost to follow-up and the management of these patients becomes a crucial programmatic activity. In antiretroviral therapy (ART) clinics in Malawi, defaulters are classified as patients failing to attend the clinic for $\geq$3 months.[8] In an operational research study to determine the true outcomes of these patients, 50% had died, 15% had stopped therapy and 8% had transferred to another clinic and failed to inform their original clinic of this move.[8] An outcome of lost to follow-up can thus change as accurate information becomes available about the true status of the patient. Similarly, an outcome of stopped treatment can change if the patient is persuaded to return to therapy.

4. Interpretation of vital signs

The adverse outcomes of death, lost to follow-up and stopped treatment are a gauge for clinic and programme performance as they indicate 'attrition' from care. High death rates show poor effectiveness of therapy and can be related to limitations of access and to late presentation for diagnosis and treatment. High rates of loss to follow-up indicate low levels of active tracing by the clinic. High numbers of patients stopping therapy indicate insufficient patient education about the disease, the necessity of continued treatment or side effects.

Patients transfer out from one clinic to another for personal, family and occupational reasons. There is little documented data on what happens to patients who transfer out in chronic care situations, although in Malawi the majority of patients on ART who formally transferred out in fact transferred in to another facility.[9] Transfer out is not an adverse outcome but, if not taken into account, can lead to double counting of patients at the national level.

The number of patients alive and on treatment is a vital piece of strategic information. This is the prevalent number of cases and the current burden of disease. If measured regularly and accurately this information is important in its own right, but it also provides the necessary data for rational drug forecasting and planning of logistics and staffing.

5. Supplementing the vital signs

Depending on the human resource base and the sophistication of the clinic, other indicators or signs can be added that may be help to understand better the case burden, gauge the response to treatment and work out drug and commodity supplies. Stratification by males and females and by age allows more in-depth epidemiological assessment of case burden and more precise forecasting of quantities of adult and paediatric drug formulations. Knowledge of types of medication for new incident and prevalent cases, for example oral hypoglycaemic drugs and short-, medium- and long-acting insulin preparations for patients with diabetes mellitus, provide a firm platform for rational forecasting and procurement, two activities that should prevent the frequent stock interruptions that plague the developing world. In patients with diabetes mellitus, regular recording of blood glucose or glycosylated haemoglobin concentrations would provide an objective measure of diabetes control quality, and regular recording of eye, vascular, neurological and renal complications would provide a measure of morbidity. Regular reviews of structured patient treatment cards also allow objective judgements about how well health workers adhere to standard case management practices, including complete diagnostic evaluation, correct classification and appropriate therapy.

6. Recording and reporting on vital signs

As with vital sign recording in individual patients, the date of an adverse outcome or a transfer-out needs to be recorded on the treatment card and patient register. The treatment card and the register are the two important tools for monitoring vital signs of chronic diseases, and how these might look and function at the clinic level have already been described.[6] Treatment cards provide the complete chronological follow-up history for each patient, whilst registers provide an up-to-date summary at any moment in time of the current outcome status of all registered patients, provided of course that data in treatment cards are regularly updated to the registers.

The treatment cards and register are then used to (a) provide cumulative outcome data at set periods of time for the whole cohort of patients ever registered for treatment and (b) survival outcome data in specified cohorts.[6] As successive registration cohorts appear in chronological sequence in the register, quarterly outcome analysis can easily be performed for different lengths of follow-up (i.e. 12 months, 24 months, 36 months and so on), thereby allowing facilities to produce and review comparable survival analyses that are standardised for the length of observation. This exercise can be done manually, but as the numbers grow it is better handled through electronic data systems. For example, using open-source software, EpiData, electronic patient records have been prepared for the management and monitoring of patients with asthma. Such data can be collected and collated at district, provincial and national levels.

7. Linkage with general health systems

The initial DOTS framework,[4] developed and disseminated in 1994, has subsequently been modified and enhanced to take account of experience gained over the previous decade, critical problems such as HIV and drug resistance, and the changing global architecture of healthcare delivery that has seen a greater emphasis on health system strengthening rather than disease-specific approaches. For example, it became apparent 10 years ago that the DOTS framework on its own would not be sufficient to control TB in areas with epidemic HIV infection.[10] As a result, an interim policy was developed to define collaborative activities that could reduce the dual burden of HIV and TB,[11] and this was then integrated into the new Global Plan to Stop TB (2006—2015)[12] and the new Stop TB Strategy.[13] TB control efforts now take account of HIV and multidrug-resistant TB, and they have also been positioned within a framework that seeks to reduce poverty, advance development and align with other strategies to meet all public health challenges. In this regard, there are new key components that (a) address how TB control can contribute to strengthening of health systems, (b) provide for greater engagement of all care providers both from public and private sectors and (c) seek to empower people with TB and the communities in which they live.

In a similar vein, the setting up of a monitoring system that seeks regularly to document incident and prevalent cases, treatment outcomes and types of medication used by patients with chronic infectious and non-infectious diseases must be sensitive to the needs of general health systems, otherwise there is a risk of setting up multiple parallel or 'vertical' programmes. This being said, many urban hospitals in developing countries already run special clinics for patients with diabetes mellitus, hypertension or asthma, but consideration could be given to merging these into single clinics for chronic diseases as has happened in hospitals and health centres in Cambodia[14] and Ethiopia.[15] In health facilities without these special clinics, patients with chronic diseases may not efficiently access the services they need: this has been our experience with asthma patients who, when there are no asthma clinics available, access care through unplanned visits, which leads to increased costs and generally poor quality management. For all clinics serving special populations, regular, structured supervision will be needed to ensure that monitoring systems are of good quality, but these supervisory activities can be developed and expanded for the wider health sector as well as for chronic diseases. There is a growing conviction that so-

called 'vertical programmes' can be used and adapted to drive broad improvements throughout the general health system, particularly in hitherto weak areas such as monitoring, supervision, quality assurance and rational drug forecasting.[16] Any attempt to improve the management and monitoring of special diseases must include a vision of how this will ultimately improve the health sector and healthcare delivery as a whole.

8. Conclusion

With TB DOTS expansion and the scaling up of ART in some of the poorest countries of the world, much has been learnt about how to monitor case registration, patient burden and treatment outcome, and these have become the vital signs used to manage and evaluate these two treatment programmes. AIDS patients take ART for life in much the same way as diabetic patients take insulin, hypertensive patients take blood pressure medication and epileptic patients take phenytoin. The same vital signs can be adapted to monitor any chronic disease and should become the 'nub' of chronic disease management.

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