**Improving clinical and laboratory hematology services in resource limited settings**

**Synopsis**

The difficulties in establishing and delivering reliable clinical hematology and laboratory services in resource-limited settings are well recognized. However, much can be achieved by better use of existing resources through a concerted quality improvement approach. The recommendations of this chapter are based in part upon work in the thalassemias, inherited disorders of hemoglobin that are widely prevalent in Asia, which may serve as a model that is applicable to other common, chronic disorders in resource-poor settings. Resources are highlighted and recommendations made regarding approaches to improving services. Over the last few years, a number of low and middle-income countries, obtaining support from appropriate governmental sources, have assessed and overcome difficulties and significantly improved clinical services for patients with thalassemia.

**Background**

The recommendations of this chapter are based in part upon work in the thalassemias, inherited disorders of hemoglobin that are widely prevalent in Asia, which may serve as a model that is applicable to other common, chronic disorders in resource-poor settings. The decline in childhood mortality rates in Asian countries over the past four decades has resulted in substantial proportions of many countries’ health-care budgets now being consumed in the management of surviving patients. We had previously estimated that in Sri Lanka, the management of thalassemia could shortly require about 5% of the country’s health budget (1) Therefore, even in Sri Lanka where care has reached a commendable standard (2), it remains critical to continue to plan not only for programs for screening and counseling in thalassemia, but for improvements in clinical and laboratory services in patients whose lengthening survival is often associated with increasingly complex care.

**A. Improving clinical services in resource-poor settings**

The approaches suggested here to improve clinical services include *education* to increase the knowledge base about thalassemia, including approaches to long-distance education. Improvements in the *delivery of care* will include those in clinical facilities as well as in the organization of health care, with emphases on continuity of care and on accountability. Meticulous approaches to history and physical examination and to record keeping in local clinics may assist development of national programs of datamanagement. Extending the *access to essential medicines* is a critical issue in almost all Asian countries. As well, there is a view -- not usually overtly expressed -- in many countries that thalassemia is a hopeless disease in which a substantial investment is wasted. This requires efforts to *change attitude*s within health care systems and governments who may not provide many basic health services to their citizens. South–South partnerships, including those outlined in chapter 6, may be critical in many of these approaches.

***1. Expansion of medical education***

Early investment to increase the knowledge base in the thalassemias, beginning in medical school and including training in pediatrics and hematology, would represent a long term positive investment in improving clinical management of these complex disorders. Examples are illustrated from Sri Lanka.

***Medical school***. In Sri Lanka exposure to thalassemia in medical school includes a few lectures on hematologic disorders, including thalassaemia, two practical laboratories including one during the later clinical rotation and, during clinical clerkship, possible opportunities to manage patients.

***Pediatrics.*** As in many other countries in Asia, in Sri Lanka thalassemia patients are generally managed by pediatricians, many of whom may have received limited exposure to thalassemia following medical school. Over four years of pediatric training, including one as a registrar, a week-long, largely laboratory-based, rotation in hematology is provided. During a mandatory subsequent year of training overseas, there may be opportunities to manage patients with thalassemia (**personal communication Professor Sanath Lamabadusuriya, June 2015**).

***Hematology***. Thalassemia patients in Sri Lanka are not managed by hematologists, whose training, as per the traditional British model, focuses primarily on laboratory experience with less extensive clinical training. During four years of formal laboratory training and a relatively shorter period of clinical training, there may be no experience in thalassaemia, although there may be clinical exposure during years as a registrar, or overseas (**personal communication, Dr. Senani Williams April 2015**).

The upshot of all this is that a newly-qualified pediatrician may be charged with responsibility of hundreds of patients in a rural setting, despite limited expertise and experience in either laboratory or clinical problems of thalassaemia; in parallel, individuals who have extensive hematology training in thalassemia may possess limited understanding of clinical issues. Similar situations exist in other emerging countries, but may be evolving, as they are in Sri Lanka. In Sri Lanka at present approximately ten pediatricians and a few consultant hematologists are trained annually. The doctor-patient ratio in 2010 in Sri Lanka was 0.7 / 1000 population (compared to 2.7 in the UK, 2.4 in the United States, and 2.1 in Canada); in many emerging countries, this ratio is much lower(3). Yet even in countries where chronic understaffing may be accepted as inevitable, the optimal arrangement and one that would improve care without additional extensive financial outlay is a network of dedicated clinicians, working with designated laboratories, in a few expert centers.

***Possible approaches to change*.** Expansion of the medical school curriculum to include exposure to the evidence for current practices in thalassemia, with emphasis on independent guidelines of management, may stimulate early scientific interest in this fascinating disease. Following medical school, more comprehensive laboratory training for pediatric trainees and extended clinical rotations for those in hematology might usher in a new era of cooperative care. Some of the country’s prominent pediatricians have suggested that in future, defined periods spent in dedicated thalassemia units be mandated as part of pediatric training. These units need to be expanded to more centers, given that in many emerging countries many patients live hours from the closest center of excellence with a potential inaccessibility to expert care. Efforts to expand the expertise that is often concentrated in urban centers have been assisted over the last decade withadvances in communication technology, including the potential for telemedicine to play a potential role (4, 5).

***2. Improved Delivery of Care***

***Organization of clinical facilities*.** In many emerging countries, in the absence of hemoglobin screening programs, thalassemia patients are often first diagnosed during an admission to an emergency department, where a variable range of understanding of thalassemia care may be encountered. In Sri Lanka, if admission is required, a patient aged older than 13 years (the age after which a child is registered as an “adult”) will be admitted to an adult way. If a pediatrician trained in thalassemia management (or if expert “on call” advice was available) a child could be reviewed and if necessary admitted to a pediatric ward, improving continuity of care. With respect to thalassemia *outpatient* management, a separate facility need not be a freestanding structure. Two or three dedicated rooms, including a transfusion and treatment area, a (private) patient consultation area and, if possible a waiting area, are sufficient.

***Re-organization of the structure of the health care team.*** Arguably the most effective approach to improve clinical services for this disorder would be to ensure *continuity* *of care.* Efforts to establish dedicated expert centers in which interested, motivated pediatricians and hematologists act as Thalassemia Center Director with extended terms of appointment, who supervise all care and mentor junior staff, would improve a common arrangement by which senior staff relocate every few years. Prior to taking up a post as a Thalassemia Center Director, dedicated short courses could be provided to consultants interested in thalassemia management, who would then be assigned ultimate responsibility for all patients, if not permanently, for extended periods.

Management guidelines providing evidence-based recommendations for clinical assessment, medication use, and patient monitoring that is tailored to the center can be provided. Regular review of all clinical and laboratory data on each patient, at not longer than three-month intervals, and seminars and meetings focusing on evidence-based management, will maintain compliance with management guidelines. Interest can thereby be promoted in trainees, for whom a process should be established for regular attendance at each center. Because ongoing assessment of complications including those in the cardiac, hepatic and endocrine systems is critical in thalassaemia care, relationships with consultants in the relevant sub-specialities should be established, and may help to expand sub-networks of interested and expert care. Related to continuity is *accountability* in care. The concept of a minimum standard of care, even in rural settings, is of critical importance. Regular mortality/morbidity rounds to document causes of death, complications, and parameters of iron control can evaluate the compliance with management guidelines, and direct optimization of care. The use of quality assessments by impartial independent reviewers can help guide physicians in appropriate practices.

In parallel, it is equally important that staff morale be maintained. Efforts toward academic work should be encouraged and promoted. Not only Center Directors, but others including nursing staff, should be provided with opportunities for continuing medical education, both locally and abroad.

***Emphasis on clinical skills and ‘low tech’ approaches to care***. Clinical care may facilitated by encouraging what could be termed “low tech” approaches with a targeted meticulous approach to history and physical examination and careful record keeping. Text boxes 1 and 2 highlight some important points from the history and physical examination, using the example of thalassemia, which when documented over time allow substantial understanding of the patient’s status.

>>Insert text boxes 1 and 2 here.

***Data management*.** In our experienceat the National Thalassemia Center in Sri Lanka,the presence ofan efficient, dedicated, multi-tasking clinic manager with broad responsibility but above all that for organizing data and charts, has been extremely valuable. Data does not have to be recorded electronically; indeed, this is often not practical in many settings. Where sufficient staff are available there is value in developing a local data base which among other goals, permits tracking of numbers and of local statistics; a uniform country-wide system of recording clinical and laboratory data assist in evaluation of national trends. It is a common but, in our view, inadvisable practice to have the patient keep even limited medical records at home as these may often be misplaced. Finally, as identified in other chronic disorders (G) maintenance of a national registry by a trusted source may assist the understanding by the government of the necessity to increase resources for care.

***Increased access to essential medicines***. In many cases high drug prices, often the result of intellectual property “protection”, are a serious barrier to access to essential medicines. Efforts to reduce drug prices are opposed by many industrialized countries and the pharmaceutical industry. The potential solutions to this are complex, including alliances with Health Directors and ministries, education and organization of parents’ groups, and continued resistance from humanitarian organizations (7).

***Changes in Attitude*.** Changes in the perception of thalassemia is critical to the success of the initiatives outlined above. There remains a contrast between the expectations of care in richer countries for thalassemia and many other once predictably-fatal disorders which have evolved to a chronic disease, and emerging countries, in which many patients remain under-diagnosed and under-treated.However, even in countries lacking the public health system of Sri Lanka, survival in thalassemia has almost doubled over the past four decades, due primarily to the wider availability of iron-chelating therapy (8). Given recent initiatives in India, the previously discouraging general lack of access to chelating (9) may be changing.

Governments, companies interested in corporate social responsibility, and interested charities may be accessed to provide resources with varying success. As an example, our charity, Hemoglobal® in cooperation with a private health facility in Sri Lanka, recently was able to begin quantitative testing to evaluate iron overload *in vivo* (10)**.** Following this effort, the Sri Lankan Director General of Health reinforced the commitment to make such monitoring available annually for a cohort of patients. Similar approaches may be feasible in other countries.

Of course, as long as governments do not support basic health priorities including sanitation and immunization, thalassaemia -- whatever its prevalence -- will not be conceived as a high national priority. But there is no doubt that continued lack of attention leading to poor physical, psychological and social functioning, as these patients survive but develop irreversible complications, is increasingly costly in social and economic terms (11). Furthermore, experience in other diseases also shows that governments respond to pressure and that individual efforts to improve care and awareness may have long-lasting impact. Our own experience in Sri Lanka emphasizes that even one dedicated individual, over years of effort, can increase the involvement of a government willing to listen. One example includes the observed doubling over the past 20 years, in Sri Lanka, of the use of iron-chelating therapy. Still another is the initiation of a screening, education and prevention program in Sri Lanka, where the government has recognized that such approaches are key to reducing the burden of disease.

**B. Improving laboratory services in resource-poor settings**

Gaps in access to essential laboratory testing are costly to excellent patient care. An early example from our work in Sri Lanka was the (former) limited availability of the measurement of serum ferritin to screen the common complication of iron overload in thalassemia. This prevented the reliable interpretation of clinical status and, therefore, the provision of safe and effective care. Expanded access to this testing has helped to encourage evidence-based management.

The difficulties in establishing and delivering reliable clinical diagnostic laboratory services in resource-limited settings are well recognised (12-16). Limited equipment, consumables, reagents, standards and quality control materials coupled with intermittent water and electricity supplies, make day to day work quite a challenge. Although these difficulties are faced in the large city hospital and reference laboratories, they are often more pronounced in the smaller district hospitals and village health centres, which are often last in the chain to receive what already limited resources are available. Unfortunately, health burdens are usually greatest in the very places where resources for health care are the most limited (17).

The problems of limited resources are compounded by difficulties in providing adequate training so that laboratory staff lack the skills necessary to deliver reliable results that are essential for effective health care. This can lead to clinical staff mistrusting laboratory results, which in turn leads to low staff morale. Morale can be further undermined by inadequate supervision and also career progression opportunities.

Degree and diploma courses in Biomedical Sciences and laboratory technology are often only available in the larger cities, in neighbouring countries or overseas. Limited laboratory staff and funding means that these courses are often not easily accessible, particularly to those based in the more remote laboratories where they may be the sole provider of the laboratory services. Furthermore, laboratory personnel may lack the necessary qualifications for enrollment. Therefore, it is often necessary to provide meaningful training for laboratory personnel, that is appropriate for their capabilities, relevant to the laboratory in which they work and the population they serve and delivered within existing resources. We will focus on what can be achieved through locally-led initiatives and without formal external training courses as these may not be available for the majority of staff.

Investments in training are justified if they result in improved practice. Therefore, to ensure that training is relevant to the local service, it is best delivered as part of broader quality improvement (QI). Simple, generic tools for improving the quality of services are readily available and can be applied to a laboratory setting.

***Implementing quality improvement***

“Everyone in healthcare really has two jobs when they come to work every day: to do their work and to improve it” (18) applies equally to laboratory staff. The World Medical Association guidelines on continuous QI in health care are targeted at physicians and health institutions but are relevant to all healthcare professionals (19).

Locally driven QI initiatives can engage all members of the laboratory team and provide a broad range of training and capacity development opportunities including leadership, team working, problem solving and communication.

QI has been defined as “the combined and unceasing efforts of everyone—healthcare professionals, patients and their families, researchers, payers, planners and educators— to make the changes that will lead to better patient outcomes (health), better system performance (care) and better professional development (learning)” (19). This definition highlights that the critical outcome is the whole service delivered to the patient, of which individual laboratory procedures are only a part. Therefore, laboratory staff need to lead or join QI initiatives that take a patient-centred and comprehensive approach and engage a broad range of stakeholders. Text box 3 presents the key elements of QI and how these can be applied to laboratory services.

<<insert Text Box 3 here>>

Improvement in services requires a sequence of activities to be undertaken (Text Box 4). It is important to note that, rather than “task and finish”, QI is an on-going, cyclical process so that continual improvements in services occur. Where laboratory technicians are working in isolation, local networks can be formed to deliver QI addressing basic procedures across several laboratory facilities.

<<insert Text Box 4 here>>

***Step 1 of QI cycle: Benchmarking***

The QI cycle starts by identifying universally accepted standards of laboratory practice that can provide benchmarks for the development of services. This is also critical in advocating for additional resources to enable practice to improve towards these standards. All clinical diagnostic laboratories in resource limited settings should strive to work in accordance with nationally agreed standards and, where possible, to International Organization for Standardization (ISO) standard ISO 15189. This ensures an excellent laboratory quality management system, technical competence and the ability to provide reliable and accurate results.

In South East Asia, laboratory accreditation programs are well established in India, Indonesia and Thailand (20). Following a WHO South East Asian inter-country laboratory accreditation workshop held in Thailand in 2006, a laboratory accreditation program was started in Sri Lanka adopting ISO 15189 as the standard. To date, many private hospital laboratories have been accredited.

In the Government sector, the National blood transfusion service laboratory is accredited and there are plans to extend the program to include all other Government hospital laboratories. With this in mind, National External Quality Assurance (NEQAs) programs have been established since 2012, and workshops for technical officers and provincial training programs are conducted regularly by the Ministry of Health, Sri Lanka College of Haematologists and the Sri Lanka Accreditation Board (personal communication, Dr. Chandana Wickremaratne, May 2015).

In Africa, the Maputo Declaration (21) and Joint WHO-CDC Conference on Health Laboratory Quality Systems (22), both in 2008, aimed to strengthen and support laboratory systems in resource-limited settings to achieve national or the ISO 15189 international standards. In 2009, the Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) and the Strengthen Laboratory Management Towards Accreditation (SLMTA) initiatives were established under WHO-Afro (23,24). At the same time, a training tool kit developed by WHO, US Centre for Disease Control and Prevention and the Clinical Laboratory Standards Institute was launched to assist laboratory trainers to educate and train laboratory staff in best practice (25). This includes a Clinical Laboratory Standards Institute library of bench aids and guidance documents. These guidelines and resources are comprehensive and are most appropriate for the larger hospital and reference laboratories, but also provide a useful template and resource for all laboratory facilities.

Findings from a recent survey conducted in 49 countries in sub Saharan Africa showed that 380 laboratories have been accredited to international standards, and 91% of these laboratories are in South Africa. However, there were no accredited laboratories in 37/49 countries surveyed (26).

***Step 2 of QI cycle: Identify gaps or deficiencies in current provision***

Based on a project in a clinical laboratory in West Africa, a requirement for patients to return the following day to collect hemoglobin (Hb) results was observed to delay clinical management (e.g. blood transfusion), incur avoidable patient expenses and increase defaulting (patients often failed to return). A multi-stakeholder QI team, including two patient representatives, analyzed the likely causes and represented them in a fishbone diagram (Fig 1.)

<<insert Fig 1 here>>

***Step 3 of QI cycle: Consider the whole system - the sample journey***

It is critical to take a whole system approach as road blocks can occur at any step. Careful attention to quality control and standardizing sample testing is important as a laboratory may use instruments and reagents from several manufacturers to measure the same parameter.

The reliability of results can be evaluated according to

* accuracy – degree of closeness to the true value (e.g. validated using a standard)
* repeatability – the same result is obtained when the same parameter is measured multiple times in a single sample by the same technician using the same method
* reproducibility – the same result is obtained from a single sample when different methods or instruments are used to measure the same parameter

Regular calibration and maintenance of equipment are essential to ensure reliability of tests, and where possible service contracts should be established at the time of purchase. External quality assurance programs such as NEQAS, tend to operate in the larger hospital laboratories in cities. However, it is also important to establish local laboratory networks that can facilitate the appropriate storage and distribution of control blood samples from a central hospital to neighboring peripheral laboratories. Control samples should be tested each morning to check instrument accuracy before testing patient samples. Control samples should also be included in subsequent batches of samples to monitor accuracy and test repeatability over the course of each day. Control results from each laboratory can be reviewed by the distributing laboratory to monitor performance across the network and identify if any remedial action is needed.

Where a regular supply of external control material is not achievable, it is still possible to establish internal quality control procedures:

* repeat measurements in previously tested samples with normal, high and low values and known positive and negative samples when testing for hemoglobinopathies.
* Perform all measurements in duplicate when possible. However, where reagents are scarce, repeat measurements in every nth sample.
* Ensure that all blood films are read twice, preferably by two independent microscopists, save every nth blood film and send to an expert microscopist at the regional hospital laboratory on a monthly basis, to check the quality of the blood film preparation and staining and the accuracy of reading.

Text box 5 outlines the key steps in the sample journey which may need attention to ensure that the whole process is performed to the desired standard.

>> Insert text box 5 here.

***Step 4 of the QI cycle - Developing a plan for service improvement***

The “Plan, Do, Study, Act” (PDSA) cycle provides a useful structure for developing a plan and can be adapted to laboratory settings. (Fig 2). Again using the West Africa project as an example, the main elements of the cycle for this project are shown in Text Box 6.

>>Insert text box 6 here.

**Steps 5 and 6 of the QI cycle: Test, monitor, implement and sustain successful changes**

Although clearly critical to improving services over the longer term, these are often the most difficult elements of QI to achieve. The initial enthusiasm often wanes as improvements are achieved and key staff move on. Establishing a continuous QI ethos amongst all laboratory staff takes time and this overall aim should be explicit in all projects. Integrating meaningful training activities to QI initiatives is a key element in engaging staff and ensuring that service improvement is a routine part of everyone’s day.

**Conclusions**

Over the last few years, a number of resource-poor countries, obtaining support from appropriate governmental sources, have assessed the gaps in care and improved clinical services for patients with thalassemia. Despite limited resources, much can be achieved through a concerted QI approach. Attention to systems and processes quickly identifies opportunities for staff training that directly improves the service. A home grown quality improvement ethos within clinical and laboratory departments is also essential to maximize the impact of any additional resources and external training that can be secured. Assisting federal or state governments to understand the many complex demands of clinical care in thalassaemia and other chronic and common disorders is a critical element in improving patient outcomes.

Useful resources:

Cheesbrough M. District Laboratory Practice in Tropical Countries. 2nd edition update, Part 1. 2006. Cambridge University press. ISBN. 978-0-521-67632-8.

Cheesbrough M. District Laboratory Practice in Tropical Countries. 2nd edition update, Part 2. 2006. Cambridge University press. ISBN. 978-0-521-67633-5.

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