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Applying operations management logic and tools to save lives: A case study of the world health organization's global drug facility☆

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Abstract

In the field of operations management, theory concerning lead-time reduction is well developed. The application of lead-time reduction theory to the not-for-profit operations context, however, has been limited. We present an illustrative case study of a not-for-profit operation in which long lead times cause a substantial increase in unnecessary deaths from tuberculosis and hinder the efforts of the World Health Organization to eradicate tuberculosis globally. The case study suggests that lead-time reduction theory may be as effective in not-for-profit (service) operations as it has been in manufacturing operations. Our results also illustrate how use of sophisticated but ''user-friendly'' queuing theory-based modeling tools can facilitate the acceptance and transfer of operations logic to a not-for-profit intergovernmental organization setting.

Keywords: Tuberculosis; Operations management; Lead-time reduction

1. Introduction

The purpose of this case study is to provide a brief illustrative example of the benefits of transferring operations management logic and tools to a not-for-profit intergovernmental organization, the Global Drug Facility (GDF) of the World Health Organization. As such, it is intended neither to provide a comprehensive literature review of queuing theory applications in not-for-profit organizations nor to extend theory concerning mathematical modeling of such operations. Rather, it provides an overview of how equipping doctors and international civil servants with basic principles of operations management and then training them to build simple queuing theory-based models of their

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process yielded lead-time reduction results that could save lives. In addition to demonstrating the clear-cut applicability of a queuing model to an intergovernmental organization, the more important contribution of this case study may well be to illustrate the benefits of combining the transfer of straightforward operations management approaches with simple modeling as a means for achieving buy-in and implementation in the not-for-profit context, where managers are not accustomed to thinking of themselves as running operations, and where the emphasis on efficiency and cost reduction makes lead-time reduction even more difficult than in the competitive arena faced by for-profit organizations.

The paper is organized as follows: Section 2 provides some brief background concerning TB and the problems caused by long lead times in the intergovernmental operations working toward the control and eradication of TB. In Section 3, we present our basic process analysis of the GDF application processing operations, followed by a discussion of the queuing theory-based model developed by the team. Results are presented in Section 4. In Section 5 we suggest implications of the study for both the WHO and not-for-profit organizations.

2. A life-saving need for lead-time reduction

It is now commonly agreed that TB control and eventual elimination have shifted from being technical problems to being managerial and political challenges. The tragedy of TB is that almost 2,000,000 people die annually (i.e., one person every 15 s) of a disease that can usually be cured in 6 months with $10 worth of anti-tuberculosis drugs (ATDs, Stop TB website, 2003).

Several decades ago, controlling TB was a top priority worldwide. The discovery of effective ATDs led to a substantial reduction in TB in most developed countries; hence, TB control became a relatively low priority. The same decline in TB cases did not occur in less-developed countries, however: By the late 1980s, it became clear that TB was an urgent problem, especially when combined with the problems of interaction with HIV infection and increasing outbreaks of multiple-drug-resistant strains of TB. Today, 8.5 million people develop TB every year, with 80% of these cases occurring in 22 ‘‘high burden’’ countries (WHO, 2003). The WHO and other partner organizations responded to this crisis by forming the Stop TB Partnership to mount a global attack on TB, setting global targets of detecting 70% of people with infectious TB and curing 85% of those detected by the year 2005 (Raviglione and Pio, 2002).

The internationally recommended primary strategy for controlling TB is known as DOTS (which originally stood for ‘‘directly observed treatment, short course’’). Between 1990 and 2001, the number of countries that had an appropriate system for tuberculosis control rose from less than 10 to 155 (WHO, 2003) due to implementation of the DOTS strategy. It is generally agreed that the DOTS strategy is the most effective strategy for controlling TB. The World Bank referred to DOTS as ‘‘one of the most cost effective strategies available’’ (Stop TB website, 2003). Dr. Gro Harlem Brundtland, then Director-General of the WHO, referred to DOTS: ‘‘We have a cure. We need to mobilize the world to use it’’ (Stop TB website, 2003).

In spite of the effectiveness of the DOTS strategy, however, the WHO estimated that in 2000, only 27% of new cases were identified, implying that global targets for TB control would not be reached until the year 2013 at the earliest (WHO, 2002). The major challenge in controlling TB is to ensure that patients take their medication daily during the 6 months required for treatment. Efforts to ensure compliance with treatment have been hindered, however, by lack of access to low cost ATDs of consistent quality. For this reason, the Stop TB partners formed the GDF in early 2001 to fund and manage procurement and quality assurance for countries applying for assistance.

The vision of the GDF is a TB-free world. Its mission is to: (a) ensure uninterrupted access to quality TB drugs for DOTS implementation; (b) catalyze rapid DOTS expansion in order to achieve global TB targets; (c) stimulate political and popular support in countries worldwide for public funding of TB drug supplies; and (d) secure sustainable global TB control and eventual elimination (Global Drug Facility website, 2003).

The GDF began their work with the objective that lead times from arrival of an application to delivery of drugs to the port of the applying country would be less than 6 months (i.e., 132 working days); lead times

would be reduced to 3 months (66 working days) thereafter. However, in the first six countries supplied, the actual lead times averaged 267 working days, and the average lead time has since increased to about 400 days (181 days for processing of applications – of which about 20 days represent actual processing time – and 219 days from placement of order for drugs to receipt of drugs in the applicant country). GDF management was uncertain regarding how to meet lead time targets: It was generally agreed within the Stop TB organization that the GDF staff members were working hard and displaying a high level of motivation.

A chance discussion brought lead-time reduction theory to the attention of the GDF manager, who then invited a professor from the Operations Management department of a local university to work with his group to explore the implications of applying existing theory concerning lead-time reduction to GDF operations. We formed a team composed of the professor, the GDF manager, and an assistant from the university who became employed by the GDF to work on the project. The objective of the GDF lead time project was to explore the application of lead-time reduction theory in a not-for-profit organization to a set of activities that would not normally be considered as an ''operation.''

3. Applying OM tools to the GDF operations

Reviewing the mathematics of lead time and carrying out a basic process analysis initiated the lead-time reduction efforts. However, a straightforward mathematical tool was required to allow the group to reach consensus on courses of action, communicate the action plan to the rest of the Stop TB unit so as to receive necessary approval and funding, and transfer the vision for lead-time reduction to other operations within the WHO.

3.1. Initial analysis of GDF operations

Following the principles of action research, the project team examined the phenomenon of long lead times while working to create an action plan to reduce the lead times. Action research, according to Greenwood and Levin (1998, p. 75), is ''committed to the idea that the test of any theory is its capacity to resolve problems in real life situations.'' Another objective of action research is practitioner learning, which results in an increase in the ability of practitioners to solve problems.

A key aspect of the project entailed training the GDF staff both in the mathematical principles that drive lead times and in building and interpreting queuing theory-based mathematical models of the GDF operations, consistent with the objective of action research that practitioners become more able to resolve their own problems through learning how to apply theory. Applying operations management theory to a real problem also permitted testing and refinement of the theory in the context of an office operation in a not-for-profit organization (see Rynes et al., 2001).

As mentioned previously, the actual processing time for applications was about 20 days, indicating that 161 of the 181 days of lead time represented waiting time. Our objective was to use OM tools to discover and make a plan for the elimination of this waiting.

We began by reviewing the relationships between bottleneck utilization, batch (lot) sizes, and lead time (shown in Figs. 1 and 2). These relationships – fundamental to OM theory – were completely unfamiliar to the group. As soon as group members understood these relationships, they immediately began to identify assumptions and behaviors that had led to increased lead times. The GDF manager and

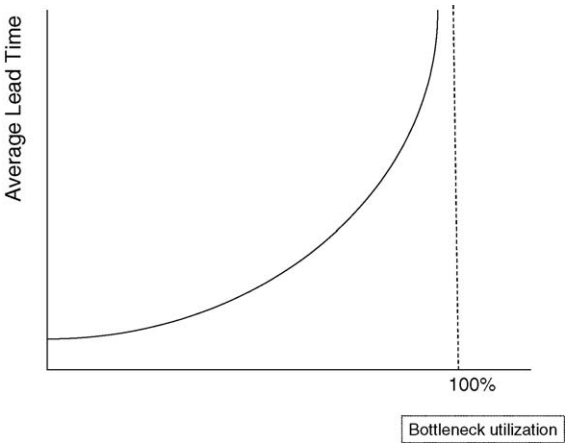

Fig. 1. As bottleneck utilization increases, average lead time increases at an increasing rate, becoming infinite at 100% utilization.

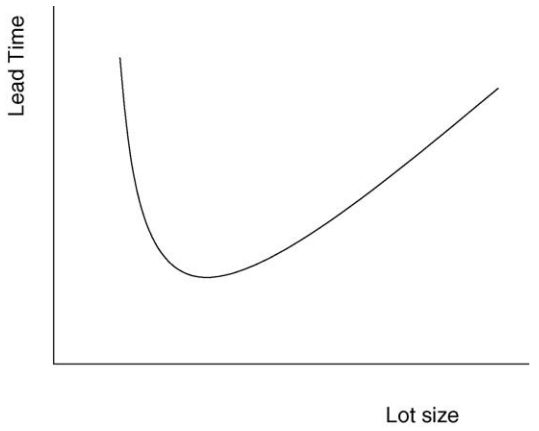

Fig. 2. Lead time increases approximately linearly with lot size. Very small lots, however, may result in long lead times if setups cause high capacity utilization.

his supervisor (the executive secretary of the Stop TB Partnership) were identified as primary bottlenecks, but it was recognized that utilizations were also relatively high for other members of the team, especially the two technical officers responsible for application processing.

Although it was initially assumed by the GDF manager that the relationship between batching and lead times did not apply to GDF operations, it was subsequently determined that applications were batched for review by a Technical Review Committee (TRC) that met three times per year. Stop TB management had decided to hold the meetings every 4 months given the costs associated with bringing together a large group of experts and because of the belief that all the experts should be together to make an optimal decision concerning the applications. This meeting frequency implied that the ''batch size'' for applications represented approximately 4 months' demand, which, according to the relationship shown in Fig. 2, led to a substantial increase in lead times.

Development of a process flow diagram based on historical GDF records (shown in Fig. 3) and review of the conceptual relationships between bottleneck utilization, batch sizes, and lead times helped the group to understand some of the factors causing the long lead times. Our initial expectation was that we would be able to explain the long waiting times using simple process analysis and commonsense reasoning. We discovered, however, that we were able to account for only a portion of the 161 day waiting time using these tools due to the complexity of the process. Quantifying the waiting time caused by high personnel utilization was complicated, for example, by the substantial overtime worked by GDF personnel, combined with the fact that team members worked half-time or less on application processing, with the rest of the time taken up by meetings or projects not related to the processing of applications.

The team then attempted to determine how much of the 161-day waiting time could be explained by the TRC-related batching of applications. Given that the TRC met three times per year, the team's analysis indicated an average increase in lead times of 2 months, or 44 working days (given 22 working days per month) for applications requiring only a single TRC round. Applications, however, made on average about 1.4 visits to the TRC[1], which was expected to add another 35 days (40% of 88 working days), for a total lead time impact of about 79 days. Commonsense reasoning, hence, suggested that approximately half of the waiting time was due to this TRC-related batching.

Moving from this initial analysis to development of an action plan proved difficult. First, although the GDF management was impressed by the impact of the TRC meetings on lead times, it was clear that the GDF and Stop TB organizations were not prepared to take action to change the structure of the TRC meetings based on this rather ad hoc analysis. The group's initial reaction was that the frequency of the TRC meeting could not be increased because TRC members were high-level officials of governments and other agencies who were working pro bono: It would not be possible to ask them to come to the WHO headquarters in Geneva, Switzerland, more frequently than three times per year. Furthermore, clearing applications through the TRC was considered to be important in ensuring due diligence.

Similarly, the difficulties in quantifying the impact of high personnel utilization on waiting time made it difficult to move acquisition of additional resources

[1] Some applications made two or more visits to the TRC. In estimating the average number of visits, we used the percentage of applications sent back to the TRC on each round, which from Fig. 3 can be seen to be $.07 + .71 \times .3 = .283$. The percentage of applications sent back n times we estimated as $.283^n$. Summing as n goes from 0 to infinity yields an estimated number of visits of $1/(1 - .283) = .395$.

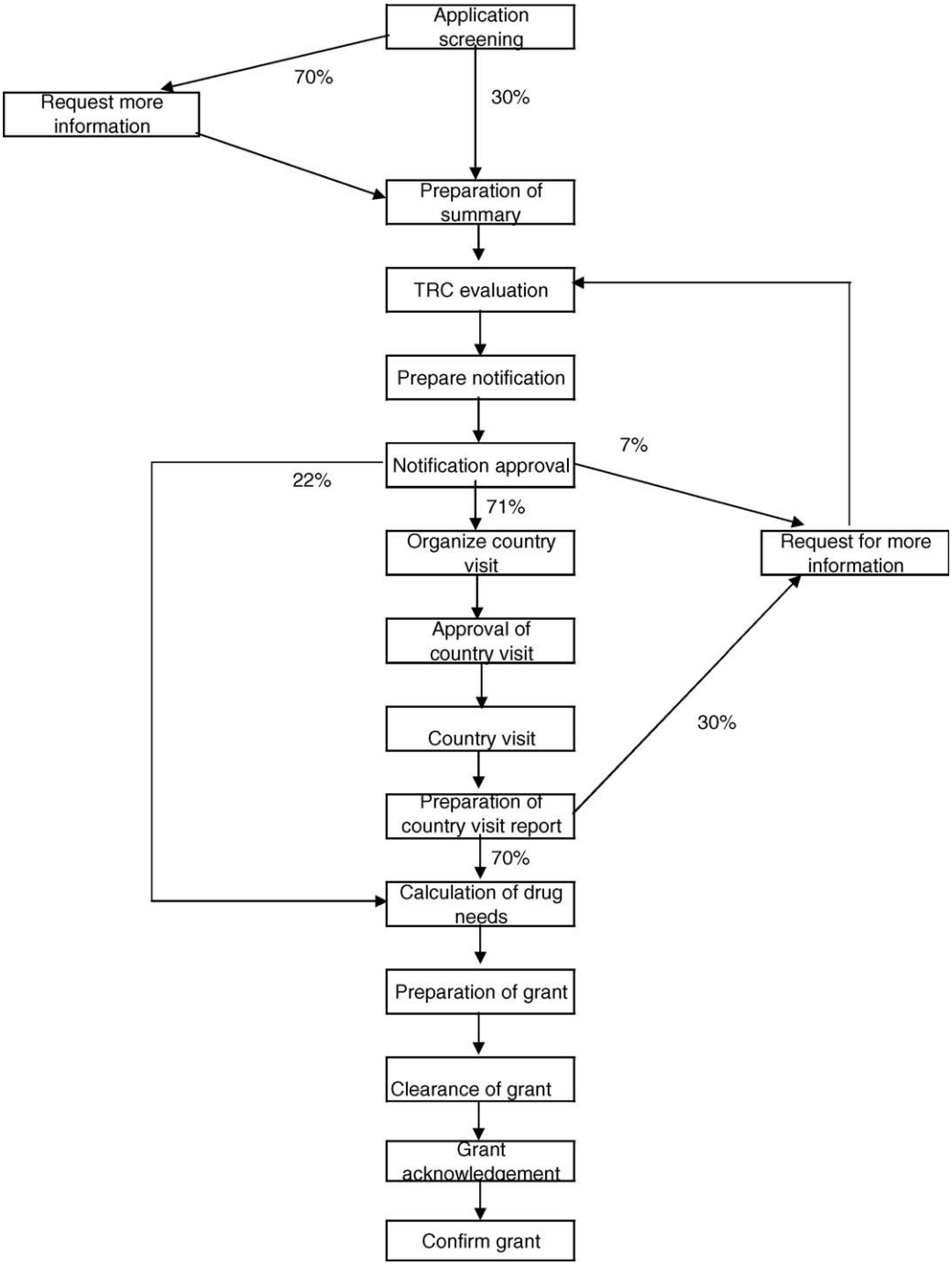

Fig. 3. The process flow of the application processing operations.

from a hope to a goal. Intergovernmental organizations such as the WHO operate under intense pressure to increase resource utilization. Getting WHO and Stop TB management to change from efforts to *maximize* resource utilization to being willing to add extra capacity (*decreasing* resource utilization) to reduce lead times was going to take more than a cursory understanding of the relationships portrayed in Figs. 1 and 2.

Finally, moving from theory to practice was hindered by the creativity generated by exposure to OM concepts. The team had difficulty in knowing how to evaluate and prioritize the large volume of ideas that arose from applying operations management theory. For these reasons, we decided to build a mathematical model of the application processing operations to aid in managing and evaluating the ideas generated, as well as to allow a more thorough analysis of the process than was permitted by manual process analysis and commonsense reasoning. Application processing was chosen as a starting point because the key parameters were under the control of the GDF. We chose to use modeling software based on queuing theory rather than simulation because of its ease of use. After this project, GDF team members should be able to construct and interpret queuing theory-based models of processes, but it is unlikely that they would have been able to master simulation-based modeling without extensive training. The software package used for the modeling was MPX (see Network Dynamics website, 2003).

3.2. Building the queuing model

The model building began from development of the process flow diagram shown in Fig. 3. Processing times were compiled by having a researcher work on site to interview and observe each member of the GDF involved in processing applications. As processing times did not appear to demonstrate high variability, we assumed a coefficient of variation of processing times of .3 (low variability according to Hopp and Spearman, 1996, and the default value in the model-building software).

As demonstrated in Fig. 3, the first step in the approval process was the screening of applications. About 70% of applications had to be returned to the applicant for further information. Once the application was judged complete, the information from the application was collected into a summary sheet and submitted to the TRC. The decisions made by the TRC were summarized into notifications by the technical officers. These notifications were approved by the executive secretary of the Stop TB Partnership (who had supervisory responsibility for the GDF). TRC decisions resulted in an average of 7% of applications being judged incomplete, requiring additional information from the applicant countries and an additional TRC round 4 months later.

Country visits were required for the first grant awarded to each country. Once the TRC judged an application coming from a first-time country complete, a country visit was planned by the technical officers, approved by the Stop TB executive secretary, and carried out by technical officers, the GDF manager, or a consultant appointed to the GDF. Country visits were arranged for approximately 71% of applications evaluated by the TRC. Applications judged complete from countries that already had been visited in connection with a previous application (approximately 22% of applications evaluated by the TRC) proceeded directly to calculation of drug needs.

After the country visit, the GDF staff member prepared a report. In 30% of cases, the report indicated a need for additional information and an additional round at the TRC. Once the country visit report indicated that the file was complete, drug needs were calculated. Finally, the grant was prepared and the application entered the drug-sourcing process.

Following the development of the process flow diagram, the next challenge was to set the lot sizes and batching policies. Given that the TRC met three times per year, our initial inclination was to set the lot size at one-third of the twenty applications processed each year. It was, however, necessary to increase the lot sizes to reflect the 1.40 TRC rounds made by an average application; hence, we used an average lot size of $20/3 \times 1.40 = 9.3$ applications.

The MPX software allows the user to set a transfer batch size that is different from the production lot size, indicating that parts in a given batch are assumed to move to the next operation without waiting for the full batch to be completed at that operation.[2] A production

[2] Our terminology here matches that in the software: lot size for production, batch size for transfer.

Table 1
Model data (MPX format)

Time units		
Operations	Hours	
Flow time	Days	
Production period	Year	
Hours per day	8	
Days per year	210	
Labor		
	Overtime (%)	Unavailable (%)
1 Applicant	0	0
1 Consultant	0	0
1 Manager, GDF	50	55
1 Executive secretary, STB	0	70
2 Technical officers, demand	15	50
1 Technical officer, supply	15	50
Equipment for all employees modeled as having unlimited capacity		
	Demand/year	Lot size
Product		
Approved application	20	9.3

lot size of ten units combined with a transfer batch of one unit would imply that the lot of ten pieces arrives together at the first workstation, with each piece moving to the next workstation as soon as it is processed, with the ten pieces reassembled into the original lot of ten after processing at the last workstation. The team compared this MPX logic to the GDF application process.

In the GDF application process, applications tended to arrive just before the TRC meetings. There was no intentional batching, but the TRC deadlines caused applications to be batched rather than arrive uniformly throughout the year. Applications entered the TRC meeting as a batch: In fact, we modeled the TRC meeting as a ''setup time'' because the time during which the meeting took place (5 days) was independent of the number of applications. The batch of applications left the TRC meeting together and tended to be batched at several of the operations following the TRC meeting. As an example, the executive secretary responsible for approving notifications and country visits usually waited to process applications until he had the entire batch on his desk.[3]

[3] The instinctive tendency of people throughout the organization to batch applications supports our claim that instruction in lead time reduction principles should not be limited to those officially working in operations.

The data used to construct the base case of the model are given in Tables 1 and 2.

4. Results

The application of the model yielded several potential improvements that could reduce the drug approval process lead time from more than 180, to less than 40, working days. According to the base case of the queuing model, lead times for processing applications averaged 183 days, compared to the actual lead time of 181 days. The model highlighted three main causes of long lead times: ''batching'' of applications, utilization levels for the technical officers handling applications, and the fact that applications made an average of 1.4 visits through the TRC process. Using the model, we were able to demonstrate that batching caused by the 4-month gap between meetings (''time waiting for rest of lot'') was the primary cause of long lead times in processing applications, accounting for approximately 113 of the 183 days of lead time predicted by the model. Waiting for labor (i.e., an application has arrived and is ready to be processed as soon as the relevant person arrives) accounted for 43 days of lead times. The 5-day TRC meeting itself caused an average of 7 days lead time, given the 1.4 TRC rounds required for an average application. Finally, run time (i.e., the time during which the application was actually being processed) accounted for about 20 days, as expected.

Lead times predicted by the model are given in Table 3. We tested six scenarios in addition to the base case:

In the first scenario, we added a technical officer on the demand side, which reduced the time waiting for labor from 43 to 32 days and also reduced the time waiting for the rest of the lot by 6 days. The total impact of adding a technical officer on the demand side was a reduction of about 17 days.

In the second scenario, we evaluated the impact of reducing the average number of TRC rounds per application. As can be seen from Fig. 3, applications were returned to the applicant countries at two points in the process: immediately after the TRC meeting (7%) and after the country visit (30%). These returns were due to incomplete information, implying that the

Table 2
Operation assignments and durations for application processing

Operation	Done by	"Setup time" (h)	"Run time" (h)
Application screening	Technical officers, application side (TODs)		2
Request more information (after screening, TRC evaluation, or country visit)	TODs		1.5
Information received from applicant country after screening	Applicant country		56 (80%) 80 (20%)
Preparation of summary	TODs		2
TRC evaluation	TRC (including TODs)	40	
Prepare notification	TODs		1
Notification approval	Executive secretary, Stop TB Partnership		0.5
Organize country visit	TODs		16
Approval of country visit	Executive secretary, Stop TB Partnership		1
Country visit	TODs (25%), Technical officer, procurement (25%), GDF manager (35%), Consultant (15%)		40
Preparation of country visit report	TODs (25%), Technical officer, procurement (25%), GDF manager (35%), Consultant (15%)		16
Calculation of drug needs	TODs		2
Preparation of grant	TODs		1
Clearance of grant	Executive secretary, Stop TB Partnership		1
Grant acknowledgment	Applicant country		24 (80%) 40 (20%)
Confirm grant	TODs		1

frequencies could be reduced substantially through improved process documentation and support to the applicant countries. To give GDF management an idea of the lead time implications of these repeat visits, we modeled a scenario in which the percentage of applications returning to the TRC after the country visit was reduced from 30% to 10%. This reduced the average number of TRC visits from 1.40 to 1.16, implying a simultaneous reduction of the lot size from 9.3 to 7.7 to reflect the reduced number of repeat visits. This scenario resulted in a 10-day reduction in waiting for labor because of the reduced processing required for applications, a 1-day reduction in average time spent at the TRC meeting ("setup time"), and a 23-day reduction in time waiting for the rest of lot. Run time was reduced by 2 days because of the reduced "rework." The overall lead-time reduction in this scenario was from 183 to 147 days.

Table 3
Impact of the different scenarios tested

Scenario			Time Waiting for Labor	Time in TRC Meeting	Time Being Processed	Time Waiting for Rest of Lot	Total Lead Time
TOD[a]	Routing[b]	TRC[c]					
- base case -			43	7	20	113	183
■			32	7	20	107	165
	■		33	6	18	90	147
■	■		25	6	18	86	135
		■	42	0	22	0	64
■		■	24	0	21	0	45
■	■	■	19	0	19	0	39

[a] Add technical officer, demand side (TOD)
[b] Reduce repeat visits to TRC (Routing)
[c] Virtual TRC meeting (TRC)

Combining the above two actions, we modeled a scenario in which an extra technical officer was added on the demand side and repeat visits to the TRC after the country visit were reduced from 30% to 10% of applications. In this scenario, lead times were reduced to 135 days, representing a 30-day improvement compared to only adding a technical officer, and a 12-day improvement compared to reducing the repeat visits to the TRC without the addition of the technical officer.

The next scenario considered a more extensive process redesign, in which the TRC was reconfigured to meet ''virtually'' to process each application, with each virtual meeting taking 16 h of technical officer time. Under this scenario, the lead times for application processing dropped from 183 to about 64 days, that is, a reduction of 119 days. Run time was predicted to increase to 22 days, as the TRC evaluation was now modeled as a per unit processing time rather than as a setup time for a batch of applications. Waiting for labor was predicted to decline slightly from the base case, dropping from 43 to 41 days. The 113 days of time spent waiting for the rest of the lot and the 7 days spent in the TRC meeting were eliminated.

Adding an extra technical officer to the virtual TRC meeting scenario reduced lead times still farther, to 45 days. Finally, combining virtual TRC meetings, an extra technical officer, and reduced repeat TRC visits resulted in a lead time of 39 working days.

The team was surprised by how much was learned from the modeling exercise. Our initial expectation was that modeling would provide limited value over manual process analysis. Not only were we able to quantify the impact of rework and high utilizations easily, but also the impact of the TRC batching was far beyond the 79 days of waiting time that we had expected. Our commonsense reasoning substantially underestimated the amount of waiting time caused by the applications exiting the TRC meeting as a batch. It was only in interpreting the model results that we realized the extent of the batching-related waiting that occurred at operations such as preparation and approval of country visits. Finally, the modeling allowed us to capture the interaction effects between scenarios. We found it much simpler to discuss, evaluate, and communicate action plans. What is more, the level of confidence in the team in OM analysis increased tremendously once we could explain exactly why lead times were so long.

5. Implications for the WHO and other not-for-profit organizations

The next step in the project was to present the model to the entire Stop TB department to illustrate the potential for lead-time reduction. In presenting the model, we explained that achieving model results consistent with observed lead times required the addition of 15% overtime for the technical officers and 50% overtime for the director of the GDF, which we then observed to be consistent with practice. A minor – but most appreciated – outcome of the modeling exercise was the opportunity it provided for Stop TB and GDF management to explicitly acknowledge the regular overtime worked by GDF staff members.

Based on the model results, Stop TB management made the decisions to: (a) add a technical officer, especially since the workload of the technical officers was expected to increase over time; (b) formulate a plan to increase the frequency of Technical Review Committee meetings—eventually to virtual meetings; and (c) increase commitment to reduce process variability through standardization and documentation, including a decision to seek ISO 9000 series certification. Based on these changes, the lead time for application processing is in the process of being reduced from 6 months to the target of less than 2 months.

The doctors and global health care specialists involved in this project were unaccustomed to considering themselves as ''operations managers.'' Consistent with Suri's (1994; 1998) empirical results, these managers were unaware of the mathematical principles that drive lead times and were therefore taking actions and making decisions that increased lead times. It was essential during the project to keep the message and the underlying OM logic as simple and straightforward as possible to ensure maximum buy-in and impact. When these doctors and specialists understood the mathematics of lead time, their behavior began to change.

We expect that similar behavioral changes would result from this transfer of knowledge in other not-for-profit organizations. To the extent that our results

generalize to other not-for-profit organizations, it may be worthwhile exploring ways to transfer knowledge concerning these OM and basic modeling principles to all managers, whether or not they intend to ''manage operations.'' Finally, the positive response of these doctors and specialists – as well as other doctors who saw the results – to mathematical modeling of operations indicates a need for research into expanding the use of easily accessible modeling software packages such as MPX.

In the for-profit arena, access to the knowledge and tools required for managing lead times can easily determine who wins and who loses competitively, with market share, profit, and investments in capacity and inventory at stake. In organizations such as the GDF, however, such knowledge and tools translate into lives saved. How many of those people currently dying needlessly of TB every 15 s will stay alive given timely access to ATDs?

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