

nator to assemble a task force of users specified by the committee. This task force then serves as an ad hoc committee responsible for the evaluation of the equipment described on the request for review (RR) form. During any specific period, there may be multiple task forces, each focusing on a specific equipment protocol.

The task-force coordinator cooperates with the Materials Management Department in conducting a market survey, in obtaining equipment for evaluation purposes, and in scheduling of vendor-provided demonstration and inservice training. After establishment of a task force, the coordinator analyses the evaluation objectives and together with input from the task force devises appropriate tests and the associated evaluation feedback form. There are two stages to this phase: an engineering test to validate safety and performance issues and a clinical trial to evaluate user interface issues and efficacy. Only equipment that has successfully passed engineering tests may proceed to a clinical trial. A clinical coordinator collects and reports the summary of experiences gained during the clinical trials to the task force. The committee coordinator then combines the results from the engineering tests and the clinical trials into a summary report and prepares recommendations for MTEC approval. In this role, the coordinator serves as a multidisciplinary professional, bridging the gap between the clinical, technical, and administrative needs of the hospital.

The technology assessment process actually begins as soon as a department or individual fills out a budget request and then the RR form previously mentioned. The form is submitted to the hospital's Product Utilization and Review Committee, which determines if a previously established standard for this equipment already exists.

On the RR form, the originator delineates the rationale for acquiring the medical device; for example, how the item will improve patient care, generate cost savings, support the quality of service or improve ease of use, and who will be the primary user.

The form is sent to the MTEC if the item requested is not currently used by the hospital or if it does not conform to previously adopted hospital standards. The committee has the authority to recommend either acceptance or rejection of any request, based on a consensus of its members.

If the request is approved by the MTEC, then the requested technology or equipment will be evaluated using technical and performance standards. The role of the medical technology evaluation program in the purchase of medical equipment is threefold: 1) assuring that biomedical equipment facilitates the delivery of quality patient care, 2) assuring that the equipment purchased meets the needs of all users, and 3) establishing hospital standards for biomedical equipment. Medical technology evaluation occurs in two phases. Phase 1 is in the submission of recommendations for the purchase of new equipment. Phase 2 is the technical and clinical evaluation. This allows the hospital to validate equipment specifications, to assess vendors' qualifications and support services, and users' capacity to deploy the technology and its impact on work practices. The evaluation process addresses pertinent issues regarding the medical equipment safety, user friendliness, and equipment performance history. Based on satisfactory evaluation results and feedback from the technical and clinical staff, a recommendation is made to purchase a specific equipment item.

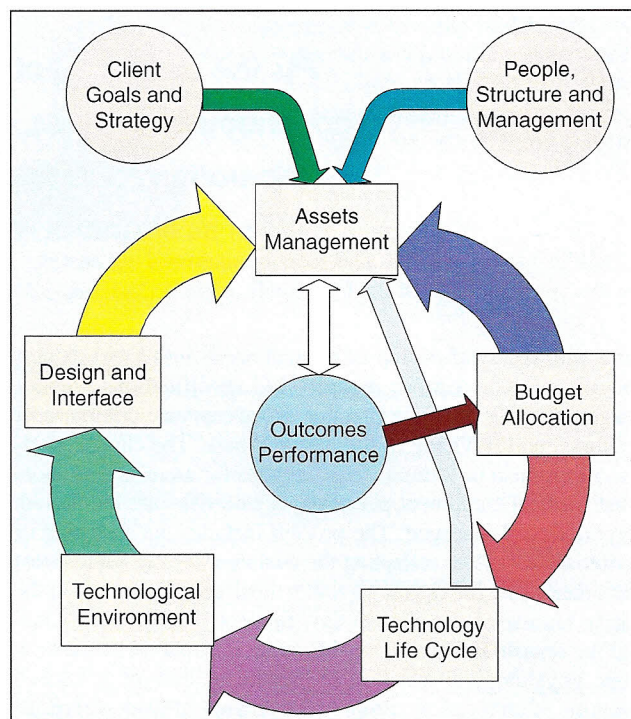


Fig. 2. The medical technology management environment at Texas Children's Hospital.

Following these product evaluation steps facilitates the standardization of the equipment selection process, and, therefore, the standardization of biomedical equipment. This will allow the hospital to obtain superior equipment at a competitive price and, in turn, provide consistent, high-quality patient care [16]. Upon completion of the review, a recommendation is returned to the hospital's Product Standards Committee, which reviews the results of the technology evaluation, determines whether the particular product is suitable as a hospital standard, and decides if it should be purchased. If approved, the request to purchase will be reviewed by the Capital Planning Committee (CPC) to determine if the required expenditure meets with available financial resources of the institution and if or when it may be feasible to make the purchase. To ensure coordination of the technology evaluation program, the chairman of the MTEC also serves as a permanent member of the hospital's CPC. In this way, technology evaluation is integrated with and impact budget decisions.

The Role of a Clinical Engineer

Advances in technology accelerated multidisciplinary approaches to healthcare management [17]. Clinical engineering, a profession based on both engineering and the life sciences, developed in response. The recently created American College of Clinical Engineering (ACCE) provides a better understanding of the profession and defines a clinical engineer as "a professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology" [18].

The role of the clinical engineer is shared between planning for new equipment and optimizing the utilization of the existing inventory [19]. The clinical engineer must be completely familiar with the procurement phase of medical equipment