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Utilization management: A European perspective

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ABSTRACT

Utilization management (UM) in health care, based on the collection, assessment and monitoring of data pertaining to patient services and treatment, ultimately assures efficiency and effectiveness. The central role of laboratory services in modern medicine created the need to utilize UM programs in clinical laboratories in order to reduce costs, enhance efficiency and improve on quality for patients. Some UM programs have focused on improving efficiency by reducing the cost per test. Consolidation and networking have been proposed as opportunities to increase test volumes, thus achieving economy of scale, and a better ratio between test volumes and fulltime equivalent (FTE) staff. However, little evidence is available in the literature to demonstrate the efficiency of these models, and concern has been expressed regarding the possible increase in pre-analytical errors and the loss of efficient communication between clinicians and laboratory professionals. In Europe, we have seen an increasing emphasis on the importance of demand management strategies as the key to reducing costs and improving on quality in laboratory medicine. The cost of inappropriate requesting includes not only test consumables and reagents, but also additional consultations, treatment and investigations. A number of studies in literature describe strategies and initiatives designed to change and improve test requesting, but the following two items are mandatory for real improvement: a) the active involvement of requesting physicians and other stakeholders, including patients; and b) the use of combined interventions instead of a single strategy. Therefore, the use of approaches for demand management that considers pre-, within- and post-laboratory initiatives is on the increase in clinical laboratories throughout Europe.

1. Introduction

Utilization management (UM), a cornerstone in managed care systems, has been described as "an organization-wide, interdisciplinary approach to balancing quality, risk, and cost concerns in the provision of patient care" [1]. Based on the collection, assessment and monitoring of data pertaining to patient services and treatment, the main goal of UM is to maintain the quality and efficiency of health care delivery by caring for patients at the appropriate level, coordinating health care benefits, ensuring the least costly but most effective possible treatment benefit and the provision of medical needs. In an increasingly dominant environment of cost containment and resource shortage, the use of UM is crucial to achieving a balance between efficiency and quality. In particular, a continual dialogue is advocated so as to obviate any risk of decreasing health costs and compromising patient safety [2]. Laboratory services, crucial tools in modern medicine, are essential for the prevention, diagnosis, prognosis and monitoring of human diseases, and the path towards personalized medicine calls for laboratory information to play an ever more dominant role [3]. Thus the laboratory utilization of UM programs has been advocated as an effective means for reducing the total cost of care and enhancing the quality of care in hospitals, medical practices, and, ultimately, patients [4]. While initial programs have focused on increasing efficiency, decreasing the cost per test, and improving staff productivity and other operational criteria [5], current laboratory economics require testing to focus on clinical benefits and, therefore, to be measured on the basis of outcomes [6,7]. The present paper aims to discuss utilization management initiatives in laboratory medicine and future developments from a European perspective.

2. Laboratory medicine: a European viewpoint

The growing pressure on national governments to reduce healthcare costs inevitably impacts on the delivery of medicine worldwide. Clinical laboratories are under pressure to improve quality and provide test results faster while decreasing costs. This ever increasing and difficult task must be undertaken in a setting of rising test volumes, increased test complexity, space constraints and workforce shortage [8]. As automation, increased workload and complex workflows become more dominant, clinical laboratory Directors are faced with new challenges, and clinical laboratories are in the forefront, integrating managerial quality principles such as total quality management (TQM), certification and accreditation according to International Standards [9], Lean and Six Sigma, and Toyota production system, in their operations [10]. The

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results of some surveys, however, highlight the differences between European and US laboratories, which seem to be "good at incident investigations and performing patient and physician satisfaction surveys but poor at clinical guidelines, studying test utilization and assessing test interpretation by physicians" [11]. In Europe, particularly in the UK and Italy, a large number of laboratories provide an advisory and interpretative service to their users both in and out of hours [12,13], as well as issuing and using clinical practice guidelines for extra-analytical issues, such as blood collection and test request [14,15]. Laboratory medicine practice has always been a "business and a profession" [16] but, ideally, a balance should be struck between business and professionalism. Yet, some of our modern environments, dominated by administrative and cost considerations, and the scale index have been upturned in favor of cost-containment initiatives. This change depends in part on evidence that laboratory cost as a whole can be readily quantified; clinical laboratories have thus often become a hot spot for efforts to reduce expenditures in hospitals and health care systems [5].

3. Utilization management in Europe

It has been reported that the use of laboratory diagnostics varies between countries, and different areas of the same country [17]. Large inter-practitioner differences in laboratory utilization do not appear to be explained by the modest demographic differences between the areas or practices concerned or by social factors, such as deprivation [18]. Differences in accessibility to laboratory tests as well as different legal and regulatory frameworks can only partly explain such variations. Therefore, although test use has risen inexorably worldwide over the last two decades, interplay between several factors may explain current differences observed both within the same country and between countries. A high-profile concern is why laboratory expenditure as a percentage of total hospital care is around 4% in the United Kingdom, 5.2% to 6.8% in Australia, approximately 20% in the United States, 7% to 10% in Canada, and 11.7% of primary medical care expenditure in New Zealand [17]. In particular, the evidence that the use of laboratory services in the US is five times greater in proportion than in the UK and almost three times greater than in Canada, seems to be related to the nature of the health care system, which covers all citizens in the UK, Italy and Canada, whilst in the US, particularly before the Obama reform, was essentially based on private insurance schemes [19]. In addition, in the US, but not in most European countries, physician's office laboratory practice and direct-to-consumer (DTC) testing, also known as "direct access testing" (DAT) are widespread [20]. However, in Europe there also large differences between states, the in vitro diagnostic (IVD) market accounting for 0.5% of total healthcare expenditure (THE) in the UK and Netherlands, 0.8% in Germany, Sweden and France, and 1.1% in Spain and Italy [21]. This underlines that any intervention aiming to influence the utilization of laboratory services must be designed in the context of the health-care system in which it is operating. In Europe, in particular in the UK and Italy, the reorganization of laboratory services has been based on the ultimate goal of a patient-centered service which, in turn, should be: a) clinically excellent, b) responsive to users, c) cost-effective and d) consolidated with other elements of the health care system [22]. According to this view, the search for efficiency and cost reduction is counterbalanced by the need for clinical effectiveness, which is based on the evidence of impact on health outcomes and on the laboratory's contribution to the care pathway, as well as to high quality, underpinned by a mandatory accreditation system. In addition, the criteria used by the service to comply with the patient-centered goal are: convenience, accessibility, equitability, personalized approach, effectiveness, and safety. Similar criteria were specified by the Italian Minister of Health on issuing the guidelines for the reorganization of laboratory services in this country [23]. In the document, the criteria of equitability, accessibility as well as quality and safety are highlighted to balance the trend towards consolidation and networking.

4. Utilization management and consolidation of clinical laboratories

Economic pressure and cost containment initiatives have encouraged clinical laboratories to substantially modify their organization by increasing consolidation using fewer sites, and establishing "mega-laboratories" to reach an economy of scale for facing current and future budget restrictions. The achievement of a higher ratio of test volume to fulltime equivalent (FTE) staff should lower the overall test cost and speed up the implementation of innovative technologies [24]. Consolidation and integration of laboratory service networks have been advocated by Health Care Departments in the UK [22], Italy [23], and Belgium [25] as well as in other European countries. However, no evidence has been collected to demonstrate the efficiency of these organizational solutions, as the majority of papers and experiences reported in literature focus on reducing the "cost per test" and, in most cases exclusively, the cost of reagents and instrumentation, thus overlooking the real value of a laboratory service, which requires more complex economic evaluations, such as cost–benefit, cost-effectiveness, and cost utility analysis. Recently, our group published a report on cost evaluation using activity-based costing [26,27] performed in several Italian laboratories in order to throw light on: 1) the relationships between costs and test volumes; 2) the contribution of different variables (human and technological resources) to the final costs, particularly in relation to different test volumes; and 3) any differences between laboratory medicine subspecialties (e.g., clinical chemistry, hematology and coagulation) [28]. The data reported confirm that several variables can affect the costs of an individual laboratory. In particular, while there is a trend towards a decrease of total costs due to increased test volumes, this attains statistical significance only for up to about 1,100,000 tests per year. Once the figure of 1,800,000 tests or more is achieved, the cost per test tends to range from 1.5 to 2.0 € irrespective of the different volumes (Fig. 1). A wide dispersion of data for clinical laboratories with similar activity volumes is clearly present. For example, for laboratories with volumes of around 2 million tests/year, the mean cost per test is 1.90 € (range, 1.54–2.41). At the detailed analysis of the main characteristics of the individual laboratories, differences were not related to a specific variable, such as the presence of a microbiology section, and/or a separate STAT laboratory, the end costs of a specific laboratory being affected by several variables, including the type of user (e.g. complexity of main organization, number and types of specialties in the hospital, number of production facilities of the laboratory and different case mix and ratio between inpatients and outpatients). On considering the relationships between volumes and number of staff, the linear relationship between the number of senior staff and volumes is evident, whereas no such trend exists for medical technologists, for whom the trend appears to plateau; this, in turn, may be explained by the degree and type of automation used, in particular, in high volume clinical laboratories. Some authors have highlighted the severe drawbacks of an organization based on consolidation models. In particular, the increased distance between blood collection facilities and the laboratory might result in longer turn-around-times, an increased risk of pre-analytical errors and, even more serious/importantly, the loss of efficient communication between clinicians and laboratory professionals [25,29,30]. This, which may translate in an over-prescription of laboratory tests, may undo any attempt at scale related saving. Evidence collected in the last decades demonstrates that the pre-analytical phase of the testing process is much vulnerable to errors than all other steps, being the source of up to 70% of all laboratory errors [31]. The increased consolidation and centralization of laboratory diagnostics implies the need to transport a large number of specimens from peripheral collection sites to the core laboratories. Although it is well-known that sample quality may be compromised by exposure to inappropriate temperature and prolonged transportation time, few experiences are available in the literature on this issue. Recently, we have demonstrated that only an integrated transportation system, which uses a tertiary and a secondary container, a data-logger for registering time and temperature at given