

The Necessity of The Establishment of The Laboratory Network And its Characteristics in Developed Countries

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Medical Laboratories: Networking and Referral System

The transition from traditional **fee-for-service** reimbursement to **global budgets** for medical services will strongly incentivize providers to control unnecessary utilization.

Ancillary services including Radiology and Medical Laboratory testing are frequent **targets of utilization management:**

- generally perceived to be over-utilized
- because they can be readily quantified
- Utilization management almost always works!

Laboratory practice and Utilization Program

- ✓ **Practicing to volume: performing more tests and charging for higher test volumes**
- ✓ **Practicing to value: performing only the necessary tests has been termed**
- ✓ **Utilization programs are a growing part of shifting the culture of laboratory medicine from practicing to volume, to practicing to value.**

Terminology C. Snozek et al. / Clinica Chimica Acta 427 (2014) 118–122

Overuse. Overuse occurs when a service is provided even though its risk of harm exceeds its likely benefit—that is, when it is not warranted on medical grounds.

استفاده بیش از حد: استفاده بیش از حد زمانی رخ می دهد که یک سرویس حتی اگر ریسک آسیب آن بیش از احتمال سود آن باشد، حتی هنگامی که دلایل پزشکی موجه ای برای آن نیست. گفته می شود

Underuse. At the same time that some services are overused, others do not get provided even though they would have been medically beneficial.

Underuse: در همان زمان که برخی از خدمات بیش از حد مورد استفاده هستند، سایر خدمات ارائه نشده است، حتی اگر آنها از نظر پزشکی مفید بوده است.

Misuse. That term includes incorrect diagnoses as well as medical errors and other sources of avoidable complications.

سوء استفاده: این اصطلاح شامل تشخیص های نادرست و همچنین خطاهای پزشکی و دیگر منابع عوارض و مشکلات که قابل اجتناب است.

Utilization management. Utilization management (UM) represents a broad array of techniques designed to influence the consumption of health care services, usually with the objective of promoting Cost containment

مدیریت بهره برداری: مدیریت بهره برداری نشان دهنده یک نظم و چیدمان گسترده ای از تکنیک های طراحی شده برای دخالت در مصرف خدمات بهداشتی و درمانی می باشد که معمولاً با هدف ترویج مهار هزینه ها می باشد.

Efficiency and effectiveness. “In the management literature, efficiency is often associated with performing activities as well as possible or ‘doing things right’ whereas effectiveness is often equated with the proper selection of the activities or ‘doing the right things’ “The United States Congressional Budget Office”

بهره وری و اثربخشی: "در ادبیات مدیریت، بهره وری اغلب با انجام فعالیت هایی که هر چه بهتر ممکن است انجام شود و یا "انجام درست کارها، اطلاق شده است، در حالی که اثربخشی است اغلب با انتخاب مناسب از فعالیت ها و یا انجام کارهای درست برابر

A Toolbox for Laboratory Utilization Management Tactics

A. Huck, K. Lewandrowski / Clinica Chimica

Acta 427 (2014) 111–117

- ✓ **Physician education**
 - Practice guidelines
 - Posting test costs
 - Physician profiling
- ✓ **Imposing limitations on testing**
 - Discontinue obsolete tests (banning)
 - Use of gatekeepers
 - Establish a laboratory formulary
- ✓ **Order entry**
 - Decision support
 - Testing guidelines
 - Use of “pop-ups”
- ✓ **Clinical pathology consultation services**
- ✓ **Financial motivation**
- ✓ **Structural changes**
- ✓ **Auditing utilization**
 - ✓ **Benchmarking against peer organizations**

Consolidation of pathology services

Provided by: Department of Health

Summary

Large-scale service consolidation in pathology, as recommended by the Independent Review of NHS Pathology Services, would provide improved service quality, responsiveness and cost effectiveness. 160 current services could be reduced to between 1 and 3 in each SHA. This would result in greater purchasing power, better utilisation of equipment, more effective management of workload and better deployment of staff. Savings of £4–5 million have been made by one network.

Evidence summary

- Yes The intervention has been successfully implemented
- No The intervention has been successfully replicated
- No The intervention is linked to standards or guidance
- Yes The intervention is supported by one or more national organisations
- No An evaluation of the effects of the intervention has been carried out
- Yes There are publications relating to this intervention

The proposal

Proposal description	Greater consolidation of pathology services to improve quality and release productivity gains of up to £500 million per year.
Purpose of change	The Independent Review of NHS Pathology Services showed wide variation in costs per investigation, based on costing and data analysis at 12 trusts. The main factors were scale of operation (and the associated economies of scale) and the way in which staff were deployed.

Regionalization/Networking: THE SPECIFIC GOALS

- ✓ No duplication of lab resources.
- ✓ **Equality.** labs must operate on an even playing field.
- ✓ Economies of scale.
 - Pooling of the technologic prowess of a community's individual labs can create economies of scale by combining testing capacities.
 - Networks can also lower unit costs by increasing the test volume.
- ✓ Logistical support.
- ✓ Continuity of care.
- ✓ Compatible data.
- ✓ Universal principles

Why Implement a Laboratory Network?

improve laboratories' quality/cost/efficiency ratio

✓ Quality:

- Centralized supply of quality controlled reagents
- National quality assurance program
- Staff receive refresher on **critical issues**
- National data management system

✓ Cost:

- Reorganization of the laboratories → optimization of all working conditions, workload
- and analytical processes → economy
- Centralized supply of reagents → economy of scale
- Preventive maintenance policy → increased equipment lifespan

✓ Efficiency:

- Sample transportation instead of patient transportation (if any)
- Improved data management
- Improved links between laboratories and disease surveillance systems
- Improvement of the prescription/interpretation of medical analysis

Risks of Laboratory Networking

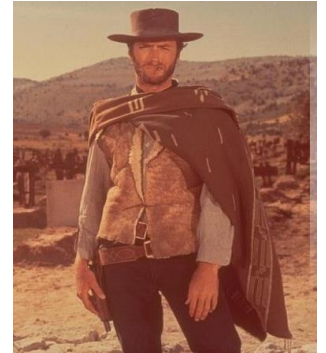
- ✓ **Reduced Competition (Managed competition).**
- ✓ **Financial risks.**
- ✓ **Pre-analytic errors.**
- ✓ **Induced demands!**

Laboratory Test Utilization: The Good, the Bad and the Overused

The Good, The Bad & The Ugly

- **A 'Good' test:**

- **Provides information that is useful in patient management decisions**
 - **Screening: High sensitivity & NPV**
 - **Diagnosis: High specificity & PPV**



- **A 'Bad' test:**

- **Uses resources but fails to provide information useful in patient management decisions**



- **The 'Ugly' test:**

- **Uses resources and provides information that is misleading or irrelevant**



Causes of Test Overutilization*

- Ordering **test panels** rather than ala carte'
 - Ordering tests **as groups**
- Repetitive test orders (esp. normal results)
- Incomplete understanding re: impact of low pre-test probability
- Poor understanding of the consequences of overutilization
- Patient pressure
- Defensive testing
- **Perverse financial incentives (more tests = more revenue)**

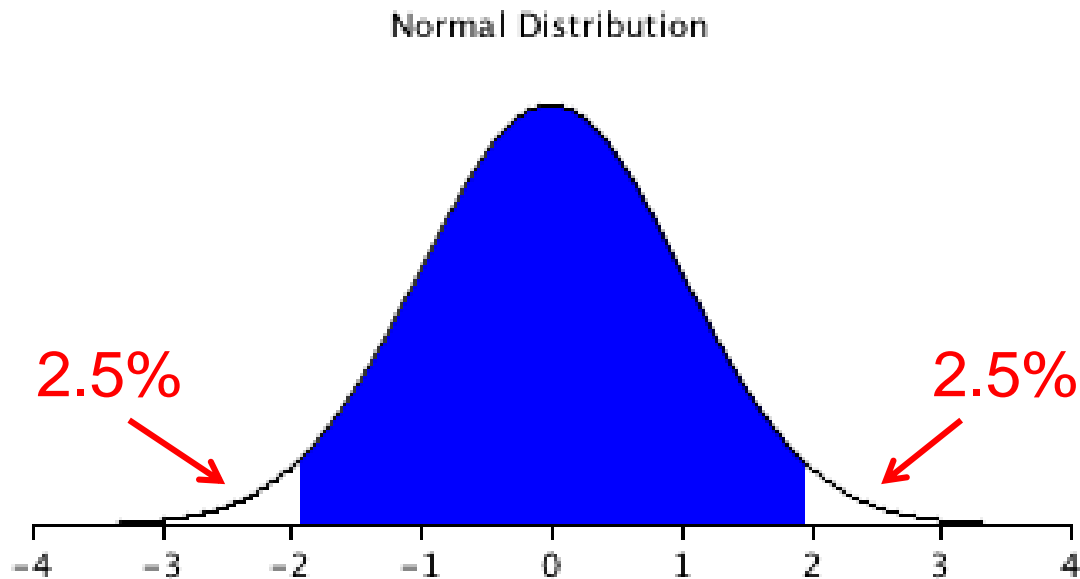
* Astion ML. 2006. Interventions that improve laboratory utilization: from gentle guidance to strong restrictions. *Laboratory Errors and Patient Safety*. 2(4):8-9

Problems with Test Over-utilization

- **Patient issues**
 - **Pain & morbidity from repeated venipunctures**
 - **Iatrogenic anemia**
- **Medical issues**
 - **Follow-up on clinically irrelevant abnormalities**
 - **Tracking just the 'numbers' instead of the entire clinical picture**
 - **Instituting inappropriate therapies**
- **Economic & Environmental issues**
 - **Lack of reimbursement for inpatient testing**
 - **Biohazardous waste generation**

Irrelevant 'abnormals'

- **Virtually all quantitative laboratory test 'normal ranges' are based on the mean \pm 2 SD (95% confidence interval) for a subject population**



- **5% of normal patients will have values that lie outside this range (magnified for ill patients)**

Irrelevant 'abnormals'

- If a patient has 10 tests ordered, each with a 5% chance that the test may have a result outside the normal range. Then there is a **50% chance** that at least one test will have an **'abnormal'** result
- This is especially true with ordering **chemistry 'panels'**

Economics & Environment

- **The vast majority of inpatient care is covered by DRG or per diem payments**
 - **Laboratory tests are not individually reimbursed and merely represent cost against the what the hospital is paid**
- **The 3 UCSF Clinical Laboratories generate approx. 11,500 lbs of biowaste per month**
 - **Cost to incinerate this waste is approx. \$88K per year**

The Solution?

- **Approaches that have been tried**
 - **Place limits on house-staff orders**
 - **Provide information on test costs**
 - **Requisition design**
 - **EMR warnings and reminders**
 - **Education**
 - **Incentives**

Factors that Impact Laboratory Test Results & Interpretation

- **Pre-analytic issues**
- **Diagnostic testing issues**
 - **Pre-test probability**
 - **Appropriateness of test in your patient**
 - **Impact of the test result on care decisions**
 - **Chasing 'diagnostic certainty'**
 - **Impact of other disorders, therapy on results**
- **Monitoring issues**
 - **Which test is going to be used?**
 - **How fast does the test change?**
 - **What is the impact of monitoring on clinical care?**

Helping laboratories meet the evolving demands of a modern Laboratory service

- ✓ The consolidation of hospital testing facilities has resulted in the creation of “mega labs” that serve larger populations
- ✓ The emergence of specialty testing centers is shifting certain types of tests to laboratories with specialist or proprietary diagnostic capabilities.
- ✓ **Demographic changes** are leading to heavier workloads as ageing populations increase the demand for hospital care and more medical tests. This trend is predicted to escalate over the next decade.

The Pathology and Laboratory Medicine in the UK

The majority of UK laboratory services are **based in NHS hospitals**. They provide a comprehensive range of services both to the hospital and to the local primary care sectors. There are approximately **250 NHS hospitals providing laboratory services** for the 60 million people of the UK and so in comparison to much of Western Europe and the USA the pathology and laboratory medicine services have been organized around a relatively small number of large centers. Traditionally, laboratories have provided a **24/7 service** for clinical biochemistry, hematology and blood transfusion. Core laboratory services for microbiology and histopathology have been provided at most hospitals, although not always on a **24/7 basis**. **Specialized laboratory services** have been provided from a small number of **expert centers**, normally based in teaching hospitals. Various systems have evolved for **sample collection** and report delivery from and **to the primary care sector**; the local laboratory has usually taken responsibility for management of this service.

The Pathology and Laboratory Medicine in the UK

- ✓ This model of pathology and laboratory medicine service provision has enabled all NHS laboratories to **benefit from economies of scale**. It has also created **a tight knit community of senior professionals who collaborate rather than compete**. National workforce planning has been developed and although not perfect it does mean that in comparison to other developed countries there are few problems with the recruitment or retention of staff to work in laboratory services.
- ✓ The four Departments of Health in the UK have determined that all pathology and laboratory medicine services **should be registered with an approved laboratory accreditation body**. The overwhelming majority of NHS laboratories are registered with and accredited by Clinical Pathology Accreditation (UK) Ltd, which uses standards benchmarked against **ISO 15189**.
- ✓ **Private laboratory medicine** services in the UK have been **small in number**, mainly associated with small private hospitals with specialised services provided from London-based centres. Private laboratory medicine services operate to the same accreditation standards as their NHS equivalents.

The Pathology and Laboratory Medicine in the UK

- ✓ Within the NHS pathology and laboratory medicine services have evolved with a strong clinical element based on **highly qualified senior staff**. Medical consultants provide direct patient care within hospitals and clinical advice on patient management to all users. They also contribute actively to clinical audit and **multidisciplinary team meetings**. In clinical biochemistry and other disciplines clinical scientists attain the same high level qualification as medical consultants (Membership of the Royal College of Pathologists, MRCPPath) and many are regarded as medical consultant equivalents. Clinical scientists undertake most of the reporting and clinical liaison, many are specialists who lead the collaborative
- ✓ Research and development that takes place within the NHS and many are **involved in high level laboratory management**. The analytical work of the laboratory is undertaken by biomedical scientists who are all graduates and many have postgraduate qualifications to Masters level. Finally, there are assistant grades who have less formal education but who perform vital tasks, usually narrow in range, working under supervision.

The Pathology and Laboratory Medicine in the UK

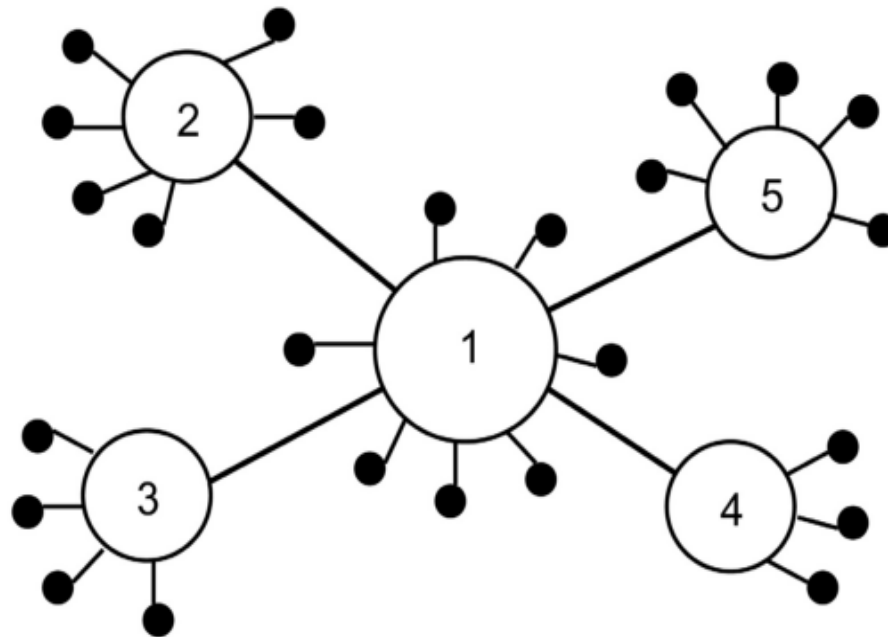


Figure 1. Illustration of the hub and spoke or disseminated laboratory medicine network. Numbers 1 to 5 represent laboratories on different sites that share common equipment, reference ranges and quality management system. All laboratories provide a common core service and specialised laboratory services are rationalised in line with clinical services. Small black circles represent centres outside the laboratory where laboratory testing is performed using point of care testing.

Recommendations the priorities for change:

- **The development of a national specification for improving quality**
- **The creation of stand-alone pathology service providers**
- **End to end IT connectivity, including where possible POCT**
- **A national tariff system for reimbursement**
- **Integrated service improvement and large scale workforce change**
- **Development of stronger clinical leadership**

Toward a new business model for the operational organization of clinical laboratory services: consolidation, integration, networks, and virtual laboratories

- **Consolidation and integration (e.g., in networks) of laboratory services has a number of benefits:**
 - ✓ **Excess capacity, fragmentation, and redundancy are decreased**
 - ✓ **The exploitation of process expertise knowledge is facilitated**
 - ✓ **Existing fixed costs of plants and equipment are spread over a larger base.**
 - ✓ **Higher analysis volume lowers the unit cost and speeds up the diffusion of (expensive) state-of-the-art technology**
 - ✓ **The turn-around time improves, allowing more rapid diagnosis.**
 - ✓ **Improve Cost and quality \longrightarrow efficiency**

THE ROLE OF THE BIOMEDICAL LABORATORY SCIENTIST IN THE FUTURE HEALTH SERVICE

- ✓ **LABORATORY MEDICINE**
 - Increased automation and use of new and more specialized analytical methods.
- ✓ **TECHNOLOGICAL DEVELOPMENT**
 - Technological developments make it increasingly important that biomedical laboratory scientists possess specialized knowledge in method development and validation.
- ✓ **DIAGNOSTIC PARTNERS**
 - Biomedical laboratory scientists as diagnostic partners can provide guidance and secure quality.
- ✓ **CONSULTANTS**
 - Greater need for biomedical laboratory scientists providing guidance and training in point of care testing and patients' self testing.
- ✓ **MANAGEMENT**
 - More biomedical laboratory scientists are heading clinics.
- ✓ **FLEXIBILITY**
 - Shared instrumentation and changed professional boundaries entails a need for greater flexibility in the tasks of biomedical laboratory scientists.
- ✓ **POINT OF CARE TESTING**
 - Point of care testing and patient's self testing will increase as a supplement but not replace the need for centralized laboratory services.

Conclusion

- The mission of clinical laboratory medicine is to improve patient care by improving laboratory testing. If the discipline wants to be positioned strategically for the future, it must enhance efficiency by consolidation, formation of alliances or partnerships, and (horizontal and vertical) integration. **Efficiency is a prerequisite for success**, but not a guarantee. The relevant standard is value .To add value, the core competency of laboratory professionals must be refocused on providing additional knowledge services related to in vitro diagnostic services

مقایسه ساختار و نظام ارائه خدمات آزمایشگاهی

ایران	کانادا	ترکیه	آمریکا	آلمان	Index
Government	CSMLS	Government	CMS CAP.FDA	IFCC	نظام اعتبار بخشی آزمایشگاهها
National	National-ISO 15189	National-ISO 15189	CLIA Lows, CLSI	National-ISO 15189	استاندارد های آزمایشگاهی
Does not exist	CSMLS	Does not exist	ASCP,AAB	IFCC	نظام ارزیابی صلاحیت و اعتبار بخشی کارکنان آزمایشگاهها
Does not exist-Fragmented	Lab.Networking	Lab.Networking	Lab.Networking	Lab.Networking	نظام ارائه خدمات آزمایشگاهی (دولتی و خصوصی)
Governmental	governmental &NGO	governmental	governmental &NGO	governmental &NGO	نظام تعرفه گذاری خدمات آزمایشگاهی
fee-for-service retrospective	global budgets Prospective	global budgets Prospective	global budgets Prospective fee-for-service	global budgets Prospective	نظام باز پرداخت هزینه خدمات آزمایشگاهی
???	High	Good	High	High	quality/cost/efficiency ratio
???	High	Good	High	High	cost-effective laboratory testing
No	Yes	Yes	Yes	Yes	نظام ارجاع و پزشک خانواده
NO	Yes	Yes	Yes	Yes	Laboratory Utilization Management

Thank you!

