Università degli Studi di Padova
Scuola di Specializzazione in Biochimica Clinica (A.A. 2005-2006)
INDIRIZZI: DIAGNOSTICO E ANALITICO TECNOLOGICO

Biochimica Clinica e Biologia Molecolare Clinica:
automazione ed informatica in Biochimica Clinica
area D SSD BIO/12 ex E05C ore 20 anno IV
-OBIETTIVO FORMATIVO: Acquisire le conoscenze informatiche per la gestione del laboratorio

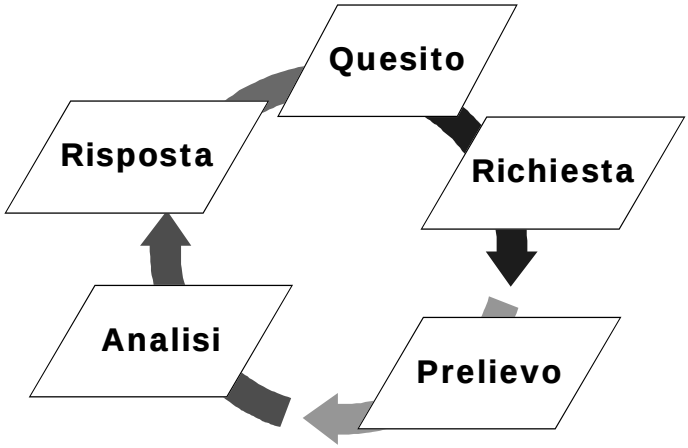
correzione, verifica e validazione dei risultati

Marco Pradella
Castelfranco Veneto

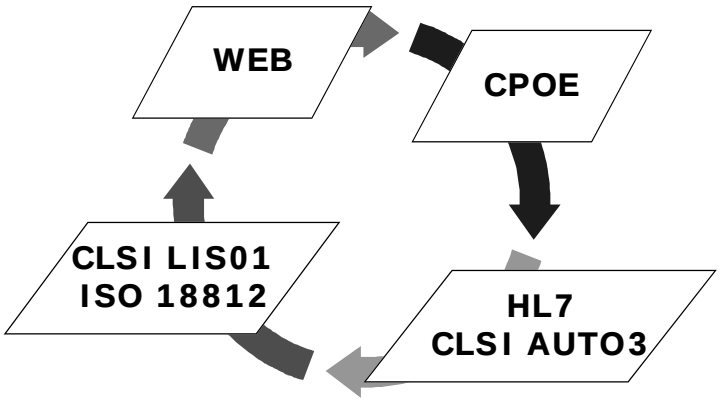
correzione, verifica e validazione

- flusso, ciclo, cicli e deragliamenti
- verifiche e algoritmi
- autoverifica

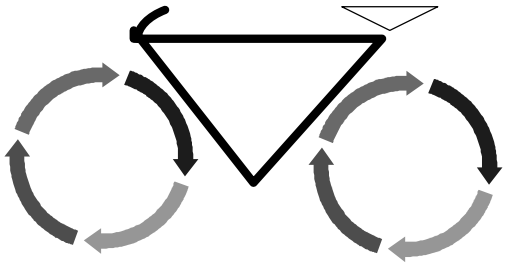
il ciclo richiesta-risposta



“. . . connettività . . .”

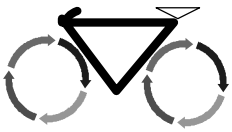


il ciclo richiesta-risposta



The Request-Report Cycle

The Request-Report Cycle: Are the wheels coming off?



Dr Jonathan Kay

jonathan.kay@ndcls.ox.ac.uk

CPD4IT 'Getting ahead of the IT Curve"
Monday, 18 October 2004

Jonathan Kay

Inevitable changes beyond our control

- **Increased discontinuities**
  - **•New models of healthcare provision**
  - **•Shorter working hours**
  - **•From doctors to nurses…**
- **Clinicians will have less experience…**
  - **•… but more formal accreditation**
  - **•… and a need for lifelong learning**
- **From clinicians to protocols…**
  - **•… some of which might be evidence-based**
- **More investigations/ patient/ year**

Jonathan Kay

Cambiamenti ineluttabili fuori dal nostro controllo

- **Discontinuità**
  - **• nuovi modelli assistenza**
  - **• riduzione ore di lavoro**
  - **• da medici a infermieri…**
- **Clinici con meno esperienza…**
  - **•… ma più accreditamento formale**
  - **•… e necessità di apprendimento continuo**
- **Dai clinici ai protocolli…**
  - **•… solo alcuni basati su evidenza**
- **Più esami per paziente e per anno**

Jonathan Kay

Problems with reports

Do they get to the **right person** at the **right time**?

- Responsibility
- Choice of medium
- Timeliness (and QC of timeliness)

Are they **interpreted** appropriately?

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Problemi con risposte

Alla persona giusta nel tempo giusto?

- Responsabilità
- Mezzo di trasmissione
- Tempestività e QC della tempestività

Sono interpretate correttamente?

Jonathan Kay

Reports

- Results and **knowledge**
- **access**
  - –Paper
  - –Computer access
  - –Browser access
- "Push" and "pull" (and **continuity** of care)
- Escalation (and **continuity** of care)
- **Mobile** devices

Jonathan Kay

Risposte

- risultati e conoscenza
- **accesso**
  - –carta
  - –computer
  - –browser (intranet)
- "spedizione" o "scarico" (==> **continuità assistenziale**)
- "escalation" (==> **continuità assistenziale**)

  Meeting Palliative Care Needs in Post–Acute Care Settings "To Help Them Live Until They Die" Laura C. Hanson, MD, MPH; Mary Ersek, PhD, RN JAMA. 2006;295:681-686.

  "To improve continuity of care, we outline communication of treatment goals and orders that anticipate symptom escalation"
- **dispositivi mobili**

preliminary reports in (CAP) Checklists

- **MIC.15000**
- **When indicated, are preliminary reports promptly generated?**
  - COMMENTARY: Results of cultures should be reported promptly to provide clinically useful information. The quality of service should be improved by submitting timely preliminary reports based on the initial reading of direct smears or wet mounts of infectious materials or the first reading of culture plates.
  -

immediate notification in (CAP) Checklists

- **MIC.15150 Phase II N/A YES NO**
- **Are documented criteria established for immediate notification of a physician or other clinical personnel responsible for patient care when results of certain tests exceed alert limits important for prompt patient management decisions?**
  - *NOTE: May be indicated either in the procedure manual and/or in a separate manual. The **bench technologists** must be familiar with alert limits for procedures that they perform.*
    - COMMENTARY: The microbiology laboratory must have documented criteria for the immediate notification of a physician or other clinical personnel when results of certain tests exceed alert limits. While sometimes informally known as "panic values," these are better described as "alert," "critical" or "life-threatening" data that usually require prompt patient management action by a clinician. These are best developed by the laboratory in consultation with user clinicians, and must be published. These may be indicated in the procedure manual and/or in a separate manual or policy. The bench technologists must be familiar with alert limits for procedures that they perform.
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immediate notification in (CAP) Checklists

- REFERENCES: 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24):[42CFR493. 1251(b)(13); 493.1291(g)]; 2) Steindel SJ, Heard NV. Critical values: data analysis and critique. Q-Probes 92-04. Northfield, IL: College of American Pathologists, 1992; 3) Kost GJ. Using critical limits to improve patient outcome. *Med Lab Observ.* 1993;25(3):22-27; 4) Tate KE, Gardner RM. Computers, quality, and the clinical laboratory: a look at critical values. *Proc Annu Symp Comput Appl Med Care.* 1993;193-197; 5) Kaufman HW, Collins C. Notifying clients of lifethreatening results. *Med Lab Observ.* 1994;26(8):44-45; 6) Lum G. Evaluation of a laboratory critical limit (alert value) policy for hypercalcemia. *Arch Pathol Lab Med.* 1996;120:633-636; 7) Emancipator K. Critical values. ASCP practice parameter. *Am J Clin Pathol.* 1997:108:247-253; 8) Dalton- Beninato K. Critical value notifications are never welcome news. *Lab Med.* 2000;31:319-323; 9) Howanitz PJ, *et al*. Laboratory critical values policies and procedures. A College of American Pathologists Q-probes study in 623 institutions. *Arch Pathol Lab Med.* 20002;126:663-669.
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alert values

- **MIC.15200 Phase II N/A YES NO**
- **Is there documentation of prompt notification of the physician (or other clinical personnel responsible for patient care) of results of all alert values?**
  - *NOTE: In addition, the laboratory should document any failure of attempts to notify the appropriate person of alert results, and document the action taken to prevent recurrence of this problem.*
    - COMMENTARY: Records must be maintained indicating the notification of the appropriate clinical individual promptly after observing results in an alert range. These records should include: date, time, responsible laboratory individual, person notified and test results. In addition, the laboratory should document any failure of attempts to notify the appropriate person of alert results, and document the action taken to prevent recurrence of this problem.
      - REFERENCES: 1) Kost GJ. Critical limits for urgent clinician notification at US medical centers. *JAMA*. 1990;263:704-707; 2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24): [42CFR493.1251(b)(13); 493.1291(g)]; 3) Steindel SJ, Heard NV. Critical values: data analysis and critique. Q-probes 92-04. Northfield, IL: College of American Pathologists, 1992; 4) Kost GJ. Using critical limits to improve patient outcome. *Med Lab Observ.* 1993;25(3):22-27; 5) Dalton-Beninato K. Critical value notifications are never welcome news. *Lab Med.* 2000;31:319-323.
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"alert" or "critical" ranges in (CAP) Checklists

- **GEN.41320**
- **Does the laboratory have procedures for immediate notification of a physician (or other clinical personnel responsible for patient care) when results of certain tests fall within established "alert" or "critical" ranges?**
  - *NOTE: This includes results received on specimens sent to reference laboratories for testing. Alert or critical values are those results that may require rapid clinical attention to avert significant patient morbidity or mortality. These values should be defined by the laboratory director, in consultation with the clinicians served.*
    - REFERENCES: 1) Kost GJ. Critical limits for urgent clinician notification at US medical centers.*JAMA.* 1990;263:704-707; 2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24): [42CFR493.1291(g)]; 3) Steindel SJ, Heard NV. Critical values: data analysis and critique. Q-Probes 92-04. Northfield, IL: College of American Pathologists, 1992; 4) Kost GJ. Using critical limits to improve patient outcome. *Med Lab Observ.* 1993;25(3):22-27; 5) Tate KE, Gardner RM. Computers, quality, and the clinical laboratory: a look at critical values. Proc Annu Symp Comput Appl Med Care. 1993;193-197; 6) Kaufman HW, Collins C. Notifying clients of life-threatening results. *Med Lab Observ.* 1994;26(8):44-45; 7) Emancipator K. Critical values. ASCP practice parameter. *Am J Clin Pathol.* 1997:108:247-253.
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unusual or inconsistent results in (CAP) Checklists

- **MIC.21950 Phase I N/A YES NO**
- **Does the procedure manual address unusual or inconsistent antimicrobial testing results?**
  - *NOTE: Acceptable results derived from testing QC strains does not guarantee accurate results with all patient isolates. When unusual or inconsistent results are encountered with patient isolates, the results should be investigated further to ensure accuracy. For example, repeat testing and/or repeat identification procedures using an alternative method (if possible) should be performed in an effort to ensure accurate results. Some examples include:*
    - *1. Escherichia coli that appears resistant to imipenem*
    - *2. Klebsiella spp. susceptible to ampicillin*
    - *3. Proteus mirabilis resistant to ampicillin*
    - *4. Staphylococcus aureus resistant to vancomycin*
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unusual or inconsistent results in (CAP) Checklists

- REFERENCES: 1) NCCLS. Methods for dilution antimicrobial susceptibility tests for bacteria that grow aerobically - sixth edition; approved standard M7-A6. Wayne, PA: NCCLS, 2003; 2) NCCLS. Performance standards for antimicrobial disk susceptibility tests - eighth edition; approved standard M2-A8. Wayne, PA: NCCLS, 2003; 3) NCCLS. Analysis and presentation of cumulative antimicrobial susceptibility test data; approved guideline M39-A. Wayne PA: NCCLS, 2002; 4) NCCLS. Aerobic dilution supplemental tables; thirteenth informational supplement M100-S13. Wayne, PA: NCCLS, 2003.
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gram-stained smear for acceptability

- **MIC.22100**
- **Is a gram-stained smear performed routinely on all expectorated sputa to determine acceptability of a specimen for bacterial culture or the extent of culture workup?**
  - COMMENTARY: A gram-stained smear should be routinely performed on all expectorated sputa to determine acceptability of a specimen for bacterial culture or the extent of culture workup.
    - REFERENCES: 1) Valenstein PN. Semiquantitation of bacteria in sputum Gram stains. *J Clin Microbiol.* 1988;26:1791-1794; 2) Miller JM, *et al.* Specimen collection, transport, and storage. In: Murrary PR, *et al*, ed. *Manual of Clinical Microbiology*, 8th ed. Washington, DC: ASM Press; 2003:55-66; 3) Baron, *et al.* Infectious disease physicians rate microbiology services and practices. *J Clin Microbiol.* 1996;34:496-500; 4) Wilson ML. Clinically relevant, cost-effective clinical microbiology. Strategies to decrease unnecessary testing. *Am J Clin Pathol.* 1997;107:154-165; 5) Merrick ST, *et al.* Comparison of induced versus expectorated sputum for diagnosis of pulmonary tuberculosis by acid-fast smear. *Am J Infect Control.* 1997;25:463-433; 6) Namias N, *et al.* A reappraisal of the role of gram's stain of tracheal aspirates in guiding antibiotic selection in the surgical intensive care unit. *J Trauma.* 1998;44:102-106; 7) Al-Moamary M. *et al.* The significance of the persistent presence of acid-fast bacilli in sputum smears in pulmonary tuberculosis. *Chest.* 1999;116:726-731; 8) Church DL. Are there published standards for Gram stain results for sputa to establish specimen quality for culture? College of American Pathologists CAP Today. 2000;14(4):97.
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unacceptable sputum notified

MIC.22110

Are unacceptable sputum samples not cultured (or cultured only by special request) and is the clinician or nursing station notified so another specimen can be collected without delay?

NOTE: It is suggested that the laboratory notify an appropriate caregiver about an inadequate specimen even in an outpatient setting, such as a reference laboratory. Notification can be by phone or computer report.

COMMENTARY: Unacceptable sputum specimens should not be cultured, and/or the clinician or nursing station should be notified of unacceptable specimens so another sample can be collected without delay.

REFERENCES: 1) Bartlett RC. Medical microbiology: quality cost and clinical relevance. New York, NY: Wiley, 1974:24-31; 2) Carroll KC. Laboratory Diagnosis of Lower Respiratory Tract Infection: Controversy and Conundrums. *J Clin Microbiol*. 2002;3115-3120.

CSF gram stains reported

MIC.22510

Are gram stains done routinely, and positive results reported in accordance with laboratory policy for alert values?

COMMENTARY: Smears must be prepared routinely, gram stains done and positive results reported in accordance with laboratory policy for alert values.

REFERENCE: Dunbar SA, *et al.* Microscopic examination and broth culture of cerebrospinal fluid in diagnosis of meningitis. *J Clin Microbiol.* 1998;1617-1620.

blood culture reported

- **MIC.22620**
- **Are initial positive cultures reported in accordance with laboratory policy for alert values?**
  - COMMENTARY: An initial positive blood culture must be reported in accordance with laboratory policy for alert values.
  -

wound gram stains reported

- **MIC.22710**
- **Are gram stains of direct smears examined and results routinely reported, when indicated?**
  - *NOTE: Gram stains are used to evaluate specimen quality and guide the work-up of the specimen. Examination of the smear may reveal morphotypes of the organisms present, acute inflammatory cells and squamous epithelial cells.*
  -

acid-fast stains reported

- **MIC.31200 Phase I N/A YES NO**
- **When clinically indicated, are results of acid-fast stains reported within 24 hours of specimen receipt by the testing laboratory?**
  - COMMENTARY: When clinically indicated, the results of acid-fast smears should be reported within 24 hours of specimen receipt in the testing laboratory.
    - REFERENCES: 1) Huebner RE, *et al.* Current practices in mycobacteriology: results of a survey of state public health laboratories. *J Clin Microbiol.* 1993;31:771-775; 2) Tenover FC, *et al.* The resurgence of tuberculosis: is your laboratory ready? *J Clin Microbiol.* 1993;31:767-770; 3) Woods GL, *et al.* Mycobacterial testing in clinical laboratories that participate in the College of American Pathologists mycobacteriology surveys. Changes in practices based on responses to 1992, 1993, and 1995 questionnaires. *Arch Pathol Lab Med.* 1996;120:429-435.
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