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19 oktober 2017

FAECES DIAGNOSTIEK

Diagnostisch scenario

Clinical Chemistry 46:8
1041–1050 (2000)

Review

Evidence-based Laboratory Medicine: Supporting Decision-Making

CHRISTOPHER P. PRICE

There is an implicit acceptance that an evidence-based culture underpins the practice of laboratory medicine, in part because it is perceived as the scientific foundation of medicine. However, several reviews of specific test procedures or technologies have shown that the evidence base is limited and in many cases flawed. One of the key deficiencies in the scientific literature on diagnostic tests often is the absence of an explicit statement of the clinical need, i.e., the clinical or operational question that the use of the test is seeking to answer. Several reviews of the literature on specific procedures have also demonstrated that the experimental methodology used is flawed with, in some cases, significant bias being introduced. Despite these limitations it is recognized that a more evidence-based approach will help in the education and training of health professionals, in the creation of a research agenda, in the production of guidelines, in the support of clinical decision-making, and in resource allocation. Furthermore, as know

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these developments.

controlled trials as the only means of meeting rigid criteria on acceptable evidence and the demise of the expert opinion *(3)*. However, the rhetoric that surrounds the debate on evidence-based medicine needs to be put into context, recognizing that the burgeoning levels of knowledge and the increasingly multidisciplinary nature of healthcare are placing increasing demands on all practitioners *(4)*.

Interestingly, to date evidence-based medicine appears to have had limited impact in the sphere of laboratory medicine. Furthermore, there are some data to suggest that adherence to criteria for the use of robust evidence in scientific papers on the use of diagnostic tests is poor *(5)*. Laboratory medicine also provides some of the more overt examples of practice lacking a good foundation of evidence—perhaps the best examples being the variations seen in testing strategies between different hospitals for the same clinical presentations *(6, 7)*. It is therefore hardly surprising that there are ardent critics of laboratory med-

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greatest challenge to laboratory medicine is the suggestion that diagnostic tests are not perceived to have a major

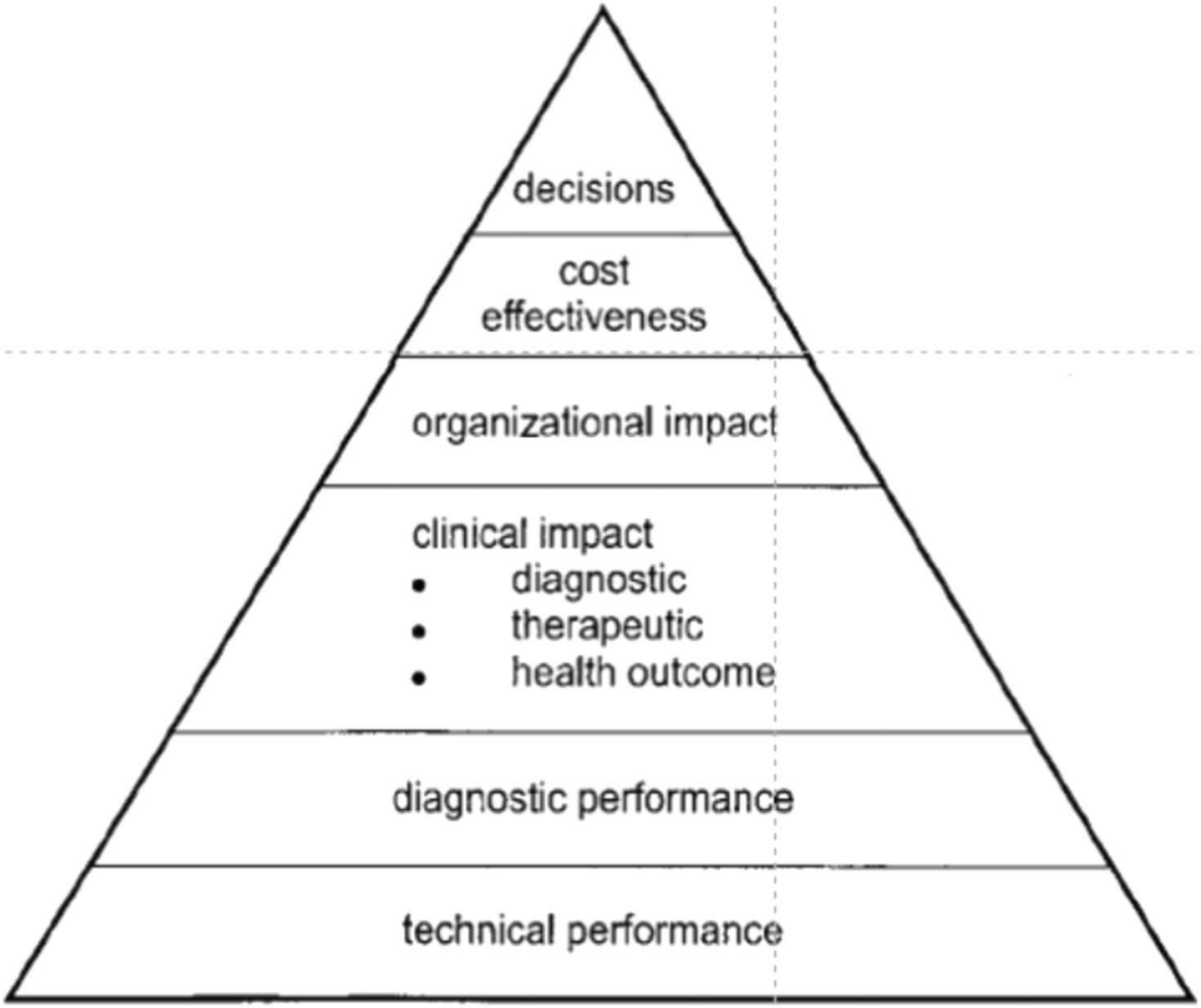


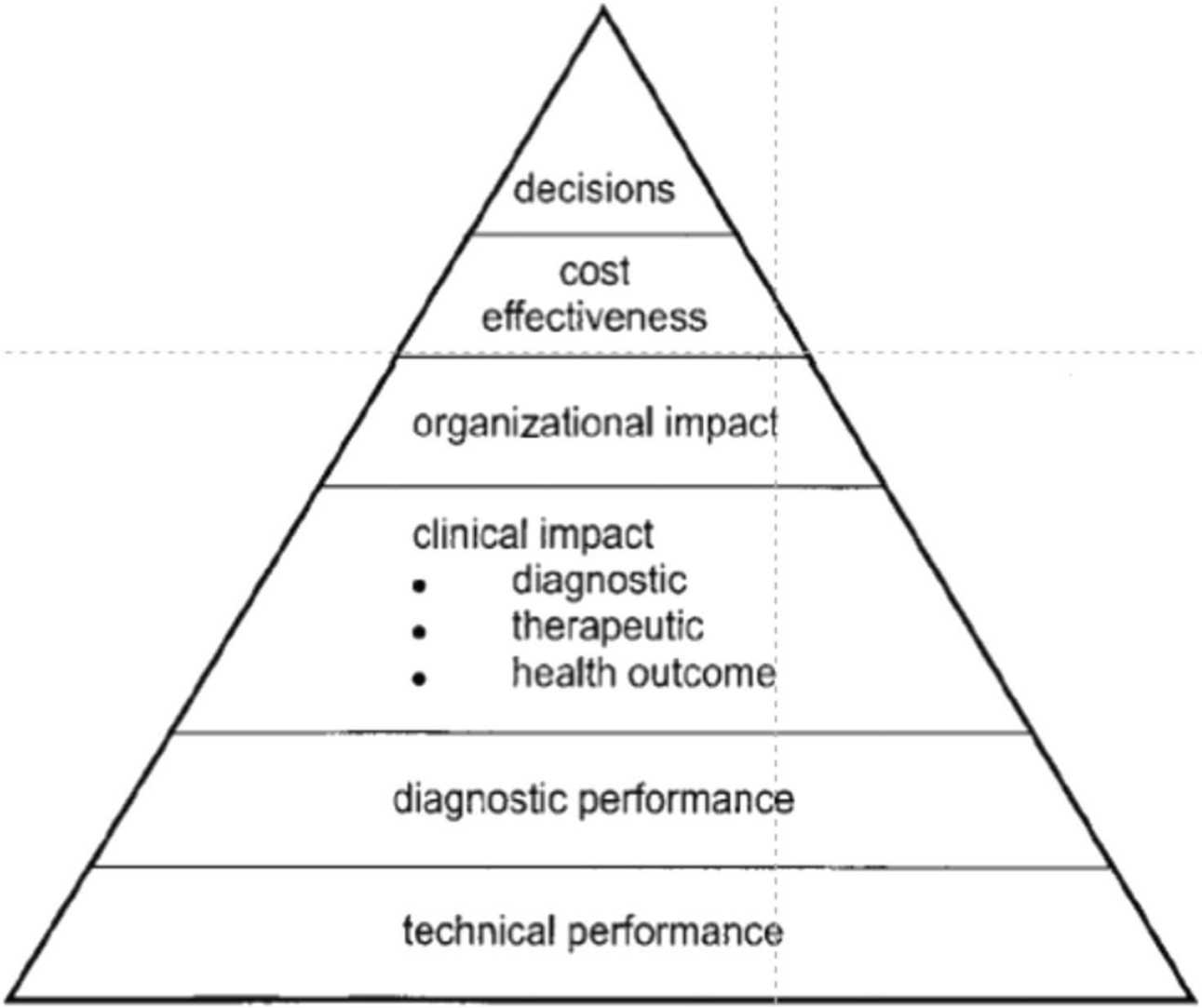
Fig. 2. Evidence of performance designed to facilitate decision-making.

TECHNISCHE PERFORMANTIE

- **Pre-analytische factoren (vaak te weinig in kaart gebracht):**
  - ✓ Patient: is er invloed van vasten, posturale houding, voorafgaandelijke inspanning, leeftijd? Wat is de belasting voor de patient?
  - ✓ Biologische variatie: timing van staalname belangrijk? (bv. drugmonitoring)
  - ✓ Interferentie: medicatie, voeding, licht, hemolyse
  - ✓ Staalstabiliteit: bewaarcondities en transportvereisten
  - ✓ Staaltype: serum, plasma, capillair, vocht, (consistentie)...

- **Analytische factoren**
  - ✓ (Im)precisie
  - ✓ Accuraatheid: (inter)nationale standaardisatie, calibratie?
  - ✓ Analytisch meetbereik
  - ✓ Klinisch meetbereik
  - ✓ Within run variatie
  - ✓ Between run variatie
  - ✓ TAT: turn-around-time, is POCT wenselijk/ noodzakelijk?

- **Kwaliteitsfactoren**
  - ✓ KAL: Klinische Aanvaardbaarheids Limieten
  - ✓ Is er een werkvoorschrift voorhanden?
  - ✓ Hoe gebeurt de kwaliteitsopvolging?
  - ✓ Werd er reeds een interne kwaliteitscontrole voorzien?
  - ✓ Bestaat er reeds een externe kwaliteitscontrole?



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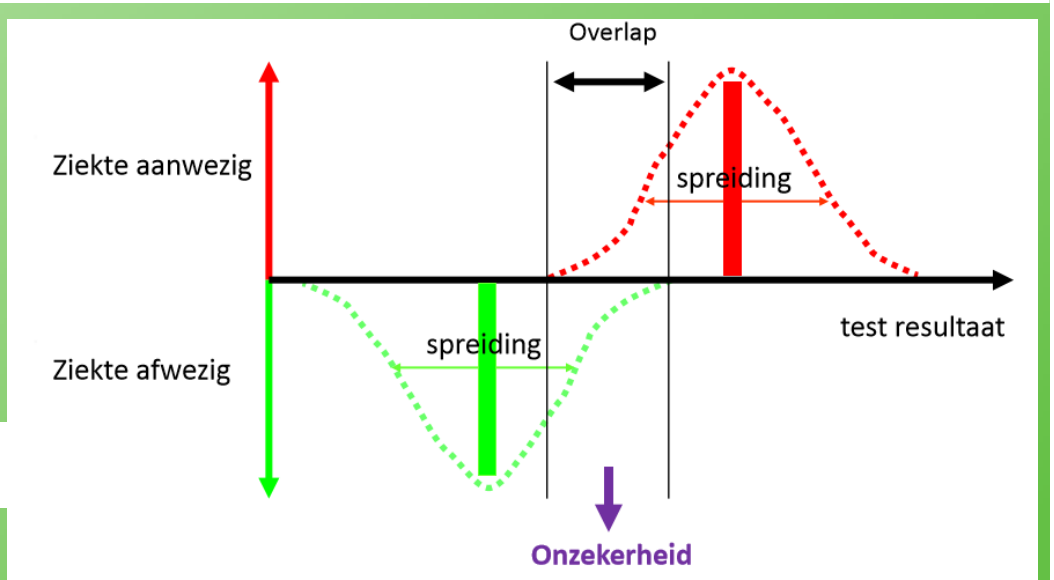
DIAGNOSTISCHE PERFORMANTIE

	ziekte (volgens "gouden standaard")		
	ziek	**niet ziek**	**totaal**
labotest positief	a	b	a+b
labotest negatief	c	d	c+d
totaal	a+c	b+d	a+b+c+d

Parameter	**berekening**	**95% confidence interval**
Sensitiviteit (Sens): proportie positieve laboresultaten (terecht-positieven) onder de zieken	a/(a+c)	Sens+/- 1.96*V[ac/(a+c)^3]
Specificiteit (Spec): proportie negatieve laboresultaten (terecht-negatieven) onder de niet-zieken	d/(b+d)	Spec+/- 1.96*V[bd/(b+d)^3]
Prevalentie: voorafkans op de aanwezigheid van ziekte	(a+c)/(a+b+c+d)	
Positief predictieve waarde (PPW): proportie zieken onder de personen met een positieve labotest (achterafkans op aanwezigheid van ziekte)	a/(a+b)	PPW+/- 1.96*V[ab/(a+b)^3]
Negatief predictieve waarde (NPW): proportie niet-zieken onder de personen met een negatieve labotest (achterafkans op afwezigheid van ziekte)	d/(c+d)	NPW+/- 1.96*V[cd/(c+d)^3]
Positieve likelihood-ratio (LR+): verhouding van de kans op positieve labotest bij zieken/ kans op positieve labotest bij niet-zieken	Sens/(1-Spec)	
Negatieve likelihood-ratio (LR-): verhouding van de kans op negatieve labotest bij zieken/ kans op negatieve labotest bij niet-zieken	(1-Sens)/Spec	

Diagnostic Test Calculator

http://araw.mede.uic.edu/cgi-bin/testcalc.pl



Search for reporting guidelines

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STARD 2015: An Updated List of Essential Items for Reporting Diagnostic Accuracy Studies

Reporting guideline provided for? (i.e. exactly what the authors state in the paper)

Studies of diagnostic accuracy

STARD 2015 checklist (PDF) STARD 2015 flow diagram (PDF)

STARD 2015 checklist (WORD)

Full bibliographic reference

Bossuyt PM, Reitsma JB, Bruns DE, Gatsonis CA, Glasziou PP, Irwig L, LijmerJG Moher D, Rennie D, de Vet HCW, Kressel HY, Rifai N, Golub RM, Altman DG, Hooft L, Korevaar DA, Cohen JF, For the STARD Group. STARD 2015: An Updated List of Essential Items for Reporting Diagnostic Accuracy Studies.

This guideline was published simultaneously in 3 journals. You can read the guideline in any of these journals using the links below.

BMJ. 2015;351:h5527. PMID: 26511519
Radiology. 2015:151516. PMID: 26509226
Clinical Chemistry. 2015. pii: clinchem.2015.246280. PMID: 26510957

Language

English

Relevant URLs (full-text if available)

The full-text of the STARD 2015 reporting guideline for diagnostic accuracy studies is available to download as a PDF file.

Reporting guidelines for main study types

Randomised trials	CONSORT	Extensions
Observational studies	STROBE	Extensions
Systematic reviews	PRISMA	Extensions
Case reports	CARE	Extensions
Qualitative research	SRQR	COREQ
Diagnostic / prognostic studies	STARD	TRIPOD
Quality improvement studies	SQUIRE	
Economic evaluations	CHEERS	
Animal pre-clinical studies	ARRIVE	
Study protocols	SPIRIT	PRISMA-P
Clinical practice guidelines	AGREE	RIGHT

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EQUATOR resources in Spanish
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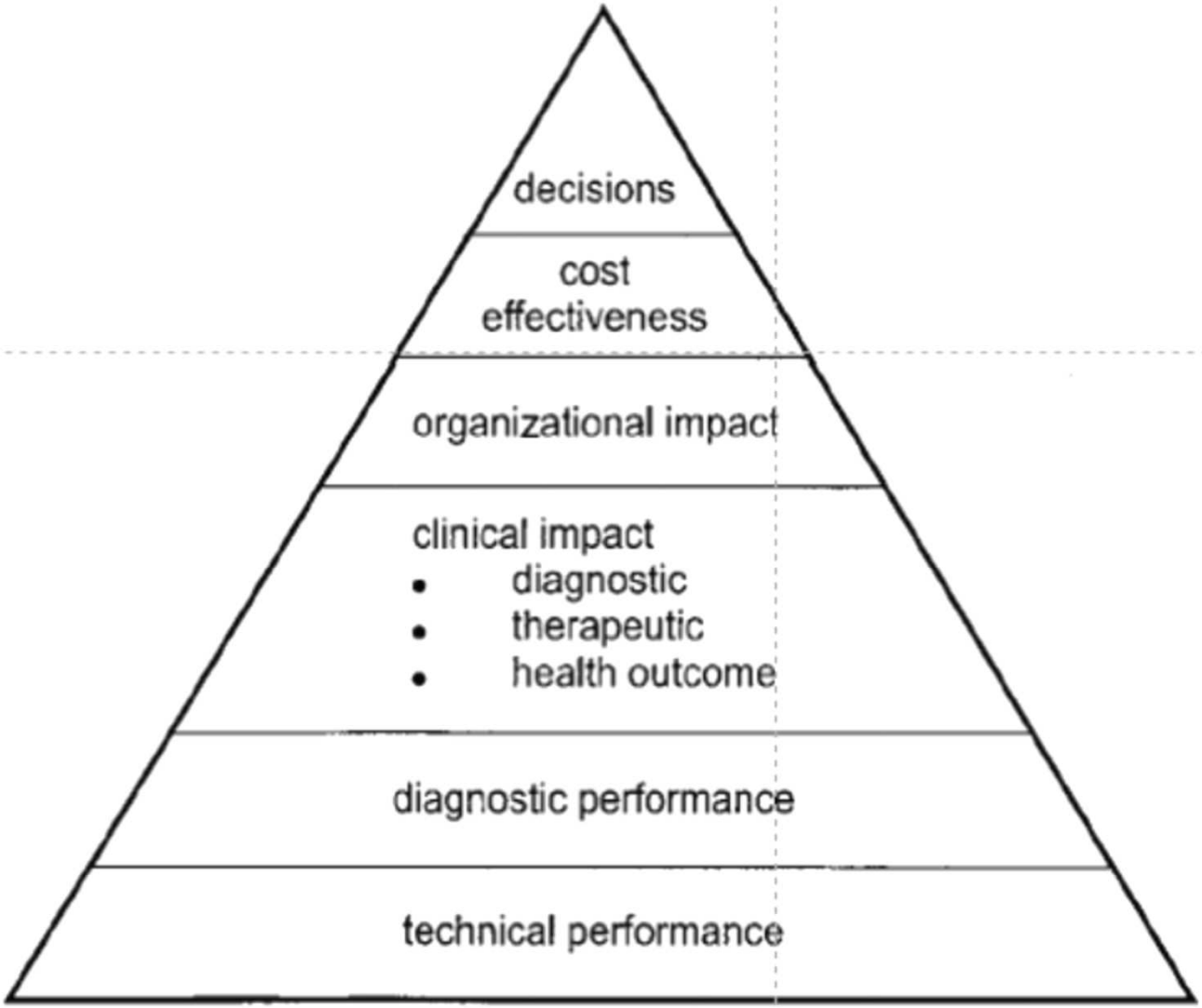

Fig. 2. Evidence of performance designed to facilitate decision-making.

KLINISCHE IMPACT

- **Diagnostisch**
  - ✓ Kunnen andere (eventueel niet-labo) testen vermeden/vervangen worden?
  - ✓ Levert de test supplementaire en/of meer adekwate informatie, niet verkrijgbaar door andere onderzoeken?
- **Therapeutisch**
  - ✓ Kan een behandeling sneller gestart of juist vermeden worden door deze test?
  - ✓ Kan een behandeling optimaler worden toegediend?
  - ✓ Kan een toxisch effect van een behandeling vermeden worden?
- **Outcome**
  - ✓ Kan een ziekte, complicatie, morbiditeit, mortaliteit vermeden worden door deze test?
- **(Andere)**
  - ✓ Wordt de test uitgevoerd in het kader van epidemiologisch onderzoek?
  - ✓ Wordt de test uitgevoerd in het kader van een onderzoeksprotokol (research-fase)?

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ClinicalTrials.gov

1: Chest 2002 May;121(5):1486-92

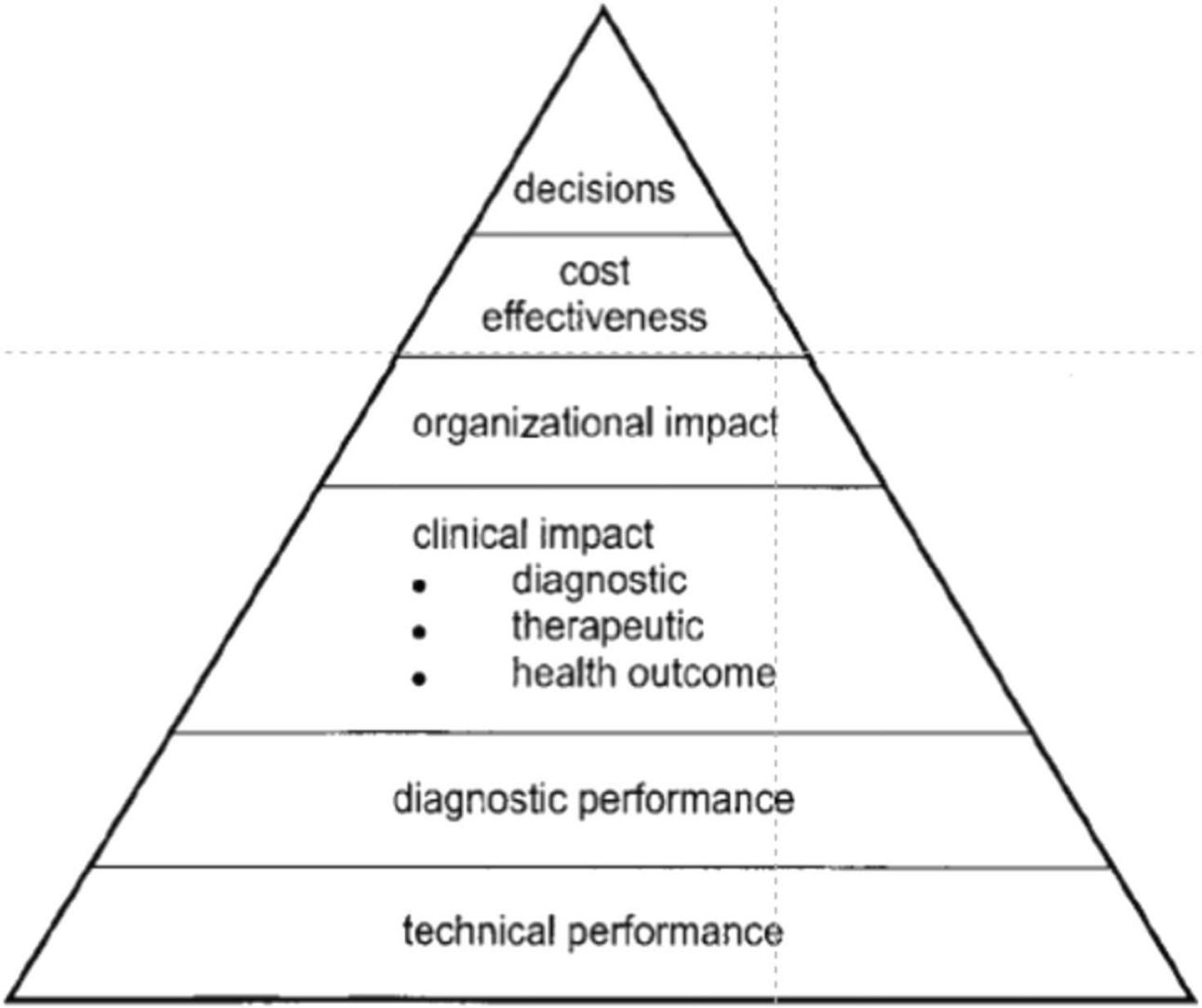
Related Articles, Links

Applying sputum as a diagnostic tool in pneumonia: limited yield, minimal impact on treatment decisions.

Ewig S, Schlochtermeier M, Goke N, Niederman MS.

Medizinische Universitatsklinik und Poliklinik Bonn, Bonn, Germany. santiago.ewig@ukb.uni-bonn.de

STUDY OBJECTIVES: We evaluated the role of sputum examination in the management of patients with community-acquired pneumonia (CAP) in a primary-care hospital without microbiologic laboratory facilities. Design and interventions: A diagnostic strategy using regular collection of sputum samples, Gram staining in a local laboratory, and mailing of samples to a commercial laboratory for culture analysis. SETTING: A 200-bed primary-care hospital without subspeciality physicians. PATIENTS: One hundred sixteen consecutive patients with a diagnosis of CAP were prospectively evaluated during a 12-month period. RESULTS: Of 116 patients, 42 patients (36%) were capable of producing a sputum sample. Age > or = 75 years (odds ratio [OR], 0.4; 95% confidence interval [CI], 0.18 to 0.93) and prior ambulatory antimicrobial treatment (OR, 3.2; 95% CI, 1.2 to 8.4) were independent predictors of sputum production. A delay in collection and processing of sputum samples of > 24 h was present in 31% and 39%, respectively. A delay in collection yielded an increased number of Gram-negative enteric bacilli and nonfermenters (44% vs. 7%, p = 0.056). A delay in processing was associated with an increased number of Candida spp isolates (33% vs. 9%, p = 0.16). The overall



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ORGANISATORISCHE IMPACT

- **Kan de test bijdragen tot:**
  - ✓ Verkorting van de hospitalisatieduur?
  - ✓ Verminderde tijdsbesteding van medische/paramedische zorgverleners?
  - ✓ Verminderd gebruik van andere personeels en/of niet personeelsmiddelen?

1: J Clin Virol 2002 Jul;25 Suppl 1:S19-26

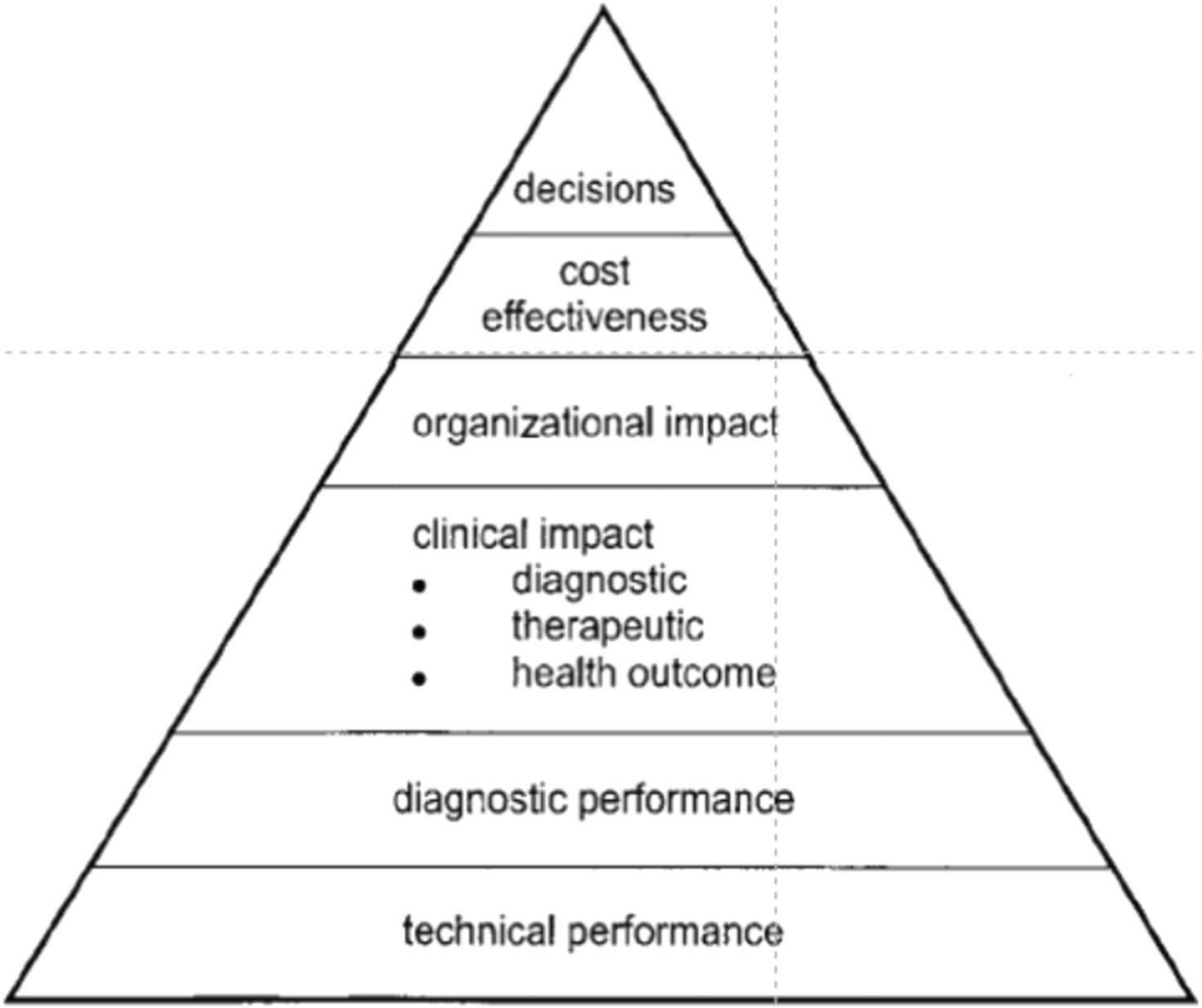
The impact of an enteroviral RT-PCR assay on the diagnosis of aseptic meningitis and patient management.

Stellrecht KA, Harding I, Woron AM, Lepow ML, Venezia RA.

Department of Pathology and Laboratory Medicine, Albany Medical College, 47 New Scotland Avenue, Albany, NY 12208, USA. stellrk@mail.amc.edu

BACKGROUND: Enterovirus (EV) is a major cause of aseptic meningitis and non-specific febrile illness in children. Since the majority of patients are hospitalized for possible bacterial infection, a rapid test for the diagnosis of enteroviral meningitis (EVM) may reduce hospitalizations and unnecessary treatments. OBJECTIVE: To review the impact of an EV reverse transcriptase-polymerase chain reaction (RT-PCR) assay for the diagnosis of EVM on patient management. STUDY DESIGN: CSF from 1056 patients admitted to the hospital between 1998 and 2001 was tested using EV RT-PCR. The results were correlated with CSF counts, diagnosis, test turnaround time (TAT) and length of hospital stay (LOS). RESULTS: EV RT-PCR was positive for 113 patients (11%). Of these cases, 92% occurred during the summer months and 77% were in children <19 years of age. Children <3 years old with EVM frequently had non-specific clinical findings and lacked pleocytosis. There was a significant correlation between decreasing LOS and TAT ($r(2)=0.97$, $P<0.001$). CONCLUSION: RT-PCR testing for EVM is an important tool to aid in the diagnosis of children with non-specific febrile illness. This test impacted patient management as measured by shortened patient stays, which should translate into significant health care savings.

PMID: 12091078 [PubMed - indexed for MEDLINE]



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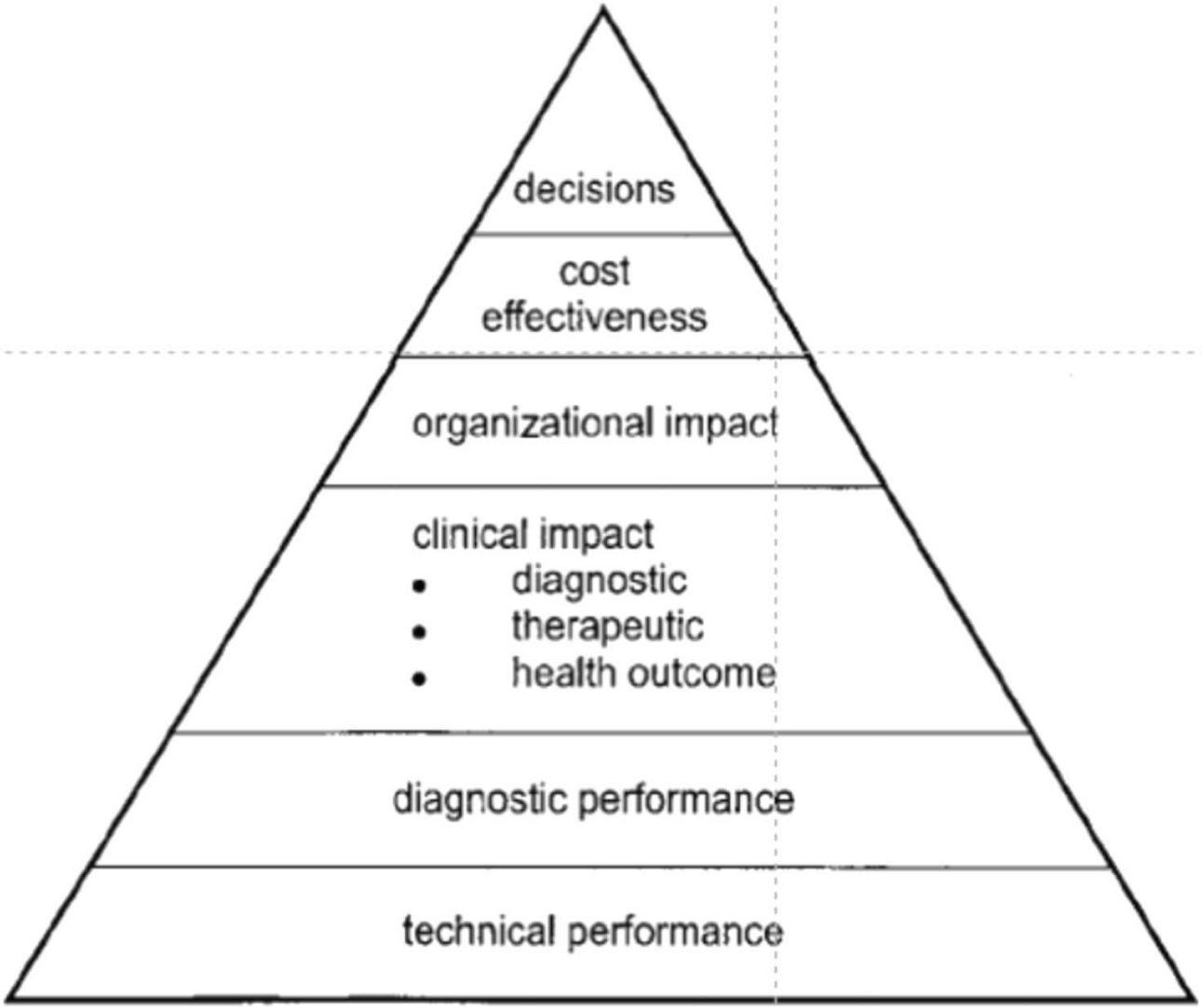
Cost-Effectiveness

- Reële produktiekost?
- Nomenclatuur?
  - ✓ Evt. kosten/ baten gegevens, ter voorstel voor ZIV-terugbetaling?
- Winst elders in het ziekenhuis gegenereerd?

Decision-Making

- **Voor welke doelgroep zal deze test dienen?**
  - ✓ zijn er bestaande guidelines die de test voor een bepaalde indicatie/ populatie aanbevelen?
  - ✓ onderdeel van een syndroomgerichte aanvraag?
  - ✓ bij welk klinisch beeld?
  - ✓ dienen eerst andere (niet-laboratorium) testen afgewacht te worden?
  - ✓ is simultane inzage van andere (niet-laboratorium) testen/ gegevens wenselijk bij de interpretatie door de klinisch bioloog?
  - ✓ werden er reeds voor de eigen (ziekenhuis)situatie flowcharts/ guidelines opgesteld?



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