



Cost drivers in Microbiology/Serology laboratory testing: some perspectives

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introduction

- Consensus on the need and desirability to reduce the money spent on pathology
- Are there opportunities for reducing pathology spend without compromising patient care? Answer: big YES – *significant* reductions are possible
- Implies that presently, there is a lot of unnecessary pathology expenditure
- Who or what is responsible for this wastage?



1. ? CLINICIAN

- YES, to an extent
 - too little reliance on clinical skills, and too much reliance on lab investigations
 - even when investigations are warranted, too many additional tests ('nice to haves') are ordered that are not crucial for diagnosis
 - ordering of inappropriate, irrelevant tests



2. ? LABORATORY

- YES, to a larger extent
 - format of test request
 - too many profiles
 - many dubious tests, of marginal or doubtful benefit
 - many tests of 'reference lab' nature are offered by routine diagnostic labs, that should be referred to centralised (state-run) reference lab services
 - many investigations are composed of too many individual tests, as a routine
 - rational, cost-saving protocols/ algorithms/ cascades are not always in place



3. ? TARIFF STRUCTURE/COST OF TESTS

- YES, definitely. Needs to be radically revised. Many tests are grossly overpriced.
Possible reasons:
 - Error of judgement when costing was done originally
 - Costing was based on low volumes, economies of scale have not been factored in
 - Business cost is built into every test
 - Pricing of kits/test systems locally by vendors based on 'medical aid' tariff for test



TARIFF STRUCTURE/COST OF TESTS contd.....

- New technology that is based on sophisticated principles, yet cheap, user-friendly (e.g. 'rapid' I/chromatographic tests in cartridge format), but tariff charge is based on immunological description or historical methods, rather than actual cost of performing the test
- New technology that is sophisticated and expensive e.g. molecular tests (PCR), Western Blot, TB immunology blood test :
 - very expensive
 - utilisation is increasing all the time
 - introduction of these tests often not based on rational or sound scientific principles
 - absence of independent regulatory body



Example 1: Bacteriology – Urine M,C & S

- Current tests that performed on every Urine M,C& S (whether culture positive or negative)

➤ Chemistry (Dipstick):	(tariff 4188)	R12.00
➤ Microscopy (manual)	(tariff 3867)	R40.00
➤ Total viable cell count	(tariff 3922)	R11.00
➤ Anti-microbial substances	(tariff 3928)	R30.00
➤ Culture	(tariff 3893)	R60.00

Total	<u>R153.00</u>
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Urine M,C & S

- *Urine Dipstick* (4188 @ R12.00)
 - comment : office/ bedside test, superflous in the lab
 - recommendation: stop performing in lab

- *Urine Microscopy* (3867 @ R40.00)
 - comment:
 - manual microscopy for urine cell count is the gold-standard, and is easy, quick, cheap, and reliable
 - tariff 3867 is for microscopy generally; tariff 4401 (CSF cell count) is more appropriate, and cheaper (R30 vs R40)
 - trend by most big labs to introduce automated urine microscopy, which is much quicker, but not necessarily superior. Attempt to charge much higher SAMA tariff (3872 @ R70), is questionable, controversial



Urine M,C & S

- *Antimicrobial substances* (3928 @ R30)
 - comments: - costing: grossly overpriced
 - test is only indicated on selected samples (= small percentage of positive urines), and on request
 - recommendation: - review costing
 - perform only on request, and if indicated (less than 5% of all urines)

- *Total viable cell count* (3922 @ R11)
 - comment: mysterious charge
 - recommendation: not justified, scrap



Urine M,C & S

- *Urine culture* (3893 @ R60 for non-fastidious culture)
 - comments: - tariff 3895 (for fastidious culture) @R90 is sometimes charged, which is inappropriate
 - how necessary is it to perform culture automatically on every sample, given that 70-80% of specimens are ultimately culture- negative?

SUMMARY:

IF UNNECESSARY TESTS/TARIFFS UPTO THIS POINT WERE ELIMINATED , THE COST OF URINE M,C & S WILL BE REDUCED TO R30.00 + R60.00 = R90.

ADD ANOTHER R10 FOR BUSINESS COST, MATERIALS = R100.

COMPARED WITH THE MINIMUM OF R150 THAT IS CURRENTLY CHARGED, THERE WILL BE AN IMMEDIATE SAVINGS OF R50/ REQUEST AT THE VERY LEAST.

1 MILLION SPECIMENS/YEAR = R50 MILLION SAVING / YEAR (FOR A START).

PATIENT CARE WILL NOT BE COMPROMISED.



Urine M,C & S

- Culture –positive urine (20-30% of samples)
 - identification of isolates can be costly, adds significantly to cost
 - the vast majority of isolates are coliforms, and E coli is by far the commonest – easily identified by colonial morphology and simple, rapid biochemical test
 - maximum charge should be tariff 3923 (abridged ID) @ R25
 - yet majority of isolates are charged at tariff 3924 (extended ID) @ R96
 - even worse, at tariff 4652 (automated ID) @ R 120.

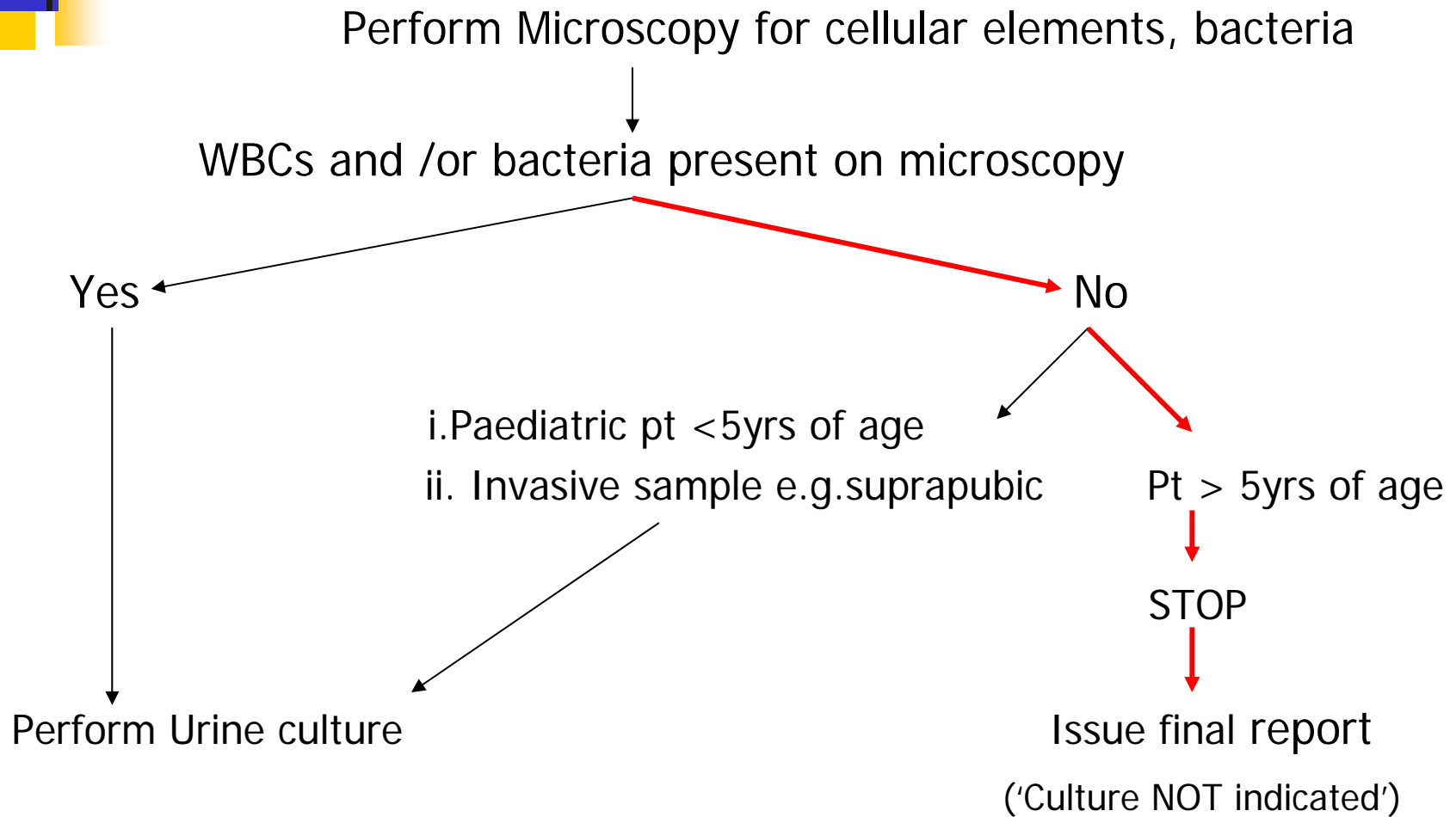


Urine M,C & S

How necessary is it to biochemically identify each and every bacterial isolate from a positive urine culture down to the species level?

- Clinically, an approximate ID based on colonial morphology and simple rapid biochemical tests is sufficient (in most instances) as long as antibiotic susceptibility results are reliable and accurate
- e.g. '>100 cfu/uL of coliform isolated', or '50-100 cfu/uL of Enterococcus spp isolated', is perfectly acceptable; cost of this by manual method is <R100.
- Automated ID and susceptibility testing is starting to become routine: total cost is > R250 for a single isolate!
- Automated testing: how affordable or necessary that it should completely replace manual testing (at current prices) ?

Suggested protocol for processing of Urine M,C & S requests
(using microscopy to screen and exclude probable culture negatives)





Diagnosis of Acute Malaria

- ❑ Mainstay of diagnosis is microscopic examination of thick/thin smears – cost R80

- ❑ Supplementary tests:
 - Antigen detection from blood

 - QBC (Quantitative Buffy Coat)

 - Malaria serology (antibody Elisa test)

 - Malaria PCR



Diagnosis of Acute Malaria

■ Antigen detection

- direct test for the detection of malaria parasite (mainly *P. falciparum*)
- available as a 'rapid' test, lateral flow I/C cartridge format
- cheap, easy to perform, suitable as 'field' test
- highly sensitive and specific
- use as a supplementary test routinely can be justified

Problem:

- costing: tariff 3792 @ R75
- testing algorithm: not necessary if smear is +ve



Diagnosis of Acute Malaria

QBC test

- Highly sensitive test for microscopic detection of parasites, based on specimen concentration and fluorescence microscopy
- Sophisticated : requires expensive equipment (fluorescent microscope) and reagents, and some technical expertise
- very expensive: tariff 3786 @ R203.00
- Is there need or justification for routine performance? Not affordable and practical
- Some drawbacks: non-specific fluorescence, no permanent record
- Probably belongs in the category of 'reference' lab test



Diagnosis of Acute Malaria

■ MALARIA PCR

- Very expensive, like all PCRs: about R750
- 'reference' lab test, mainly for QC purposes, evaluations, research
- Probably no need or justification for routine diagnostic labs to offer such tests
- Adds virtually no diagnostic value to the conventional tests



Diagnosis of Acute Malaria

- MALARIA SEROLOGY (ANTIBODY ELISA TEST)
 - expensive: about R110
 - Has very little place or value in the diagnosis of acute malaria
 - Main diagnostic value is in the diagnosis of chronic malaria (HMS)
 - Useful for epidemiological studies
 - 'reference' lab test



Diagnosis of Acute Malaria

Summary:

- Giemsa-stained Microscopy (thick and thin) is still the 'gold-standard'
- Rapid Antigen detection as a routine supplementary test is rational and can be justified
- Combination of Microscopy + Antigen is rapid (TAT of 1-2 hrs), cheap and reliable, and sensitive enough for the routine diagnosis or exclusion of malaria
- However, average cost of investigation should be about R100-R120
- cf with current situation: microscopy + antigen = R160



Diagnosis of Acute Malaria

- additional tests (e.g. QBC, serology) that are routinely performed by some labs can easily push the cost to R500 or beyond
- add PCR (non-routine), but starting to become fashionable: total cost >R1000
- Repeat testing when initial test is negative, and malaria is still suspected: whole profile is repeated twice, thrice or even four times over a 24 hr period



Diagnostic Serology

Serology for Herpes viruses

- ❑ Herpes simplex
- ❑ CMV
- ❑ EBV serology

Common features:

- 1⁰ infection in childhood, usually symptomatic -> IgM, followed by IgG Abs
- Followed by lifelong latency (IgG antibody positive)
- Recurrent reactivation infections, which are often subclinical (inapparent), occasionally symptomatic: however, often no IgM response
- If there is IgM response, antibodies can persist for a long time



Diagnostic Serology : Herpes viruses

- Implication: - presence of IgG usually doesn't mean much
 - presence or absence of IgM also does not usually mean much
- Summary: serology for Herpes viruses is seldom clinically meaningful (exceptions e.g. neonates, primary infection)
- Yet, serology for Herpes viruses is very commonly requested
- Costly: - Elisa for IgG and IgM @ about R120 each
 - Additional Elisa to distinguish between H.simplex 1 and 2 (? how necessary, how accurate)



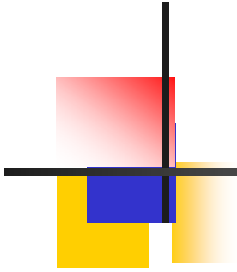
Diagnostic Serology : Herpes viruses

EBV serology :

- often consists of 4 Elisa tests (VCA IgG, IgM, EBNA, EA)
- results are usually not meaningful or helpful for reactivation infection, which is the commonest indication for requesting serology e.g. CFS
- serology is useful exceptionally e.g. primary infection (IM), but then simple algorithm is sufficient e.g. heterophile antibody test, VCA IgG and IgM

RECOMMENDATION:

- Serology for Herpes viruses should be curtailed, and not offered as a routine diagnostic test
- For suspected life-threatening herpes infections where it is imperative to make diagnosis e.g. suspected herpes simplex encephalitis, severe EBV infection in a transplant patient, disseminated CMV infection, then more definitive tests such as culture, PCR, etc, although more expensive, are justified.



thanks for your patience -

that's all for now -

watch this space, more to follow later...

