Australian Institute of Health and Welfare

Office pathology testing

A case study

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Comments on this paper are welcome and should be forwarded to:

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Contents

Foreword

The material presented in this publication was originally prepared for the Comett-Assess project, a program to develop health technology assessment activities with industrial organisations in Europe, which was supported by the European Community. The case study evolved as an approach to a self-guided instruction course on the assessment of a particular area of diagnostic technology. It has been issued as a working paper in view of continuing interest in non-laboratory pathology testing. The diagrams prepared for the self instruction course have been included in an appendix.

A shortened version of this material, together with chapters by contributors to the Comett-Assess project on a number of other topics, will appear in *Assessment of Health Care Technologies: Case Studies, Key Concepts and Strategic Issues* (A. Szczepura and J. Kankaanpaa, Eds), to be published by John Wiley, London, during 1995.

Assessment perspective

Office pathology involves the use of analysers and kits outside the laboratory setting to detect and measure substances in body fluids. Such testing is usually performed by persons without extensive background or training in laboratory work.

This case study is framed to reflect perceptions of health authorities and insurers. However, it also includes discussion and criteria that should be essential both for users and suppliers of the technology.

The material should be relevant to the following target groups:

- policy makers in health authorities and financing agencies;
- professional organisations;
- administrative, medical, paramedical and technical staff in hospitals and other institutions;
- physicians in general practice; and
- manufacturers of products for office pathology services.

Definition and scope of the topic

Pathology testing is an essential service, used as an aid to diagnosis and monitoring of disease and in the measurement of health status.

In this case study the emphasis is not so much on the types of pathology test, as on the method of provision. Both the nature of certain tests and the way in which they are used by doctors and others are considered.

Most pathology tests are undertaken in laboratories by or under the supervision of staff with lengthy training and experience in this area. Pathology tests conducted outside the laboratory by physicians and others have typically been based on use of dipsticks, simple colorimetric methods and microscopy. Examples are microscopical examination of gram-stained film, erythrocyte sedimentation rate and tests for fecal occult blood.

Availability of low capital cost, easy-to-operate systems has made possible a trend to counter the tendency for pathology services to be centralised in specialised laboratories. This development has been assisted by evolution of new chemistries, availability of cheap microprocessors and efficient packaging techniques.

Two of the product areas which have widened the options for office pathology are:

1. *'Desk top' analysers*—some offering a number of tests. In these devices, as many decision-making and manipulatory steps as possible have been eliminated from the test procedure. This approach has been helped by use of bar-coded slides or cartridges containing the reagents. The bar coding allows the microprocessor within the instrument to recognise which test is being performed, and to use appropriate calibration data to compute the result.
2. *Simple-to-apply, specific kits*—procedures which require no capital outlay for instrumentation. Many kits are based on developments in biotechnology such as use of monoclonal antibodies (MCAs). The analytical 'flag' used with the MCA methodology is usually a colorimetric procedure. These products increasingly include built-in controls to detect errors in the order of addition of reagents.

Important developments in biotechnology, such as hybridisation assays using DNA probes, and recombinant DNA applications, will provide less costly testing for diseases with a genetic component and will be increasingly used in pathology testing. Eventually, some use of such technologies in the non-laboratory settings can be expected.

In this case study, examples are given of tests undertaken with analysers and with kits. Much of the discussion and information given is relevant to pathology tests conducted in laboratories as well as office pathology testing. However, a number of points require special emphasis in the context of office testing because of the less well developed infrastructure for undertaking analytical work of this nature.

In developed nations, office pathology has to be compared with laboratory services which are already in place when costs and benefits of the technology are being considered.

Settings for the technology

Decentralised pathology tests have often been considered in the context of:

- general practice - physicians' rooms
- hospitals - the Intensive Care Unit and other specialised units
  - application in general wards
- population screening - for example in health promotion campaigns
- self-testing - self-monitoring and diagnosis at home.

This case study focuses on pathology testing in general practice, with briefer discussion of issues which apply to other settings.

Some aspects of office pathology testing are complex and the subject of continuing investigation. In many instances, there will be no single 'correct' answer or standard. The information included here is intended to illustrate a number of points which should be borne in mind by those who use or fund this type of testing.

Rationale for office pathology testing—and some questions

Office pathology has been promoted as offering the following benefits:

- elimination of laboratory overheads;
- a closer doctor-patient relationship;
- prompt feedback of results;
- greater patient convenience; and
- cost savings to health care.

Potential attractions are that the doctor may be able to give a faster diagnosis or treatment decision, and that the patient will avoid follow-up consultation with further travel expense and inconvenience. If tests are ordered from a pathology laboratory there will inevitably be some delay.

There has been relatively little consideration of possible disadvantages of office pathology. These might include:

- potential for poorer quality results;
- inappropriate testing;
- misinterpretation of data; and
- potential for increased overall cost.

If the tests undertaken by the doctor are inaccurate or unnecessary, there is potential for a waste of resources and for incorrect management decisions with consequences for the health and convenience of the patient.

A common presumption is that use of office pathology testing will provide benefits in terms of cost, quality of life, influence on patient management and influence on patient health status. Assessment of this technology is required to test such assertions.

A hierarchy of assessment questions

The questions to be asked of a test used in office pathology can be framed as:

- does the technology work?
- will it be useful in a clinical setting?
- will if affect (improve) health status?
- how will it affect costs of health care?

As is the case with other health care technologies, office pathology testing needs to be considered in relation to its *efficacy*, *effectiveness* and *efficiency*. These can be tied to a series of assessment issues ranging from the performance of an office pathology product under ideal conditions—such as the manufacturer's laboratory—to its ultimate effect on health status and whether it represents good value for money within a health care system.

- Performance under ideal conditions *(efficacy)*
  - Does the product meet its 'label claim' when used by laboratory-trained staff over the concentration range of the substance being measured or detected?
- Performance in a non-laboratory ('office') situation *(effectiveness)*
  - What is the performance of the product in the hands of an operator without a background in laboratory science. *This is a key issue for this technology.*
- Clinical use in the non-laboratory situation
  - Which types of test are most commonly used and for what?
  - What effect do tests have on management decisions?
- Impact on health status
  - Are there any changes in numbers of consultations or use of other services as a result of office pathology testing?
  - Is morbidity or biochemical status of patients significantly influenced?
  - What are patients' perceptions of this technology?
- Impact on health care costs
  - What are the cost impacts on doctors using the tests, patients and insurers?
  - Is this a technology which is good value for money in a health care system with a limited budget? *(efficiency)*

These areas will be considered in office testing for the detection of urinary tract infection using a kit, and measurement of blood glucose and serum cholesterol using an analyser.

Assessment of product performance

The performance of diagnostic tests is often described by their *sensitivity* and *specificity*. These terms are derived from the proportions of true positive (TP) and true negative (TN) results obtained with a test.

True positive: the test correctly identifies a substance

True negative: the test correctly excludes the presence of a substance.

Sensitivity is the ability of a test to identify a substance or disease when it is present.

$$\text{Sensitivity} = \frac{\text{True positives}}{\text{True positives} + \text{False negatives (FN)}}$$

Specificity is the ability of a test to correctly exclude the presence of a substance or disease when it is absent.

$$\text{Specificity} = \frac{\text{True negatives}}{\text{True negatives} + \text{False positives (FP)}}$$

Ideally, a test should have 100% sensitivity and specificity. In practice, high specificity and sensitivity may be hard to achieve. Manufacturers may choose to bias towards high sensitivity, at the expect of specificity, if it is particularly important to detect a substance in the population (detection of HIV, for example). High specificity may be important when there is a need to exclude one of several possibilities in a differential diagnosis. These concepts will now be applied to a test for urinary tract infection (UTI). For the first product considered (Test A), the performance data can be calculated as follows from the results of 200 tests.

Test A

	Disease present	**Disease absent**
Positive results	96 (TP)	4 (FP)
Negative results	20 (FN)	80 (TN)

$$\text{Sensitivity} = \frac{96}{96+20} \times 100 = 82.8\%$$

$$\text{Specificity} = \frac{80}{80+4} \times 100 = 95.2\%$$

For Test B, calculate the sensitivity and specificity from the following data. How does B compare with A in terms of its ability to detect or exclude disease?

Test B

	Disease present	Disease absent
Positive results	80	15
Negative results	5	100

Sensitivity = ?

Specificity = ?

Sensitivity and specificity apply to the performance of a test over a population, but do not address the question of the chance that a result obtained on an individual patient is correct. This is measured using the positive predictive value (PPV) and negative predictive value (NPV).

Positive predictive value = Proportion of persons with a positive test result who actually have the disease

$$= \frac{\text{True positives}}{\text{True positives} + \text{false positives}}$$

Negative predictive value = Proportion of persons with a negative test result who are actually free of the disease

$$= \frac{\text{True negatives}}{\text{True negatives} + \text{false negatives}}$$

i.e.

$$PPV = TP/(TP + FP)$$

$$NPV = TN/(TN + FN)$$

Product performance may be more comprehensively defined by plotting sensitivity against specificity to obtain the receiver operating characteristic (ROC). See references 1 and 2 for further details.

Performance of quantitative tests

The situation with assessing analyser-based tests is somewhat different. Here the doctor is dealing not with detection or exclusion of particular substances, but with measurement of the concentration of various substances in body fluids.

Because of biological variability, there is no single correct concentration for a substance such as glucose. Rather, doctors will be referring to a range of concentrations that has been established for the local population. A concentration within this normal range will be an indication of absence or control of disease. A result outside the normal range is an indication that action may be required in the management of the patient.

For this sort of quantitative test, the terms sensitivity and specificity are less frequently used.

Analytical reliability of analysers used for pathology tests will commonly be determined by their:

Imprecision: the distribution of results when repeated analyses are performed on the same specimen.

Inaccuracy: the deviation (or bias) of the results from that determined by an accepted comparative (reference) method on the same specimen.

Linearity: the extent of deviation from straight line relationship between concentration of the substance being measured and instrument response.

(*Im*precision and *in*accuracy is the usage generally adopted by clinical chemists.)

Each test offered by an analyser should be assessed against these measures.

A useful means of assessing performance of analysers is to use the results achieved by pathology laboratories in approved quality assurance programs as a basis for comparison. Standards of acceptability for efficacy (performance under laboratory conditions) used in a trial of office pathology equipment were as follows:[3]

Imprecision

Imprecision is deemed acceptable if the coefficient of variation (CV) is less than the CV based on twice the median standard deviation (SD) obtained by laboratories in a designated quality assurance (QA) program.

I.e.

Mean value obtained in QA program	=	x
Median standard deviation from QA program	=	s
Coefficient of variation	=	(s/x) x 100

Imprecision of office pathology test is considered *acceptable* if:

Coefficient of variation of a series of measurements is less than 2 (s/x) x 100.

Inaccuracy

Inaccuracy is assessed using the method of simple linear regression,[4] comparing test results on the instrument being assessed with those from a reference method, using a wide spread of concentrations over the range of the instrument.

I.e.

Inaccuracy is considered *acceptable* if:

The correlation coefficient is greater than 0.95.
The slope is between 0.90 and 1.10.
The intercept is less than the standard error of the estimate, Syx.[5]

Worksheet—calculation of imprecision

Calculate the coefficients of variation from these two sets of results from cholesterol tests:

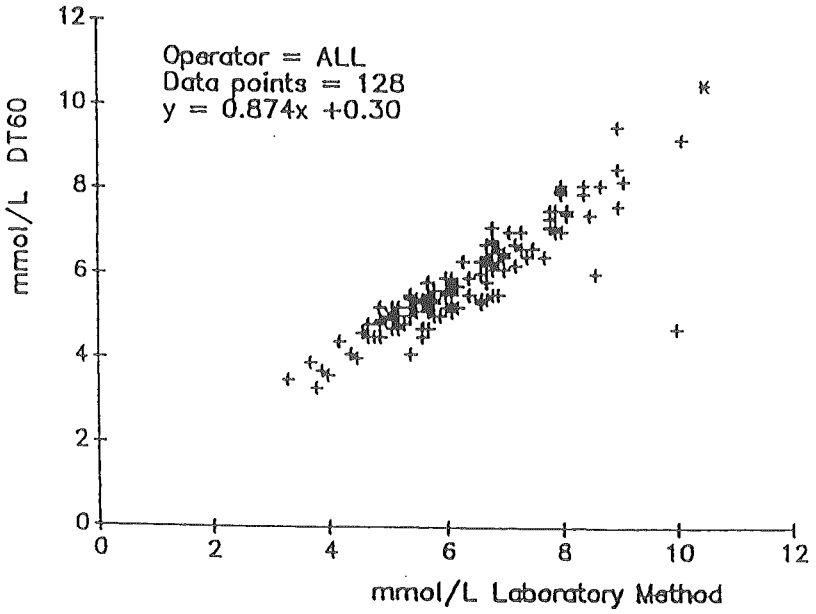
(a)	(b)
9.4	10.3
8.9	11.9
9.2	8.4
9.6	8.7
8.7	9.7
10.8	10.8
10.1	10.9
8.3	10.8
9.2	9.9
8.9	10.6

1. Determine the mean.
2. Calculate the standard deviation.
3. Divide standard deviation and multiply by 100 to obtain the coefficient of variation.

   For test (a), CV = 7.75% For test (b), CV = ?

Worksheet—assessment of inaccuracy

In this example, an office pathology test is compared with a laboratory test, using a regression analysis.



n	Slope	Intercept (mmol/L)	Syx (mmol/L)	r
128	0.874	+0.30	0.43	0.886

(n= number of samples, Syx = standard error of the estimate, r = correlation coefficient.)

These data indicate that the office test does not meet requirements for correlation coefficient or slope.

Inspection of the graphical representation of the data suggests that this result may be improved by rejection of outliers. The rule used to reject data is that the points should be further from the regression line by 4 x Syx.

Draw in the line of best fit and judge whether rejection of any outliers is justifiable, using the value of Syx.

Should the two points furthest from the line be rejected, the regression data become:

n	Slope	Intercept (mmol/L)	Syx (mmol/L)	r
126	0.920	0.06	0.28	0.95

On this basis, the office test would meet the criteria for acceptability given on page 9.

An alternative measure of inaccuracy

For each type of test monitored through a quality assurance program for laboratories, allowable limits of performance (ALP) have been derived, based on standards achievable by analysts and the clinical significance of departures from the correct result. Results from laboratory tests on material provided in a quality assurance program would be expected to fall within the ALP.

For the further discussion in this case study, inaccuracy of glucose and cholesterol tests is considered in terms of the ALP values set for pathology laboratories in approved quality assurance programs.

For glucose:

Imprecision acceptable if CV <6.4%

ALP = ± 1.0 mmol/L

Normal range =3.8 to 5.8 mmol/L

Test C Imprecision, CV = 2.5%

Inaccuracy 100% within ALP

Test D Imprecision, CV = 8.0%

Inaccuracy 100% within ALP

Test C has acceptable inaccuracy and imprecision

Test D has acceptable inaccuracy but its imprecision is above the limit for CV.

For cholesterol:

Imprecision acceptable if CV <8.9%

ALP = ± 0.5 mmol/L

Normal range = 3.5 to 5.5 mmol/L

Test E Imprecision, CV = 4.0%

Inaccuracy 86% within ALP

Test F Imprecision, CV = 11.0%

Inaccuracy 90% within ALP

Both tests E and F are unacceptable.

For E, imprecision is within the limit, but inaccuracy is outside the ALP.

For F, both imprecision and inaccuracy are unacceptable.

Standards such as these should apply to all tests on analysers offered for office pathology testing. They should be used both by manufacturers and those regulatory and professional agencies with responsibilities for appraising the performance of equipment under 'ideal' conditions.

Similarly, kits should be subjected to performance tests for sensitivity and specificity, using reference methods to check the results.

Product performance under 'office conditions'

Undertaking product performance testing under laboratory conditions is an important check on the quality of the product. However, for the purposes of office pathology testing, it is not sufficient.

The common experience is that poorer performance is achieved under office pathology conditions than in a laboratory. This may be due to a number of factors. Typically, office pathology operators will have less experience and training in the performance of tests, and possibly in the recording and reporting of results. In many situations, non-technical staff will be used to perform tests, and rapid turnover of staff may make adequate training difficult. There may also be less appreciation in the office setting of the need for quality assurance and to reinforce good standards of practice in the performance of tests.

This commonly-encountered discrepancy between the 'ideal' results obtained in a laboratory and those obtained in the office setting should not be too surprising, given the different backgrounds of the operators. Laboratory-based professionals will in general be better able to routinely deliver good quality results and to cope adequately when troubleshooting is required.

Such considerations point to the need for tests intended for use by persons outside the laboratory to be as simple as possible to perform (minimising the chance of error through various steps such as those involved in measurement of samples) and to be reasonably robust.

Robustness of a test

The concept of robustness of a test relates to the degree to which it is able to deliver an acceptable results when used under conditions that are not recommended by the manufacturer. For example, challenges to the performance of a test may come through the operator not storing reagents correctly, applying the incorrect volume of sample to a test strip or kit, or failing to time a procedure correctly.

To date, a common experience with products intended for office pathology testing is that their performance has been validated only under laboratory conditions.

From the point of view of health authorities and professionals using the products, there is a general need for such analyser tests and kit methods to be validated under office conditions, with tests being performed by general practitioners and others who would be expected to use them routinely. The technology of office pathology testing includes not only the devices used for testing but also the interaction between these and the people who use them.

Much can be done to lift standards of performance in office pathology testing through education of those operating analyser or kit methods and through accreditation-linked quality assurance programs.

The results from an Australian trial[3] point to the need for such validation and, where necessary, participation in educational and quality control programs. For three types of cholesterol test the proportions of results within the ALP were respectively 90.0%, 65.5% and 54.4%. The corresponding figures for glucose tests were 96.8%, 84.8%, and 86.7%. Poorer results than these were obtained with some other substances.

These figures represent early experience in certain general practices, and performance would probably have improved since then due to the influence of accreditation provisions and technical developments in the tests concerned. Nevertheless, they point to the need to validate test performance in the office setting.

Checking the result of a test

It is of course always possible for the doctor to check the results of a test for further assurance. This may raise further dilemmas:

- If a check test is undertaken within the office setting, the same type of error may be present, so that the incorrect result is potentially confirmed and the decision for incorrect treatment strengthened. If the second result is substantially different to the first, then the doctor is faced with the usual dilemma of which to believe—or perhaps whether to take an average of the two. Either way, the doctor has gone to the expense and inconvenience of undertaking a further test and the confidence in the result may have been shaken.
- An obvious back-up is to refer the specimen to a pathology laboratory for a confirmatory test. The problems here are, firstly, that there will be the usual delay in getting the result back (one of the things that office pathology is supposed to avoid), and secondly, that additional expense will have been incurred.

There will be an understandable tendency on the part of the office pathology operator to seek confirmation of a test that is apparently seriously abnormal. What may be overlooked is the possibility of test inaccuracy leading to apparently in-range results which are also incorrect.

Use in the clinical setting

In general, the doctor will decide to perform or order a test as part of an algorithm of patient management. Any tests will be in addition to the examination by the doctor and, in association with the medical history of the patient, will be used to inform the decision on future management.

In some cases, the pathology tests will be used for diagnosis of a disease, but very commonly the doctor will be using a test to monitor a condition of a patient or to exclude disease.

In using tests, doctors should be aware of the normal range of the substance being measured in the population, the reliability of the test and its relationship to the suspected disease or condition.

A pathology test should not be performed if there is no likelihood of it influencing decisions on patient management. Ordering or performing batteries of tests on the chance that 'something may show up' or perhaps for medico-legal reasons is poor practice and is to be avoided.

The usefulness of a test method to the general practitioner will depend, among other things, on the prevalence of the disease for which the test is being used. Although the range of tests offered by analysers is continuing to grow, the number of analytes (substances) actually tested for in doctors' offices tends to be relatively limited.[6]

Substances commonly tested for in doctors' offices include:

- glucose
- cholesterol
- potassium
- hemoglobin
- urea
- triglycerides
- uric acid
- creatinine

Tests for creatinine kinase and bilirubin have also been performed frequently in some countries.

These tests will commonly be required to assist management decisions. Other tests will be less commonly required—some conditions are rarely seen in general practice, some tests make a smaller contribution to the medical decision.

Similarly, the range of kits available for use outside the laboratory continues to grow, but major areas of need by the general practitioner may be relatively limited:

- sexually transmissible diseases (STDs);
- urinary tract infection; and
- respiratory tract infection.

Other tests will be required less often by the general practitioner, to some extent because various conditions will rarely be seen and also because other tests may make a relatively limited contribution to the management decisions undertaken by the doctor.

A further factor in many countries is the availability of good quality laboratory services which are well able to provide less commonly required tests. Laboratory testing may be more convenient for the general practitioner in situations where the test is less common and the result is not required urgently.

Product options for the non-laboratory market may therefore have some limitations.

Overall, there is a need to consider:

- how often the test may be needed;
- how significant it is in the algorithm of patient management;
- the reliability of the results obtained in the office setting;
- the urgency with which they are required; and
- the convenience to the doctor and the patient.

Examples in the case study

Consideration is given here to three types of test—the use of a kit to detect or exclude the presence of urinary tract bacterial infection and measurement for levels of blood glucose and serum cholesterol on an analyser.

In a test for urinary tract infection, the standard approach for a general practice would be to send a urine specimen to a laboratory for bacterial culture. There will commonly be a delay of several days before a result is obtained, and antibiotics may often be prescribed for the patient in the interim. Experience in pathology laboratories is that about 80% of such specimens test negative. In such cases, where bacteria are absent, prescription of antibiotics is unnecessary.

The alternative is to use a kit method in the doctor's office, which will give a positive or negative result on a urine specimen within a few minutes. This will then provide a basis for an informed decision by the doctor on patient treatment. If the test is negative, then unnecessary antibiotic treatment is avoided and the doctor can consider other causes of the patient's symptoms.

Glucose is a common test for the office situation in the detection of diabetes mellitus and the monitoring of patients with this condition. High glucose concentrations are also an indication of other conditions including effects of some drugs, burns and sepsis, while low levels may indicate reactive hypoglycemia, alcohol consumption, insulinoma or malignancy. The focus here will be on management of diabetes, commonly undertaken through use of insulin or hypoglycemic medication.

Serum cholesterol measurements are commonly undertaken because of the known association between high levels of this substance and the risk of coronary artery disease. High levels of cholesterol are also a factor in other conditions such as obstructive jaundice, while low levels are an indication of various conditions, including malabsorption, hypothyroidism and pernicious anemia.

For the purposes of the case study, the use of cholesterol testing to identify a risk factor for coronary artery disease will be considered. Management here may include advice to the patient on diet modificaton and other lifestyle changes and prescription of lipid-lowering drugs.

Clinical consequences of product performance

Urinary tract infection

It is of interest to consider the consequences of product performance for the decision reached by the doctor and the subsequent effect on patient outcome. However, this is not easy task.

The pathology test will usually be only one of several pieces of evidence available to the doctor. The effect of a test result on a decision will depend on many factors including the medical examination, patient history, need or availability of other tests and the seriousness of the condition under consideration.

In the following scenarios, various assumptions are made and the models have been kept simple. More detailed analyses, using data applicable to individual populations and health care systems, would be needed to produce definitive results.

In the test for UTI, Test A had a sensitivity of 82.8% and a specificity of 95.2%.

Experience in pathology laboratories has shown that 80% of patient urine specimens sent for bacterial culture by general practices prove to be negative.

This suggests that for patient specimens examined with Test A:

Actual proportion of 'positive samples' (bacteria present)	=	20%
Proportion of samples correctly identified as positive	=	16.6%
Actual proportion of 'negative' samples (bacteria absent)	=	80%
Proportion of samples correctly identified as negative	=	75.2%

For every 100 patients with infection:

- Eighty-three will be correctly diagnosed. There will be benefits through avoiding laboratory tests and delays and possibly through avoiding additional consultation.
- Seventeen will be incorrectly diagnosed. The infection will not be detected, with the possibility of increased morbidity and additional consultations. Another possibility is that the disease is self-limiting, and the symptoms will disappear despite the incorrect result and decision. A third alternative is that the doctor may prescribe antibiotics for another suspected condition (e.g. vaginitis) and that these may be effective.

For every 100 patients without infection:

- In 95 the disease will be correctly excluded, thus avoiding unnecessary medication and allowing earlier investigation of the cause of the presenting symptoms.
- For five patients, there will be incorrect diagnosis of disease present, with unnecessary prescription of antibiotics and delay in treating the actual condition, if this is not self-limiting.

There would appear to be benefits in respect of the large majority of patients, particularly for those without bacterial infection where use of the kit may avoid unnecessary medication. For those patients who are correctly shown as having the infection, there may be cost savings through avoidance of laboratory work and additional investigations.

Concerns arise in regard to the incorrectly diagnosed patients, with the possibility of the conditions becoming worse for those who are infected and of unnecessary treatment and delay in finding the true condition.

An assumption in this scenario is that the general practitioner will in any case prescribe antibiotics prior to the results of a laboratory test, should the kit not be in use—this relates to the inevitable delay in getting a laboratory result. It is also assumed that costs of bacterial culture at a laboratory will be considerably more expensive than use of a kit within a general practice, and that the doctor will prescribe the appropriate antibiotic in cases where the disease is detected.

Slide 25, covering the consequences of testing for urinary tract infection, gives some possible follow-up actions that may be taken by general practitioners following different results. It should note noted that these options are only indications of possible actions and that in reality a decision tree quickly becomes very complex.

Note also that laboratory testing will not be infallible, although standards of performance can be expected to be high. Even the bacterial culture undertaken at a laboratory will give some false positives and false negatives.

Glucose

The impact of a test carried out using an analyser is not easy to determine. Commonly, there will not be a clear-cut decision on the basis of a single result. Rather, the result will contribute to the decision.

In considering analyser data, some thought needs to be given to the probability of obtaining a correct result. The following illustration contrasts the results from tests which have 100% and 90% of their results within the allowable limits of performance (ALP).

For glucose, the normal range (concentration in blood) for the population is 3.8–5.8 mmol/L, and the ALP are ± 1.0 mmol/L.

This means that for a test with all results within ALP, all the results obtained on a sample with a glucose concentration of 4.8 mmol/L would fall within the normal range.

Next, assume that the results from the test on this specimen are normally distributed. As an approximation, all results will then fall within plus or minus three standard deviations from the true value of 4.8 mmol/L. The standard deviation of a test with acceptable accuracy is therefore no greater than 0.33 mmol/L (and may be much lower).

For a sample at the upper limit of the normal range (5.8 mmol/L), a test which is just acceptable may give up to 50% of results out of range—up to 6.8 mmol/L, though only 5% would be greater than 6.47 (outside two standard deviations from the mean).

(This points to a general consideration for doctors using pathology tests, whether undertaken in a laboratory or under office conditions. There is a need to be aware of the performance of the test, so that a level of confidence can be placed on the results.)

Consider now the consequences for a test where 90% of results meet the ALP. It is assumed that the results are normally distributed and also that the poorer performance is due to inaccuracy, and that the standard deviation is the same as for a test with 100% of results within ALP.

(Other possibilities are that the poorer performance is due to increased imprecision, with inaccuracy the same or, more realistically, that imprecision and inaccuracy in combination are contributing to poorer performance.)

These points on test performance need to be taken into account when considering Slide 26 (Appendix 2). As with the UTI diagram, an indication is given of potential options after testing, and the chart/decision tree quickly becomes complex.

Some effects of blood glucose testing indicated in the slide can be summarised as follows:

Type of result	Treatment decision/effect
Result normal and correct	Exclude disease (diabetes), proceed to other treatment.
	Maintain current treatment.
Results normal but incorrect	Misdiagnosis of disease; delay treatment, increase chance of morbidity, complications, further complications.
	Incorrectly adjust dose of medication.
Result abnormal and correct	Diagnosis of disease; commence treatment.
	Indication of need to change current treatment.
	Make appropriate adjustment.
Result abnormal but incorrect (should be normal)	False diagnosis, incorrect treatment commenced.

The actual consequences of an incorrect decision will vary considerably and more complex scenarios can readily be envisaged. Previous discussion has indicated that:

- even for tests with 100% of results within ALP, not all results will correctly assign the patient as being within or outside the normal range for blood glucose;
- with a test that has fewer than 100% of results within ALP, the chances of incorrect assignment of a patient will increase;
- however, nor all results which are outside ALP will lead to incorrect assignment; and
- even if a patient is incorrectly assigned as being within or outside the normal range for blood glucose, this may not mean that the result leads the doctor to make an incorrect management decision.

Many of the correct results will lead to appropriate decisions on patient management, with potential savings to patients and improved outcome.

For the costing model used later in the case study (p. 25), it is assumed that using an office-based test, 5% of results are outside the ALP, and 2% lead to false allocation of the patient being in or out of the normal range for blood glucose. Furthermore, these 2% of incorrect results lead to significantly wrong information for the doctor. It is then assumed that in 50% of these (1% of all glucose tests) an incorrect decision is made.

For half of the incorrect decisions, the results indicate—incorrectly—that the result is within the normal range for glucose—corresponding to a false negative.

In the other half of the results leading to an incorrect decision the figure for blood glucose is outside the normal range, corresponding to a false positive.

For the 'false negative' results which are incorrectly within the normal range, the implication is that either diagnosis of the disease may be missed with delay in treatment and an increased chance of additional morbidity and complications, or else the required adjustment to the dose of medication is not made. Consequences will range from additional discomfort and inconvenience to the patient, with further consultation and tests, to development of complications, perhaps leading in a minority of cases to hospitalisation.

For an abnormal result which is incorrect (the false positive), the possible consequence is an incorrect diagnosis, perhaps leading to commencement of unnecessary treatment. In the case of established disease, the apparently elevated results could lead to an inappropriate change to the patient's medication.

While these incorrect results and treatment decisions may occur only in a small minority of patients, the consequences of such inaccurate results may be significant. The possible consequences underpin the need for those providing pathology tests in whatever setting to be properly trained, competent in the use of the test equipment, aware of the need for adequate quality assurance and to have an appreciation of the performance and limitations of the tests being used.

Cholesterol

For cholesterol tests, the ALP is ± 0.5 mmol/L and the normal range for the substance in blood is 3.5–5.5 mmol/L. Using similar arguments to those for the glucose tests, the limit for standard deviation of results from a test which gives all results within ALP is 0.17.

For a sample at the upper limit of the normal range (5.5 mmol/L), 50% of results will be out of range. For a test with 90% of results within ALP, this proportion will increase to approximately 100% of results being outside the normal range.

Effects of blood cholesterol testing can be summarised as:

Type of result	Treatment decision
Result normal and correct	Patient and doctor reassured.
Result normal but incorrect	False reassurance, opportunity to counsel patient missed; medication not prescribed; risk factor not modified.
Result abnormal and correct	Advice on modifying lifestyle (especially diet); possibly prescription on lipid-lowering drugs.
Result abnormal but incorrect	Unnecessary anxiety to patient; possibly incorrect prescription of medication, additional consultations.

The arguments regarding the effect of inaccurate tests are essentially the same as those given for glucose. A number of the inaccurate results will have no real consequence for the decision taken by the doctor as they will not result in patients being incorrectly assigned as being within range or out of range. However, use of the tests which have poorer performance than specified will increase the chance of a significant incorrect decision.

The actions to be taken on the results from cholesterol testing are of a different nature to those for glucose. Glucose concentration is an important major indicator for diabetes. In the case of cholesterol, the testing is being carried out to give an indication of the level of risk of coronary artery disease. However, the cholesterol blood level is only one of a number of risk factors for this condition, and there is still considerable debate on the effectiveness of the measures available to reduce its concentration.

If a cholesterol test is correctly within range, then patient and doctor are reassured with regard to health status. A correct abnormal result (high) would lead to advice by the doctor on modifying lifestyle and especially diet. In the case of patients with cholesterol level well above the normal range, lipid lowering drugs may be prescribed.

If the result is incorrectly estimated as being within the normal range, then there is false assurance of health status, and the opportunity to counsel the patient may be missed—essentially the risk factor will not be modified (though the consequences of this may be hard to determine). If the result is incorrectly out of range, then the patient may be given unnecessary anxiety with perhaps further unneeded consultations and potentially incorrect prescription of medication.

(One of the current debates in this area is the value of cholesterol testing as opposed to strategies such as media campaigns, and whole population approaches to modifying habits associated with risk factors—particularly diet and smoking. Some of the arguments concerning alternative strategies for prevention of heart disease are discussed by Hall et al.)[8]

Measures of the effects of office pathology testing on health status

Given the many factors that influence health status, and the uncertain impact of a pathology test result on the decision taken by the doctor, it is not easy to measure the influence office testing may have within a health care system, or at practice level. For some conditions it may be possible to obtain an indication by monitoring relevant biochemical parameters over time for a population of patients, to see whether levels of cure or control of a disease are improved.

At another level, of interest to health authorities and insurers, it may be possible to make use of surrogate measures of effect such as changes to the number of prescriptions for medication, and changes to time off-work for those patients who are employed.

An important player in use of this technology is the patient. A significant measure of effective office testing would be the level of satisfaction of patients with the service provided compared to the situation where no pathology testing was carried out within a general practice.

Information on measures such as these is difficult to obtain. Some indications—for example, levels of prescription of drugs—may be obtainable from data bases held by health insurance organisations. However, these may not be sufficiently detailed and there could be problems of linkage of data. Measures related to biochemical parameters and patient perception will be obtained only through well organised trials and few of these have yet been attempted.

In an Australian trial,[3] availability of office pathology testing was not shown to affect biochemical measures of control in diabetic patients, hyper/hypokalemia and hypouricemia in diuretic users, or the number of cases of anemia diagnosed by the practices. In the diabetic patients, the measure of control was glycated hemoglobin—an indicator of long-term glycemic status. These results in part will reflect the case mix of patients in the practices concerned, and a significant change in biochemical markers might have emerged over a longer period and with greater number of patients. Nevertheless, other studies have tended to indicate that availability of office pathology testing does not appear to have a very strong effect on biochemical measures.

In the same trial, of 91 patients who were diabetics or users of diuretics, 96% rated their experience of pathology analysers in their general practitioners' offices as good or very good. These patients tended to regard normal pathology services less favourably when their general practitioner had access to an analyser. Such patient perceptions may be important but difficult to quantify.

A further consideration is the routine that may actually be adopted in practices for analysis of specimens. It is not uncommon in some health care systems for general practices to batch samples collected from patients and then run these through an analyser at the end of the day. This may produce results of acceptable standard (although care will be needed in labelling, preparing and storing the specimens), but clearly the tests would not be done while the patients were still in the practice, so that a major potential advantage of the technology is lost. It can be argued that batching of tests in this way leads to little advantage over forwarding specimens to a pathology laboratory.

Cost considerations

A major consideration in the assessment of office pathology testing is the cost of such services. In this discussion, attention is given to two aspects of costs associated with office testing—the effect on total costs of pathology services in a health care system, and costs associated with the consequences of product performance.

Cost impact on different sectors

The cost impact of office pathology testing will fall on several sectors. Costs will involve the performer of the test (the general practitioner in this example), health insurance organisations, patients and society generally.

General practitioners undertaking pathology testing will be faced with the costs of equipment and reagents, of any licensing/accreditation requirements imposed by health authorities, quality control, training of staff, overheads and bad debts. The general practitioner may be able to offset some or all of these costs through increasing volume of business as a result of having a pathology testing facility on the premises, coverage of costs through reimbursement from insurers, and through payment by patients.

Direct costs to health insurers related to office pathology testing will include fees paid to general practitioners for such services, the cost of back-up testing by laboratories and the cost of any additional treatment or diagnosis through decisions based on incorrect results or interpretation. Offsets may arise through any net decrease in laboratory tests, through savings due to more effective patient management and decrease in use of some services.

Costs to the patient will include payment to the doctor for the test, costs through inappropriate treatment and diagnosis, and additional consultation because of incorrect results. Possible benefits to the patient may arise through any increase in improvement in health status as a result of the test, decreased travel costs and earlier return to work or normal activity.

Costs to society will include any additional burden of treatment and illness costs associated with inappropriate decisions or unnecessary testing, and the costs of administering any regulations applying to office pathology testing. Any decrease in services as a result of office testing and earlier return of patients to normal activity will provide offsets.

Effect on number of pathology tests

Use of office pathology testing has the potential to increase the total volume of pathology tests, Practitioners may be motivated to check the biochemical status of their patients, seek to increase revenue through such testing, and feel less inhibited in undertaking a test than in ordering a test from a laboratory.

An Australian study of 28 general practices showed that there was a 9% reduction in the biochemistry tests ordered from laboratories during the period

of the trial, and that an overall 46% increase in the total number of such tests was observed in the trial period.[3]

This potential increase in the volume of testing at the office level may be offset by the lower fees that will be applicable to tests carried out by general practitioners as compared with those available to laboratories (at least in some health systems).

The additional testing may also result in benefits to patient care. These are not necessarily restricted to clinical or diagnostic outcomes, but may include the patients' sense of satisfaction and well-being. However, strong evidence of such benefits as a result of office pathology testing has been slow to emerge.

Costs associated with product performance which are less often explicitly considered are those associated with the consequences of product performance. If a test with poor performance is used on a number of patients, there will be consequences to the health care system and to the individuals through incorrect treatment decisions, additional tests and consultations and, in a minority, further complications and hospitalisation. Benefits will result from better-informed and prompter decisions by the doctor as a result of information from tests which give correct results.

In the scenarios that follow, costs are calculated on the basis of a health system with 1,000 office pathology establishments each undertaking 500 tests of each type per year. The costs of tests and other services used in the calculations approximate those applicable to Australia in 1993. As with other modelling used in this case study, the data would require modification to correspond to other health care systems.

These cost models for the most part reflect the perspective of the health authority or health insurer. A number of assumptions are made and these should be questioned, and alternative data considered, to reflect possible circumstances in different health systems. For the most part, relatively short term costs and benefits are considered. Longer-term consequences of pathology tests are to a large extent uncertain. The potential decision tree for any test and associated management options rapidly becomes very complex, and firm data are lacking for most situations.

Tests for urinary tract infection

Consider a kit test for detection of urinary tract infection using the performance data given earlier for Test A (sensitivity 82.8%, specificity 95.2%). Of 500,000 tests:

- 100,000 will be performed on patients with infection, and in 82,800 the disease will be correctly identified;
- 400,000 will be performed on patients who do not have infection, and in 380,800 the disease will be correctly excluded.

Unit costs to the health authority/insurance agency are as follows:

	$
Cost per kit test (Test A)	5
Cost of culture at a laboratory	20
Cost per GP consultation	25
Cost of antibiotics (UTI)	9
Cost of antibiotics (vaginitis)	8
Cost of cervical culture at a laboratory	25

Table 1 gives comparative costs associated with use of the kit in the doctor's office and use of a laboratory test (bacterial culture) on all patients. Some of the assumptions made are that:

- antibiotics are prescribed in the large majority of patients for whom laboratory tests are ordered;
- the laboratory tests are 100% accurate;
- other types of antibiotics are (inappropriately) prescribed for those patients who had a false negative office test; and
- laboratory tests and additional consultations take place for half the patients who have incorrect office results.

Slide 36 (Appendix 2) shows the likely outcome for patients whose specimens are referred for laboratory culture.

These estimates include costs associated with additional treatment for those patients for whom incorrect results are reported. For those with false negative results, the doctor may in a majority of cases proceed on the assumption that the symptoms are due to vaginitis or chlamydia and prescribe other medication.

Possibly a small minority of patients with incorrect results would have complications requiring additional treatment. This factor has not been costed in, but could reasonably be assumed as minor.

Table 1: *Costs of testing for urinary tract infection*

Item	Office test (Test A)	Laboratory culture
Initial testing	$2,500,000 (500,000 patients)	$10,000,000 (500,000 patients)
Antibiotics for UTI	$918,000 (82,800 patients TP, 19,200 FP)	$4,050,000 (90% of patients)
Antibiotics for presumed vaginitis	$138,000 (17,200 patients FN)	
Additional tests (lab culture)	$407,000 (50% of FN @ $25, 50% of FP @ $20)	
Additional consultations	$455,000 (Additional consultations for 50% of FP & FN)	
Total	**$4,418,000**	**$14,050,000**

On this model, the comparative costs would seem to favour the office-pathology approach, because of the lower test costs and more rational ordering of antibiotics.

It is unlikely that the office test would gain a 100% market share. If the test led to a 40% substitution for laboratory testing and a 10% increase in total number of tests, total cost of testing and associated follow-up would be $10,639,000.

This cost scenario does not reflect the patent's perspective, so that savings due to reduced travel costs and time off work are not included. These would be significant gains for the patient and for society (perhaps two hours' loss of work/travel time averted in 50% of cases).

Consider the costs of kit testing using some other assumptions:

- the sensitivity and specificity of the test are both 80%;
- the cost of the office test is $15;
- the unit cost of antibiotics is $25; and
- substitution for laboratory tests is 60%, and increase in total tests is 30%;

How do these changes affect the cost comparison?

Test for blood glucose

For glucose testing the unit costs are:

	$	
Cost per 'office' glucose test	15	
Cost per laboratory glucose test	20	
Cost per GP consultation	25	
Cost of medication –insulin	105	(171)
–hypoglycemics	10	
Cost of follow-up tests	40	
Cost of hospitalisation	370	/day

For this costing model it is assumed that 95% of office tests are within ALP and that these are associated with appropriate decisions on patient management. It is also assumed that:

- 2% of tests are associated with incorrect assignment of patients as being within or outside the normal range (50:50 in each category);
- in half of these cases (5,000 patients), incorrect management decisions are made; and
- all laboratory tests are within ALP and lead to correct decisions.

Table 2 shows the comparative costs of office and laboratory testing for glucose, taking into account incorrectly prescribed medication and an allowance for additional treatment for those cases where incorrect results led to continuing symptoms and complications.

Table 2: *Comparative costs associated with testing for blood glucose*

Item	Office test ($)	Laboratory test ($)
Initial testing	7,500,000	10,000,000
Additional pathology tests (80% of cases with incorrect decisions)	$80,000	
Additional consultations (80% of cases with incorrect decisions)	100,000	
Inappropriate medication (4,000 with hypoglycemics, 1,000 with insulin)	145,000	
Hospitalisation (200 cases, three days each)	222,000	
Dialysis—treatment for renal failure (three cases)	50,000	
Total	**8,107,000**	**10,000,000**

If there was 40% substitution for laboratory tests and a 25% increase in total numbers of tests, overall costs to the health system would be $11,270,000—an increase over laboratory-only testing.

The break-even level on additional testing would be 9.2%.

There would be benefits through prompter correct decisions on patient management, leading to avoidance of unnecessary services, but these are hard to quantify. As noted previously, the relationship between numbers of glucose tests and degree of glycemic control obtained is not clear.

Many assumptions are made in this model. Consider the implications of the following alternatives:

- cost of office tests are the same as those of laboratory tests (as is the case in some health care systems);
- incidences of hospitalisation and end stage renal failure as consequences of inaccurate testing are one tenth of those given in the model; and
- there is a 50% increase in total number of tests, with 30% substitution for laboratory tests.

Again, this cost model has been derived from the perspective of the health authority/insurer. It does not take into account benefits to patients and society through avoidance of travel costs and time off work. Some of these benefits would be lost if the test was not performed during consultation but at the end of the day as part of a batch of specimens.

Data from the Australian study[3] indicated that 70% of office pathology was performed in the presence of the patient. Possible savings of $5 per patient episode for travel and two hours of lost production at $20 per hour could result.

Test for blood cholesterol

For cholesterol testing, the unit costs are:

	$
Cost per 'office' cholesterol test	15
Cost per laboratory cholesterol test	20
Cost per GP consultation	25
Cost of lipid-lowering drugs:	
Cholestyramine—1 month's treatment	100
Clofibrate	14

It is assumed that:

- 90% of office tests are within ALP and are associated with appropriate patient management;
- 4% are associated with incorrect assignment of patients as being within or outside the normal range (50:50 in each category);
- in half of these cases (10,000 patients) incorrect management decisions are made; and
- all results from laboratory tests are within ALP and lead to correct decisions.

Table 3 shows comparative costs of office and laboratory testing for cholesterol, taking into account inappropriately prescribed medication and additional consultations.

Table 3: *Comparative costs associated with testing for blood cholesterol*

Item	Office test ($)	Laboratory test ($)
Initial testing	7,500,000	10,000,000
Additional consultations (60% of 'false positive' cases)	785,000	
Inappropriate medication (40% of 'false positive' cases)	200,000	
Additional testing (50% of 'false positive' cases plus laboratory tests for 10%)	47,500	
Consequences of not counselling/treating 5,000 'false negative' cases	?	
Total	**7,822,000**	**10,000,000**

If office testing substituted for 20% of laboratory testing and there was a 40% overall increase in total numbers of tests, overall cost to the health system would be $12.69m—an increase over laboratory-only testing. The break-even limit on additional testing would be 5.6%.

The potential benefits of office testing for blood cholesterol would be through prompter and possibly more effective counselling for patients with high levels, leading in a proportion to lowering of blood levels (modification of risk factor) and in a smaller minority to avoidance of major symptoms of coronary artery disease, interventions such as angioplasty or bypass surgery and sudden death.

The extent to which office testing would increase such benefits in comparison to laboratory testing is uncertain, as also are the cost consequences of not counselling/treating patients who are incorrectly tested as being within normal range.

Once again, many assumptions have been made.

Consider and calculate the implications of the following alternatives:

- cost of office tests are the same as those for laboratory tests;
- 50% substitution for laboratory tests and 20% increase in total tests occurs; and
- medication is prescribed in only 10% of the 'false positive' cases.

Benefits from the patient and society perspective may include prompter advice and decrease in consultation/travel/time off work but are difficult to quantify.

Note that information on cholesterol levels will be obtainable in the absence of office testing—the point of interest in the comparative benefits obtained from two types of test provision. As was the case with glucose, much of the potential value of office testing over laboratory testing will be lost if cholesterol tests are performed in batches after consultation with patients is completed.

Value for money

On the basis of these basic cost models and the assumptions they incorporate, do the tests considered in this case study represent good value for money within a health care system? The answer will depend on a number of factors, including:

- availability/coverage of pathology laboratory services;
- levels of reimbursement for office and laboratory tests;
- total numbers of tests undertaken following introduction of office pathology;
- standards of performance of office testing;
- effects of office testing on management decisions, use of other services (in comparison with effects of laboratory testing); and
- effects of office testing on patient outcome and health status (again, in comparison with laboratory testing).

Clearly, there are many variables, and firm data on various aspects may be difficult to obtain. In this case study, some indicative costs have been derived, but information on the benefits that would be necessary for a full economic analysis are not available. For the three types of test that have been considered, some general points can be made, based on the assumptions made.

The test for urinary tract infection may well represent value for money, as it is a cheaper alternative to laboratory testing, gives prompt results and enables a more efficient strategy for the use of antibiotics (with consequent cost savings). The test performance measures will be important in determining the degree of advantage.

The test for glucose is more expensive overall to the health care system, as it is associated with some costs due to incorrect decisions and with an increase in overall testing (using the assumptions in the model). It may still represent good value for money if the prompter decisions through office testing improve management of diabetics. Some of the less common consequences of inaccurate results, such as diabetic coma, will be expensive. Good quality results would be essential for cost-effective use.

The situation with the test for cholesterol is less easy to decide. Again, the data used in the model lead to higher costs of testing when the office pathology service is available.

The reason for undertaking cholesterol testing is to assist in preventing morbidity and deaths from coronary heart disease. The extent to which office cholesterol tests would improve patient outcome as compared with laboratory tests might depend on the degree to which prompt availability of results improved the impact of counselling on the patient.

The wider question of whether routine cholesterol testing is an effective strategy for reducing the risk of coronary heart disease is still a matter of debate. It raises wider issues for a health system with limited resources, including consideration of the effectiveness of alternative strategies such as media promotion of healthy diets and lifestyle.[8]

For all three types of test, there may be benefits to the patients, such as greater convenience, reassurance, less travel, that are not of major significance to health insurers.

Political and organisational factors

Going beyond the immediate assessment requirements for office pathology testing, including test performance and effect on patient management and health services costs, there is a need to consider the wider context for this technology. The overall view of the place of office pathology within a particular health care system will be influenced by various political and organisational considerations.

In political terms, there is concern in many countries at the high and increasing cost of pathology testing. Numbers and costs of pathology tests have been increasing steadily in many countries for a number of years. Some of this increase has been associated with introduction of new types of test. It has also involved the use of more advanced technologies which have increased efficiency and decrease the unit costs of tests. These efficiencies have been offset by the increase in volume of testing and by some increases in overheads.

The following information summarises some trends in Australian pathology services funded through Medicare. The rapid growth in numbers and costs of pathology tests over the four years to 1988–89 was followed by a decline over the next two years. This decrease was associated with cuts in fees paid by government for some tests, and possibly also to a shift in testing to hospital laboratories which are funded under different arrangements.

Table 4: *Numbers and costs of pathology tests funded through Medicare*

Item	1984–85	1988–89	1990–91	1992–93
Clinical chemistry tests:				
Numbers of tests (x 1,000)	5,640	10,176	9,528	9,843
Fees paid ($m)	173	230	219	141
All pathology tests:				
Numbers of tests (x 1,000)	22,217	31,826	25,779	26,877
Fees paid ($m)	490	559	583	579

Notes: Costs are in constant 1989–90 dollars.
Data from the Health Insurance Commission.

The high cost of pathology tests represents an opportunity cost to other health services. Concern by many health authorities regarding the volume and cost of pathology tests is linked to a perception that some pathology testing is inappropriate. An element in countering the inappropriate use of pathology services is the need for education of medical practitioners and others. Typically, use of these diagnostic services is still covered only in a very limited way within medical schools. Efforts have been made in many countries by professional bodies and individual pathology services to develop guidelines on appropriate indications and sampling for general practitioners and others who order pathology tests.

These factors have implications for office pathology testing from the perspective of health authorities and insurance agencies. There will be a general perception that office pathology testing will need to substitute for some of the services provided by laboratories and/or provide additional benefits to health care, particularly in terms of patient management and overall health status. Other potential benefits of office pathology, such as greater convenience for patients, may be less significant from the perspective of health care insurance agencies.

Decentralisation of services

The development of office pathology is an input to the ongoing debate on the merits of decentralising various types of health services rather than concentrating them in major centres. Some of the features in the moves to decentralisation has been a wish to decrease institutional costs, increasing potential through advances in information technology to link a number of centres with an expert unit and progressive advances in the design of various technologies.

In the case of pathology services, increased linkage between laboratory and non-laboratory providers through information networks is clearly an option. However, there may be organisational and conflict of interest considerations mitigating against such arrangements an the evolution of pathology services as mentor laboratories to provide advice, back-up and training for the general practitioner.

The ease with which most pathology specimens can be transported and processed at a central laboratory facility tends to argue against the worth of decentralisation for this type of service, particularly for less common tests. An alternative scenario would be to increase the efficiency with which specimens can be transported to a central facility and the speed with which results can be transmitted back to the referring practitioner.

Status of general practitioners and laboratory staff

In some health care systems, there is a perception that the status of the general practitioner has been eroded over the years with many functions being taken up by specialists in various areas of medicine. This seen by some to have resulted in a decline in professional standing, work satisfaction and income. One view is that the increasing availability of office pathology testing would provide a boost to the status of general practitioners. This point should be borne in mind as creating some of the pressures from the professional sector for wider adoption of this technology.

A contrary influence is the concern that has been expressed by pathology laboratory staff at what they perceive as significant competition from office pathology. Office pathology has been seen as having the potential to remove workload from laboratory facilities with downstream consequences for employment and out-of-hours duties of laboratory scientists and technicians.

An Australian report[9] has noted that such reactions point to the need for adequate consultation by hospital administrators with laboratory and other staff prior to introduction of decentralised testing. Also, the advent of desk-top analysers and other simpler technologies for pathology testing is just one step in what has been a progressive de-skilling of some aspects of the duties of professional staff in pathology laboratories. The view of the Australian study was that the effects of office pathology testing on laboratory staff was a sensitive area which required careful consideration and discussion between unions, health authorities, professional bodies and administrators.

Implications for new biotechnology-based products

Application of biotechnology has already led to important advances in diagnostics. Developments in biotechnology offer the potential for better test performance and greater confidence in results obtained. More selective reagents may simplify complex tests. Current developments with polymerase chain reaction and other signal amplification technology seem likely to lead to a range of new kit tests for infectious diseases. As with other products, the impact of the new biotechnology on office pathology will be sensitive to cost, reimbursement policy, availability of laboratory services, relevance to case mix and practice routine, and to perceived effect on health outcome.

In the immediate future, major applications of new technology may be in the laboratory setting rather than in office pathology. The impact of new biotechnology on office pathology will be sensitive to cost, reimbursement policy, availability of laboratory services, relevance to case mix and practice routine, and to perceived effect on health outcome.

Previous experience in some health systems with new biotechnology products of good technical quality suggests that these will not necessarily make a large impact on non-laboratory testing. One such product was a diagnostic kit for chlamydia—a common sexually transmissable disease. This was not a market success because the performance of the test did not fit in comfortably with practice routine. The kit was technically successful, but did not meet the requirements of the potential user as it took too long to obtain a result.

In another case, a test was developed for quantitative estimation of theophylline and anticonvulsants, using MCAs plus a separation technique. The test was robust and had good performance, but was not applicable to office pathology in Australia because of its cost and the limited need for doctors to test for these substances in the general practice setting. Technical excellence will not necessarily mean that the product is appropriate for the office setting or for a particular health care system.

An area of major potential for biotechnology-based products is genetic testing—for example in detection of markers for inheritable disease. Such tests could prove popular with insurance agencies and employers and screening for the likelihood of certain diseases.

Genetic testing is an area of enormous technical, ethical and legal difficulty. In the context of any 'office testing', not only would tests have to give excellent performance under non-laboratory conditions, but practitioners would need to be trained to provide any necessary counselling. There would also have to be well-defined and accepted options for follow-up diagnosis and management.

There is potential for new technology to provide additional information, but the medical and societal machinery for dealing with such information is not yet in place.

Synthesis

Office pathology testing has the potential to improve patient management, increase doctor and patient satisfaction and help contain costs. The degree to which this technology is able to achieve these aims will depend on a number of factors. In particular, it is necessary for a product intended for office pathology testing to meet a number of criteria related to performance, relevance, usefulness, effect on management and health status, and costs.

The 'gold standard' against which office pathology is compared is laboratory pathology. Comparative costs and benefits of these two approaches to testing are of interest here.

Performance

Office pathology tests must be able to achieve acceptable sensitivity, specificity, imprecision and inaccuracy under the conditions expected in office testing. Achievement of such standards implies a reasonably robust product, adequate training of the operator, participation in quality assurance programs (and possibly accreditation schemes) and appropriate product support by the manufacturer. General practice staff will have many other duties besides pathology testing so that the tests must be simple to conduct and be able to fit realistically within practice routines.

Relevance

To be successful in the office pathology setting, a test will need to be related to a condition, disease and type of patient likely to be seen frequently by the general practitioner.

Patient management

The effects on management will relate to whether the test is likely to significantly influence patient management decisions and the speed with which a result is needed. Overall, there is a need to assess whether patient health status is influenced for the better through the presence of office pathology.

Costs

It is necessary to consider effects of office testing on overall costs of pathology services to a health care system as well as to the patient, doctor and insurers, both through the direct provision of tests and the consequences of their use. Major points to consider are the degree of substitution for tests performed within laboratories, any additional services or morbidity created as a result of incorrect results and savings through prompter availability of correct results leading to more appropriate management decisions.

Political and organisational matters

The place of office pathology will also be influenced by various political and organisational factors, the significance of which will vary from country to country. Many of the data and arguments used in this case study relate to a Western health care system with well-developed networks of pathology laboratories and other services. Types and numbers of tests, their method of provision and action taken on the results may be very different in the context of a health system within a developing nation.

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Appendix 1

Other settings for office pathology

This case study has focused on the performance of pathology tests in general practice. There are a number of other settings for pathology tests undertaken outside the laboratory, including the intensive care unit and general wards within hospitals, population screening (as may occur in health promotion campaigns and testing of employees), self-testing at home and testing at sites which are remote from laboratory services.

While each of these share some attributes with general practitioner pathology testing, there are also some differences and special characteristics.

The ICU

In the intensive care unit (and some other specialised units within the hospital) similar considerations apply to the choice of tests that will be routinely required. Typically, staff within the ICU have immediate interest in monitoring only a small number of analytes, such as electrolytes and blood gases. Results of these tests will often be needed very urgently and frequently in the acute management of patients. Savings of even a few minutes in reporting of a test result can be of real benefit in this situation.

Standards of staff training and associated protocols may be particularly good in such settings. However, while high levels of competence applicable to pathology testing may exist in the ICU, back-up by the pathology laboratory within the hospital is highly desirable. Laboratory staff will be able to assist with troubleshooting, training and quality control in addition to providing back-up for tests that cannot be immediately undertaken. Overall, this appears to be an area of office testing where benefits of the technology have become well established.

Hospital wards

The situation in the general hospital ward is somewhat different, although it will vary from institution to institution. Probably only a limited number of results will be needed urgently and some of these may be monitored sufficiently well in the routine situation by use of basic test strip measurements.

General ward testing may face difficulties through ensuring that staff are sufficiently competent to achieve adequate levels of performance-rotation of staff within hospitals may pose a real problem. Laboratory back-up would be essential for all tests. Cost-effectiveness of ward testing would need to be considered closely by institutions. In many instances, it may be more convenient and more efficient for general ward testing to be undertaken by the hospital laboratory. Key points to consider would be the urgency with which results are needed for patient management and levels of performance routinely achievable.

Screening programs

Pathology testing has been commonly used in population screening programs, some of which have been undertaken without immediate laboratory assistance. Population testing has included, for example, performance of cholesterol tests and testing of fecal occult blood in health promotion campaigns.

In a technical sense, such exercises may impose further demands on the performance of the test and simplicity of operation and robustness are important considerations. Very often the test may be conducted in a setting where there is no technical back-up at all. Clearly, there are also major implications for the training of operators in this sort of situation.

Some other features require consideration. Firstly, there is the usual situation of needing to consider the prevalence of the disease or condition for which people are being screened. If the prevalence is very low, there are obvious implications for the sensitivity/specificity required for the test to be useful. If the ability to correctly detect or exclude disease is relatively limited, then use of pathology tests in the screening situation will generate substantial numbers of false positives or false negative results. The false positives will lead to additional testing, and possible unnecessary anxiety in those who have been tested. Screening needs to be linked to availability of realistic treatment or intervention, which may include counselling. It would seem inappropriate for such tests to be offered in isolation.

The cost-effectiveness of screening, taking account of follow-up tests and treatment, requires close consideration.

Self-testing

Self-testing, especially in the home, has been advocated as a means of enabling people to take further responsibility for their own health and of reducing the costs of health services. Self-testing for blood glucose is commonly undertaken by diabetics, and pregnancy testing kits are widely available.

Some of the considerations applying to population screening are relevant here. For a test to be useful in this setting, product performance will need to be high, with excellent robustness. The test should also have some relevance to the individual's decision and actions regarding health status.

People performing self-testing must have adequate training and sufficient functional literacy to enable performance of the test to be carried out correctly and appropriate action taken on the basis of the results. Typically, links will be required with professionals for advice, back-up, counselling and awareness of notifiable disease requirements. In the common application of glucose testing, back-up by a laboratory or clinician appears to be highly desirable if sufficiently accurate results are to be obtained consistently by the patient. (The effectiveness of self-monitoring in terms of ensuring glycemic control appears to vary between countries and groups.)

The cost-effectiveness of home testing, particularly from the patient's perspective, needs close assessment. Potential benefits are the prompt availability of advice and the convenience of avoiding visits to the doctor's

office or the hospital. Potential dangers are inaccurate results and failure to take appropriate action on the basis of a test, including seeking advice.

Remote sites

Office pathology testing may be particularly useful in locations which are remote from laboratory facilities and where there is real difficulty in arranging for transport of specimens and subsequent reporting of results.

If the site is remote, then availability of back-up from the manufacturers is likely to be restricted. Tests will need to be robust and it is also probable that only a limited number will be commonly performed. While back-up may be restricted, there will nevertheless be a need for analysers or other equipment to be supported effectively by the distributor, so that limited servicibility does not become a major restriction.

A challenge for the technology is the provision of low-cost, robust tests for use in remote sites in health systems within developing countries, where there may be requirements for tests that can be applied widely to the population by persons with limited training in laboratory or medical techniques.

Appendix 2

Slide material

Provision of pathology tests

- Pathology testing is used as an aid to diagnosis and for monitoring the progress of treatment.
- Most pathology tests are performed in laboratories by experienced staff with strict quality control.
- Until recently, office-based testing relied on the use of simple dip-sticks, colorimetric methods and microscopy.
- More recently, the scope of office testing has been widened by availability of cheaper, easy to use, specific test systems.

Some office pathology systems

'Desk top' analysers:

—Manipulatory steps minimised.

—Microprocessor-controlled.

—Reagents on slides or in cartridges, bar-coded for identification/ calibration.

—Often offer panels of tests.

Specific kit procedures:

—Many based on biotechnology developments.

—Instrumentation not needed.

—Usually qualitative or semi-quantitative results.

—Often have built-in controls to minimise errors.

Settings for office pathology

General practice —doctors' rooms

Hospitals —Intensive Care Units, other specialised units

—application in general wards.

Population screening —health promotion campaigns

Self–testing —self-monitoring, diagnosis at home.

This case study focuses on application in general practice with briefer discussion of use in other settings.

Possible benefits from office pathology testing

- Elimination of laboratory overheads.
- A closer doctor–patient relationship.
- Prompt availability of results.
- Greater patient convenience.
- Cost savings to health care.
- Professional status, income (benefits for the doctor).

Potential disadvantages of office pathology testing

- Potential for poorer-quality results.
- Inappropriate testing.
- Misinterpretation of data.

(All of which have consequences for patient convenience.)

- Potential for increased overall cost (disadvantage for health insurers and patients).

Questions in the assessment of a health care technology

Efficacy – performance under ideal conditions.

Effectiveness – performance under average conditions of use.

Efficiency – the extent to which it is economical and worthwhile to use a technology in a health system with limited funds.

A hierarchy of assessment questions

The questions to be asked of office pathology tests include:

- Does the technology work?
- Will it be useful in a clinical setting?
- Will it affect (improve) health status?
- How will it affect costs of health care?
- Is it good value for money?

Analytical performance of pathology tests

Sensitivity – ability to detect a disease or substance when present

Specificity – ability to correctly exclude a disease or substance

Outcomes of diagnostic test use

Test result	Disease present	Disease absent
Positive	True positive (TP)	False positive (FP)
Negative	False negative (FN)	True negative (TN)

$$\text{Sensitivity} = \frac{TP}{TP + FN}$$

$$\text{Specificity} = \frac{TN}{TN + FP}$$

Data from tests for urinary tract infection

Product A

Test result	Bacteria present	Bacteria absent
Positive	96	4
Negative	20	80

$$\text{Sensitivity} = \frac{96}{96+20} = 82.8\%$$

$$\text{Specificity} = \frac{80}{80+4} = 95.2\%$$

Product B

Test result	Bacteria present	Bacteria absent
Positive	80	15
Negative	5	100

What are the sensitivity and specificity?

Performance measures for quantitative tests (analysers)

Imprecision

Distribution of results of repeated analyses on the same specimen.

Inaccuracy

Deviation of the result from that obtained by a reference method on the same specimen.

Linearity

Straight line relationship between instrument response and concentration over a given range

Performance criteria for quantitative tests (analysers)

Imprecision

Coefficient of variation (CV) less than CV based on twice standard deviation obtained by laboratories:

$CV < 2(s/x) \times 100$

Inaccuracy

A. Based on simple linear regression, comparing test with reference method

   Acceptable if:
   correlation coefficient > 0.95;
   slope = 0.90–1.10
   intercept <Syx

B. Not more than the allowable limits of performance (ALP) derived for appropriate quality assurance programs.

Data from tests for blood glucose

Standards

Imprecision acceptable if CV < 6.4%
ALP ± 1.0 mmol/L
Normal range of concentration in patients = 3.8 – 5.8 mmol/L

Test C	Imprecision	CV = 2.5%
	Inaccuracy	100% within ALP
Test D	Imprecision	CV = 8.0%
	Inaccuracy	95% within ALP

Do these tests have acceptable performance?

Data from tests for blood cholesterol

Standards

Imprecision acceptable if CV < 8.9%
ALP ± 0.5 mmol/L
Normal range of concentration
in patients = 3.5 – 5.5 mmol/L

Test E	Imprecision	CV = 4.0%
	Inaccuracy	86% within ALP
Test F	Imprecision	CV = 11.0%
	Inaccuracy	90% within ALP

Do these tests have acceptable performance?

Product performance under non-laboratory conditions

- Less experience and training in performance of tests.
- Use of non-technical staff to perform tests.
- Possibly more rapid turnover of staff.
- Less appreciation of the need for quality assurance.

Robustness of a test

The degree to which its performance is affected by inconsistent or incorrect use, such as:

- incorrectly storing reagents (e.g. room-temperature storage when refrigeration is specified);
- incorrect dilution of reagents or specimen;
- incorrect timing of a procedure; and
- failure to clean instruments.

Use of tests in a clinical setting

Medical history of patient

Decision to perform test
(diagnosis, monitoring, exclude disease)

Use result as input to decision on patient management

In general—a test should not be performed if there is no likelihood of its influencing patient management.

Analyser tests commonly performed in doctors' offices

Most pathology testing with analysers in doctors' office settings relates to a small number of substances:

- Glucose
- Cholesterol
- Potassium
- Hemoglobin
- Urea
- Triglycerides
- Uric acid
- Creatinine

These tests will commonly be required to assist management decisions.

Other tests will be less commonly required—some conditions rarely seen, some tests make a smaller contribution to decision.

Qualitative tests (kits)—potential areas of need for general practice

- Sexually transmissable diseases
- Urinary tract infection
- Respiratory tract infection

Need to be frequently used, easy and reliable, and compatible with normal practice routine.

The alternative of laboratory testing

For less commonly performed or more complex tests, laboratory testing may be more reliable and convenient for the general practitioner.

Need to consider:

- how often a test may be needed;
- how significant the test is in the algorithm of patient management;
- reliability of results obtained outside the laboratory;
- urgency with which the result is needed; and
- convenience to the doctor and the patient.

For manufacturers, product options for the non-laboratory market may in practice be limited.

Use of a test for urinary tract infection

- Standard approach—specimen sent to laboratory for bacterial culture; delay of several days before result; antibiotics may often be prescribed in the interim.

- Alternative—kit method in doctor's office; result (positive/negative) on specimen within a few minutes; basis for decision on patient treatment.

Use of glucose and cholesterol tests in patient management

Glucose

High concentration indication of diabetes mellitus (also effects of some drugs, burns, sepsis).

Management—insulin, hypoglycemic medication.

Low levels indication of (e.g.) reactive hypoglycemia, alcohol consumption, insulinoma, malignancy.

Cholesterol

High levels—risk factor for coronary artery disease; (also factor in various conditions such as obstructive jaundice).

Management may include advice on lifestyle changes and diet, use of lipid-lowering drugs.

Low levels—include malabsorption, hyperthyroidism, pernicious anemia.

Consequences of testing for urinary tract infection

For Test A

For every 100 patients with infection:

- 83 will be correctly diagnosed, benefits through avoiding lab. costs and delays
- 17 will be incorrectly diagnosed (disease missed).

For every 100 patients without infection:

- In 95, disease correctly excluded, avoidance of unnecessary medication.
- In five, incorrect diagnosis of disease present, unnecessary prescription of antibiotics, delay in treating actual condition, if this is not self limiting.

Effects of testing for urinary tract infection

True positive result

Diagnosis confirmed, commence treatment with antibiotics.

False positive result

Incorrect diagnosis, inappropriate treatment (antibiotics), correct treatment delayed (or could be self-limiting).

True negative result

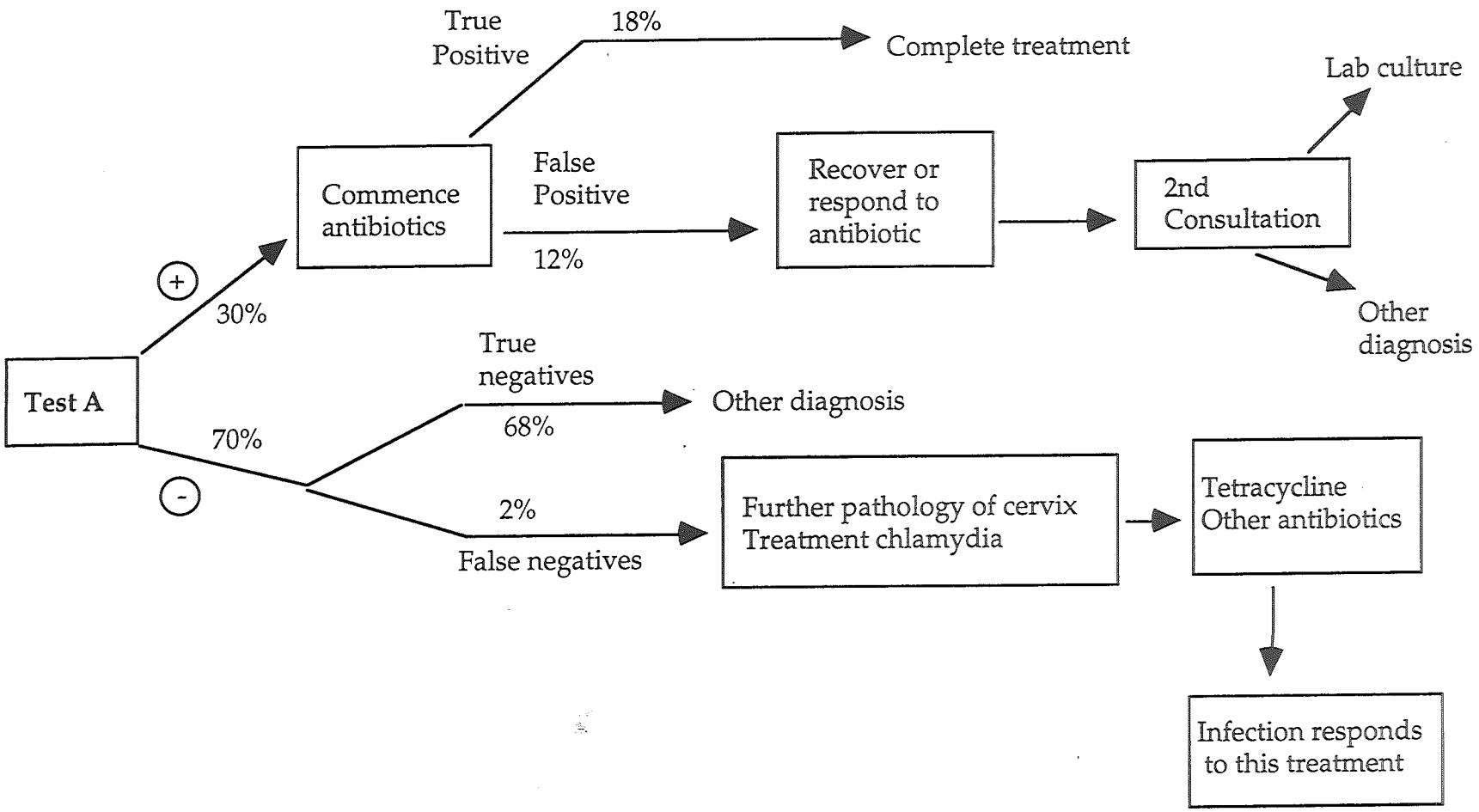
Disease excluded. Consider other treatment options, Avoid use of antibiotics. Possibly self limiting.

False negative result

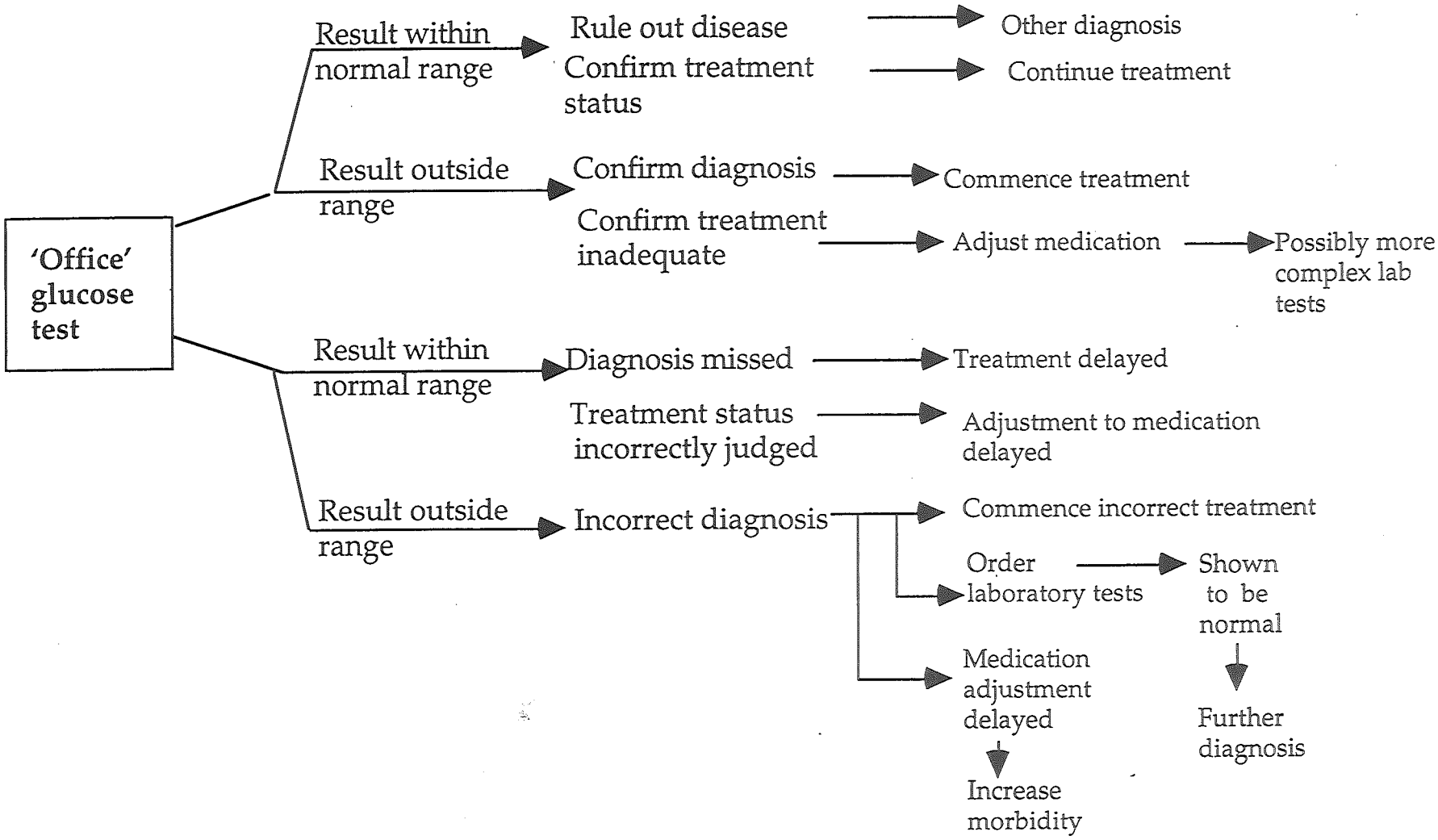
Diagnosis missed, correct treatment delayed, inappropriate treatment started.

[With all of these, possibility of additional testing if a laboratory is used as a back-up.]

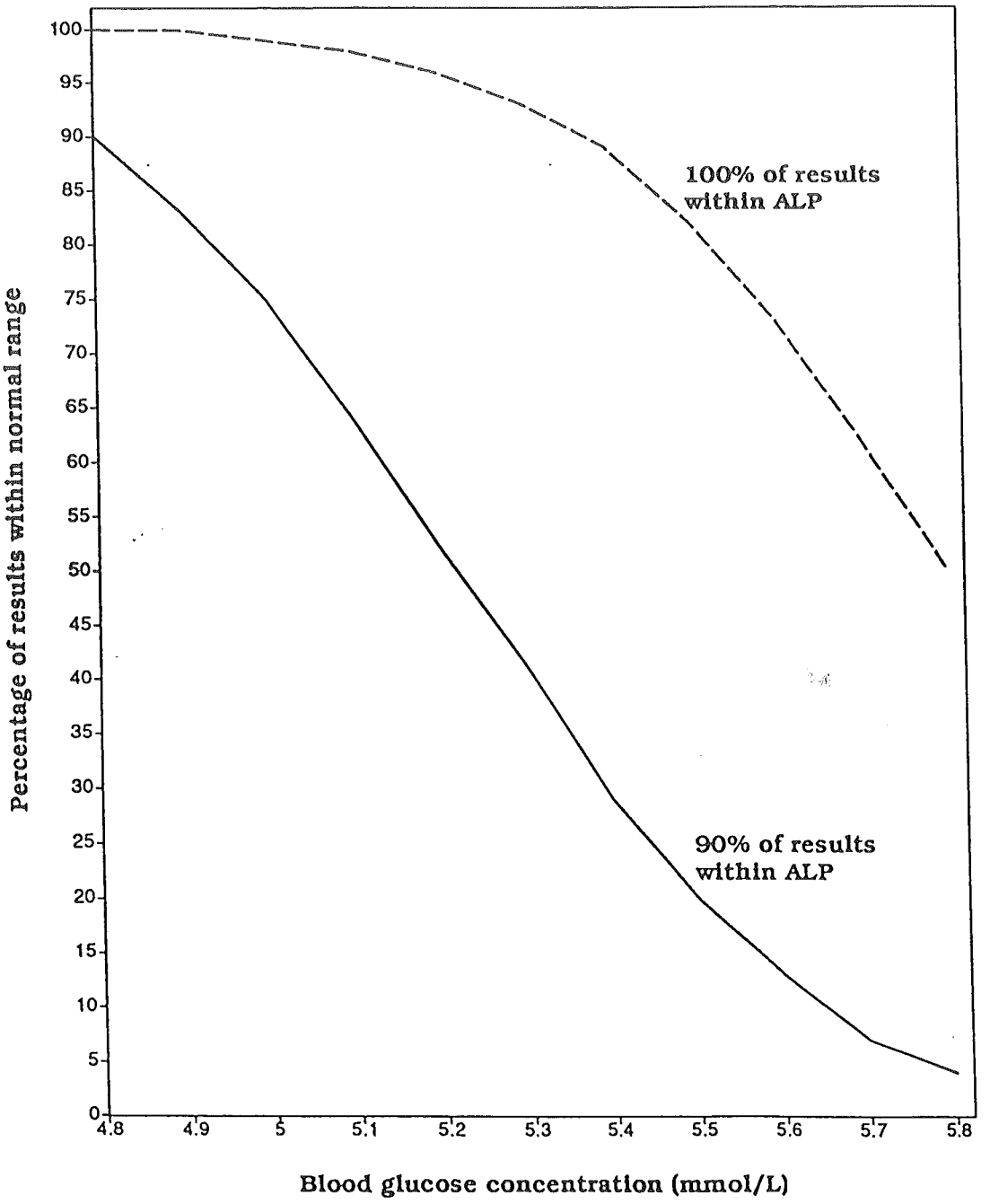
Consequences of testing for urinary tract infection, kit method



Consequences of blood glucose testing



Consequences of glucose test results falling outside allowable limits of performance



Consequences of cholesterol testing

Type of result	*Treatment decision*
Result normal and correct	Patient and doctor reassured
Result normal but incorrect	False reassurance, to patient not counselled; medication not prescribed; risk factor not modified
Result abnormal and correct	Advice on modifying lifestyle (especially diet) possibly prescription on lipid-lowering drugs
Result abnormal but incorrect	Unnecessary anxiety to patient; possibly incorrect medication; additional consultations.

Effects on health status

Health status is determined by many factors:

- Genetic, biological
- Environmental
- Nutritional
- Heeding warnings
- 'Well being'
- Use and application of health services.

- It is often difficult to define the effect of a diagnostic test on health status.
- One approach is to consider possible consequences of decisions based on test results.
- Test results will typically be only one input to a treatment decision, though they may have a major influence.

Example of attempts to measure health status

In one study, during the period when office pathology tests were being performed by a group of general practices:

- there was no change in the number of cases of anemia detected (hemoglobin measurement);
- no significant improvement was seen in control of diabetes (gycated hemoglobin measurement);
- there was no difference in complications from diuretic use (potassium and urate measurements); and
- patients rated office testing highly in comparison with laboratory testing.

(Dunt et al., 1991)

Impact of office pathology testing on costs of health service.

Impact will be on several sectors and have numerous components:

- **Cost to performer of the test.**
- **Cost to health insurers.**
- **Cost to the patient.**
- **Cost to society generally.**

Costs to performers of office pathology tests

- Capital and consumable costs.
- Licensing and accreditation fees.
- Quality control and training.
- Overheads, bad debts.

Offsets: Increased volume of business, coverage by insurers, payment by patients.

Costs to health insurers

- Reimbursement for office testing.
- Cost of back-up testing by laboratories.
- Cost of any additional/ inappropriate treatment or diagnosis through decisions based on incorrect results/interpretation.

Offsets: Any net decrease in laboratory tests; savings associated with more effective patient management and earlier return to normal activity.

Costs to the patient

- Payment for testing.

- Costs through inappropriate treatment/diagnosis, additional consultations because of incorrect results.

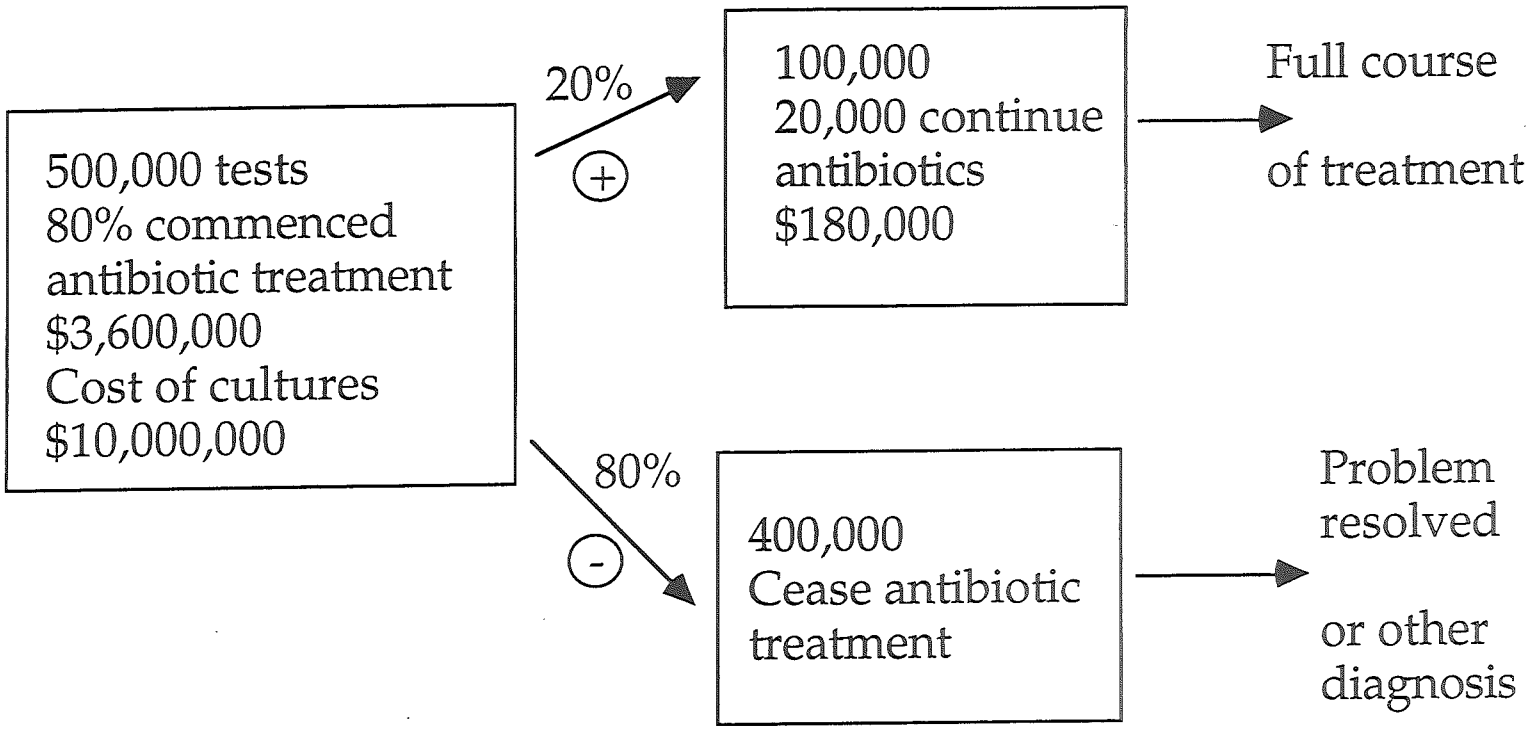
Offsets: Any improvement in health status, lower travel costs, earlier return to work.

Costs to society

- Any additional burden of treatment and illness costs associated with inappropriate decisions.

- Costs of administering office pathology regulations.

Diagnosis of urinary tract infection—the laboratory culture option—costs



Comparative costs associated with testing for urinary tract infection

	Office test (kit)	Lab. test (bacterial culture)
Initial testing	$2,500,000	$10,000,000
Cost of antibiotics	$1,056,000	$ 4,050,000
Additional tests	$ 407,000	
Additional consultations	$ 455,000	
Total	$4,418,000	$14,050,000

- Based on use of kit with sensitivity 82.8%, specificity 95.2% on 500,000 patients with 20% prevalence of infection.
- Costs reflect perspective of health insurer.
- Refer to notes for other assumptions.

Comparative costs associated with tests for blood glucose

	Office test (kit)	Lab. test (bacterial culture)
Initial testing	$7,500,000	$10,000,000
Additional testing	$ 160,000	
Additional consultations	$ 200,000	
Inappropriate medication	$ 145,000	
Hospitalisation	$ 555,000	
Dialysis	$ 100,000	
Total	$8,560,000	$10,000,000

- Based on testing 500,000 patients, for 5,000 of whom inappropriate decisions are made.
- Costs reflect perspective of health insurer.
- Refer to notes for other assumptions.

Comparative costs associated with tests for blood cholesterol

	Office test	Laboratory test
Initial testing	$7,500,000	$10,000,000
Additional testing	$ 48,000	
Additional consultations	$ 75,000	
Inappropriate medication	$ 200,000	
Consequences of not counselling or treating	$?	
Total	$7,823,000	$14,050,000

- Based on testing 500,000 patients, for 10,000 of whom inappropriate decisions are made.
- Costs reflect perspective of health insurer.
- Refer to notes for other assumptions.

Some factors which will determine if an office pathology test is good value for money

- Availability of laboratory tests within the health care system.
- Standards of performance of office tests.
- Impact of office testing on total numbers of tests.
- Levels of reimbursement for office and laboratory tests.
- Effects of office test results on management decisions and use of other services.
- Effects of office tests on patient outcome and health status.

Notional cost-related outcomes

	Office test ($)	Laboratory test ($)
Test for urinary tract infection:		
Cost per infection correctly diagnosed and treated	53.4	140.5
Test for blood glucose:		
Cost per correct decision in management/diagnosis	22.7	20.0
Test for blood cholesterol:		
Cost per correct decision in management/diagnosis	25.9	20.0

(Takes account of increase in total number of tests.)

Some further possible cost measures

Test for urinary tract infection:

- cost per hospitalisation avoided;
- cost per day off work saved.

Test for blood glucose:

- cost per diabetic coma averted.

Test for blood cholesterol:

- cost per angioplasty or bypass operation prevented.

(All these in comparison with the laboratory testing scenario.)

Political and organisation factors—1

- Concern by governments at high and increasing cost of pathology testing—an opportunity cost to other health services.
- Concern and action in some countries regarding inappropriate testing or over-servicing.
- Perceived need for office pathology testing to substitute for laboratory testing and/or to demonstrate benefits.

Political and organisational factors—2

- Debate on merits of centralised versus decentralised services.
- Perceptions of the role and status of general practice.
- Concern of laboratory staff at competition from office pathology.

Implications of new biotechnology-based products

- Potential for better test performance, simplification of tests.
- In short term, major applications may be in the laboratory rather than in office pathology.
- Level of use of new biotechnology-based products will depend on cost, relevance to case mix, practice routine and effect on outcome.
- Some areas of potential application, such as genetic testing, are complex. The ethical and legal implications will require an infrastructure to deal with the consequences of testing.

Synthesis—1

Office pathology testing has the potential to improve patient management, increase doctor and patient satisfaction and help contain costs.

To realise this potential, a product intended for office pathology testing must meet a number of criteria related to:

- performance
- relevance and usefulness
- effect on management
- cost

Synthesis—2

Elements of the various criteria include:

- Performance: acceptable imprecision, inaccuracy and linearity under 'office conditions'; reasonable robustness; adequate operator training and quality control.

- Relevance/usefulness: whether the test is related to a condition/type of patient likely to be seen frequently by the doctor; whether performance of the test fits comfortably within practice routine.

- Effect on management: whether the test is likely to influence management decisions; speed with which a result is needed; whether, overall, patient health status is worse than in the absence of office testing.

- Cost: effects on total costs of pathology services, total cost of health services (also cost to patient, cost to doctor).

Other settings for 'office pathology'

- The intensive care unit
- The general ward
- Population screening (e.g. health promotion campaigns, testing of employees)
- Home testing
- Sites which are remote from laboratory services

The intensive care unit

- Typically, only small number of analytes of immediate interest, e.g. electrolytes, blood gases.
- Results of these will commonly be needed quickly and frequently in acute management of patients.
- Standards of staff training may be particularly good in such settings.
- Back-up by the laboratory (for trouble shooting, training, quality control) desirable.
- An area of 'office testing' where benefits of the technology have been established.

The general ward

- Probably only a limited number of analytes needed urgently; some can be monitored routinely by simple test strip/dipstick measurements.

- Laboratory back-up would be essential.

- Training/quality control requirements may be demanding, given turnover of staff.

- Cost-effectiveness may be poor compared with use of in-house laboratory facilities. Evaluation of costs and benefits is needed.

Population screening

- Examples of tests used in health promotion campaigns include cholesterol, fecal occult blood.
- In some situations, dealing with a disease or condition with very low prevalence; this has major implications for the sensitivity/specificity required of a test.
- Also major need for robust tests and training of operators.
- Screening needs to be linked to availability of a realistic treatment or intervention (including counselling).
- Those persons with positive results will often need follow-up.
- Cost-effectiveness of screening requires close scrutiny, taking account of follow-up tests, treatment, counselling, outcome

Home testing

- Home self-testing for blood glucose widely used, as are pregnancy test kits.
- For a test to be useful in this setting, it should have some relevance to the individual's decisions and actions regarding health status.
- It must also meet acceptable standards of performance, implying a highly robust system, adequate training and reasonable functional literacy.
- Home testing will typically require links with professionals for advice, back-up, counselling and awareness of notifiable disease requirements.
- Cost-effectiveness (especially from the patient's perspective) needs close assessment.

Remote sites

- Office pathology testing may be particularly useful in places which are remote from laboratory facilities.

- To fulfil potential, the test systems will need to be robust, have good performance, and be supported by efficient customer services.