PRINCIPLES OF BEST PRACTICE

A World Union of Wound Healing Societies' Initiative

Diagnostics and wounds
A consensus document

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PRINTED BY:
Printwells, Kent, UK

FOREIGN TRANSLATIONS:
RWS Group, London, UK

PUBLISHED BY:
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Supported by an unrestricted educational grant from **3M Health Care**.
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How to cite this document:
World Union of Wound Healing Societies (WUWHS). *Principles of best practice: Diagnostics and wounds. A consensus document.* London: MEP Ltd, 2008.

FOREWORD

In June 2007, an international group of experts met to discuss the use of emerging diagnostic technologies in wound management. Specific areas that could usefully form the focus of further research were identified and analysed.

This document, based on expert consensus opinion, emphasises the importance of effective assessment and diagnosis in the treatment of wounds, and presents details and clarification on the individual markers that might become the subject of the diagnostic tests of the future. It is hoped that this will generate important debate within the field of wound healing and serve as a platform to develop dedicated test kits that may influence the future management of problem wounds.

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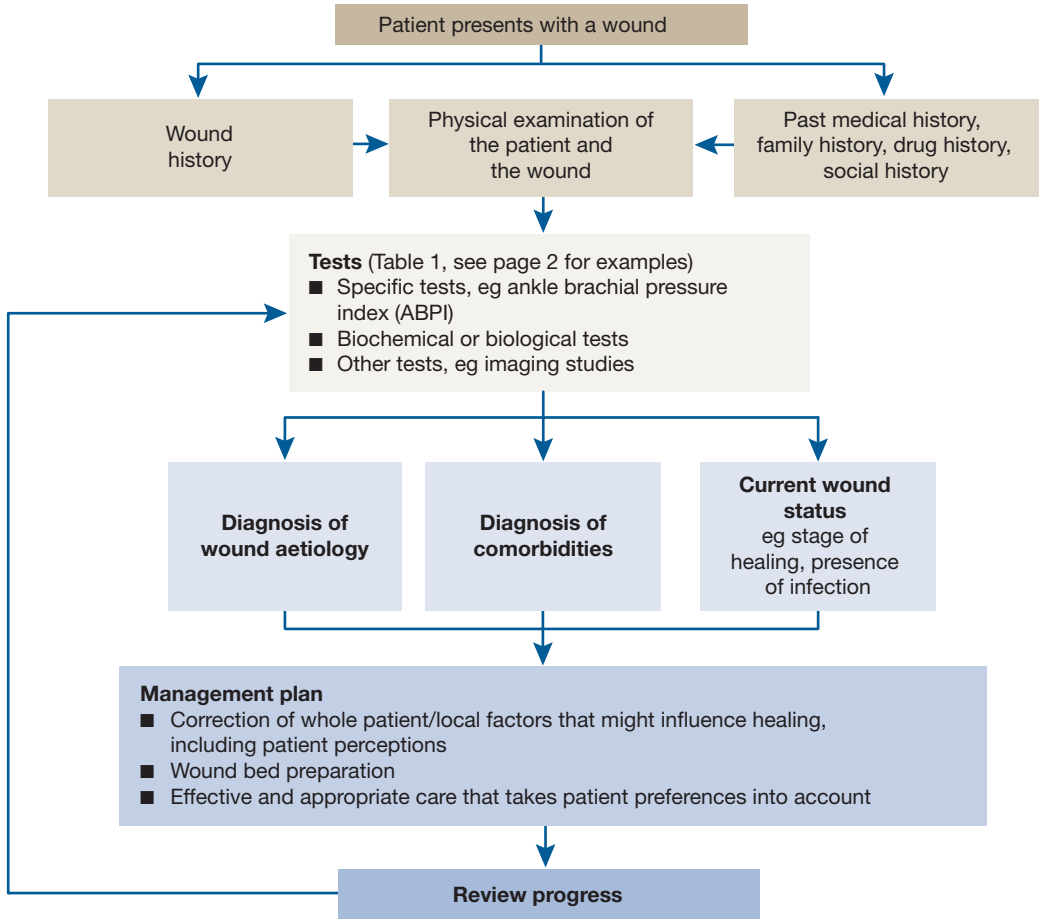
PRINCIPLES OF BEST PRACTICE

The process of diagnosis identifies a disease or medical condition from the patient's signs and symptoms, and from any tests performed. In the effective treatment of patients with wounds, the diagnostic process will:

- determine the cause of the wound
- identify any comorbidities/complications that may contribute to the wound or delay healing
- assess the status of the wound
- help to develop the management plan.

Once the management plan has been implemented, repetition of elements of the diagnostic and assessment process, eg re-examination and repetition of tests, can assist in monitoring healing progress and detecting complications such as infection (Figure 1). Re-evaluation may also indicate the need for different tests and/or for adjustment of the management plan.

Figure 1 | An overview of diagnostic processes in wound management



In the diagnosis and evaluation of a wound, it is essential that clinicians ensure that comprehensive assessment considers all aspects of the patient and the wound

CURRENT TESTS

Clinicians use a variety of tests to determine/assess wound aetiology, comorbidities and wound condition (Table 1, see page 2). However, the monitoring of wound healing and management of wounds that are slow-to-heal remain largely reliant on somewhat subjective tests and observations.

Table 1 | Examples of tests currently used to assist with assessment of wound status, aetiology and comorbidities

Type of test	Directly related to the wound	Other
Physical tests and observations	■ Wound dimensions (two- or three-dimensional) ■ Wound or periwound oedema, or erythema/heat ■ Wound bed – eg type of tissue, presence of exposed bone/tendon, colour, odour ■ Wound margin – eg undermining, rolled edge ■ Surrounding skin and wound edge characteristics (eg punched out ulcers may be arterial; oedema, pigmentation and induration may indicate a venous ulcer) ■ Wound site (eg sacral wounds may be pressure ulcers, lower leg wounds may be arterial or venous ulcers) ■ Colour, odour, viscosity and quantity of exudate ■ Presence/level/character of pain[1]	■ Temperature (pyrexia, infection) ■ Blood pressure (hypertension) ■ Neurological examination – reflexes and sensation (diabetic neuropathy) ■ Arterial pulses, response to limb elevation and lower limb rest pain (peripheral arterial disease)
Biological tests	■ Microbiological culture – qualitative and quantitative (infection) ■ Wound histology and cytology (vasculitis, malignancy)	■ White cell count (infection) ■ Erythrocyte sedimentation rate (ESR) (inflammation, infection)
(Bio)chemical tests		■ Glucose (diabetes mellitus) ■ Haemoglobin (oxygenation) ■ Plasma albumin (malnutrition) ■ Lipids (hypercholesterolaemia) ■ Urea and electrolytes (renal function) ■ HbA_{1c} (long-term control of diabetes) ■ Rheumatoid factor, autoantibodies (rheumatoid arthritis, connective tissue disease) ■ C-reactive protein (CRP) (inflammation, infection)
Others		■ Oxygen – eg transcutaneous O_2 (perfusion) ■ Ankle brachial pressure index (ABPI), arterial Doppler, angiography (perfusion, peripheral arterial disease) ■ Imaging studies – eg X-rays, high frequency ultrasound, Duplex scanning (venous disease), CT/MRI scans (gas gangrene, osteomyelitis) ■ Photoplethysmography (venous disease) ■ Nutritional screening/assessment – eg body mass index (BMI)[2], mini-nutritional assessment short form (MNA-SF)[3] (malnutrition, obesity) ■ Psychological screening – eg Hospital Anxiety and Depression Scale (HADS)[4] (depression, anxiety)

NB: This table lists examples of the wide range of tests and test types that may be appropriate; it is not intended to be exhaustive

Specific biochemical tests that identify the causes of delayed healing in wounds that are slow-to-heal have yet to be developed

DIAGNOSTICS IN PRACTICE

Clinicians use a wide range of tests to determine wound aetiology, comorbidities and current wound status, and to guide management

Re-evaluation of the patient and the wound may include or indicate the need for repetition of certain tests or new tests

Diagnostic tests vary in the degree to which they indicate a diagnosis and guide treatment

CURRENT ISSUES IN DIAGNOSIS

1. World Union of Wound Healing Societies. *Principles of best practice: Minimising pain at wound dressing-related procedures. A consensus document.* London: MEP Ltd, 2004.
2. *Obesity: preventing and managing the global epidemic.* Report of a WHO Consultation. Geneva: World Health Organization, 2000 (WHO Technical Report Series, No. 894).
3. Rubenstein LZ, Harker JO, Salvà A, et al. Screening for undernutrition in geriatric practice: developing the short-form mini-nutritional assessment (MNA-SF). *J Gerontol A Biol Sci Med Sci* 2001; 56(6): M366-72.
4. Zigmond A, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand* 1983; 67(6): 361-70.

The management of wounds is complex and multifaceted, mainly because of the:

- diverse aetiology of wounds
- complexity of the healing process
- multiplicity of factors that can affect healing
- extensive and widening range of dressings/devices/drugs/surgery and advanced wound therapies.

Advances in the understanding of the mechanisms of wound healing at a cellular level are gradually providing a more scientific foundation upon which to base treatment decisions. They are also indicating new therapeutic approaches, eg inactivation of matrix metalloproteinases (see pages 8–9). Even so, there are some wounds that do not heal. Sometimes, it may be possible to identify the cause of the delay in healing, eg:

- inaccurate diagnosis of wound aetiology
- undiagnosed comorbidities or contributory factors
- inadequate management of underlying aetiology, comorbidities or contributory factors
- poor wound treatment, eg inappropriate dressing use, lack of recognition/inadequate treatment of complications such as infection, or inadequate knowledge/skills/resources
- difficulties with patient cooperation.

Even when these factors are addressed, however, there remains a significant subset of patients whose wounds do not respond to current treatments as anticipated. It is particularly for these patients that current approaches to wounds need to be complemented by rigorous scientific research and new diagnostic tests that will identify the causes of the underlying problems and guide management decisions.

It is anticipated that these new tests will also ensure more rational use of the increasing range of advanced treatments by identifying which of these is appropriate (or inappropriate) for a specific wound in a particular patient.

For wounds that remain recalcitrant despite re-evaluation and optimisation of basic care, future diagnostic tests may aid a more structured, cost-effective and timely approach to management

When new tests present opportunities for improving wound care, it will be important for clinicians to remember their responsibility for the interpretation of test results in the context of each patient's condition and for any ensuing decisions about patient management. In current practice, for example, a patient's ABPI should be interpreted with caution if the patient has diabetes mellitus, arterial calcification or peripheral oedema.

DIAGNOSTICS IN PRACTICE

Current tests are not always able to determine the reason for non-healing in an optimally managed wound

The development of specific diagnostic tests for use in wounds has the potential to revolutionise their treatment

For maximum benefit, these tests need to provide objective support for treatment decisions. This will help to improve standards of wound care and aid the cost-effective use of limited resources

TYPES OF TEST USED IN DIAGNOSIS

The wide range of clinical or laboratory tests used in wound diagnosis, assessment and management vary in their degree of helpfulness in proving or excluding a diagnosis and their usefulness in indicating appropriate interventions (Figure 2).

The parameters measured during tests may be called **markers** or **indicators**, and may be:

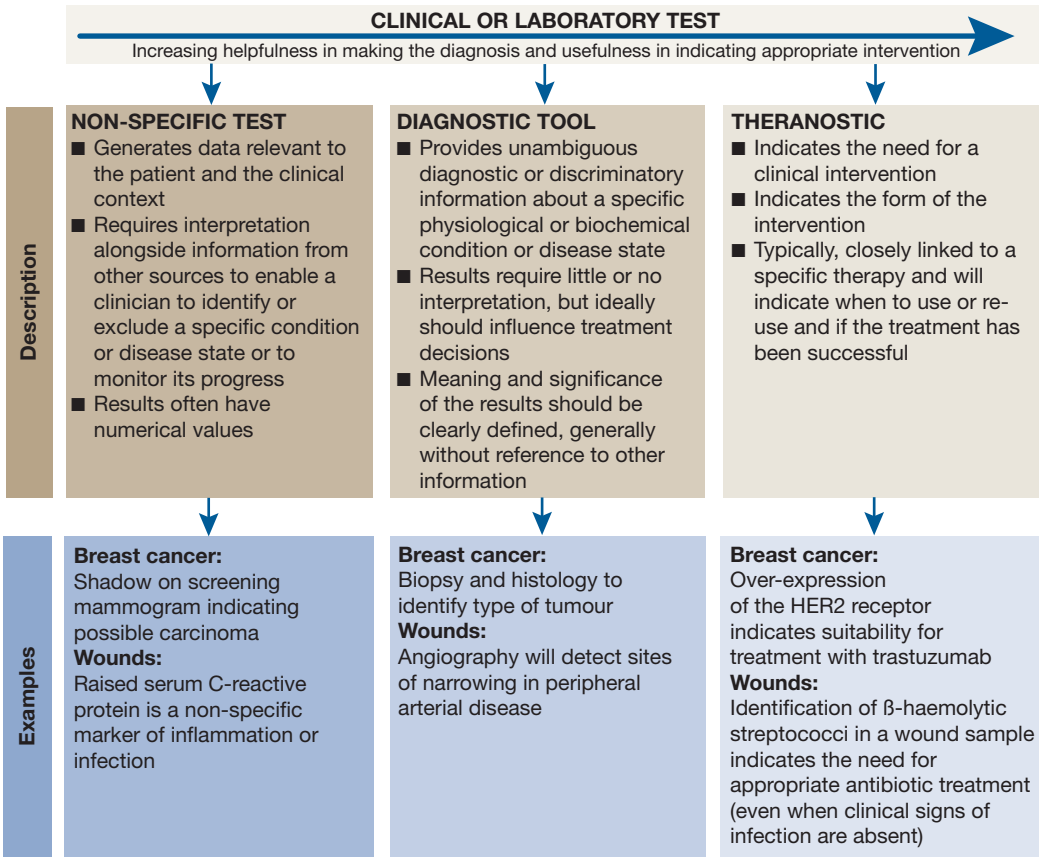
- molecules detected in body fluids such as blood or urine, eg blood glucose (raised in diabetes mellitus) or plasma albumin (reduced in malnutrition or hepatic disease)
- physical findings, eg wound size and depth, body temperature (raised in infection) or blood pressure (raised in hypertension; reduced in shock).

Some tests provide information that requires little or no interpretation and clearly indicates the diagnosis (usually without reference to other sources). Such tests will be referred to as **diagnostic tools** within this document. A classic example of a diagnostic tool is the home-based pregnancy test, which uses detection of human chorionic gonadotropin (hCG) in urine to confirm pregnancy.

Some tests do not necessarily provide or lead to a diagnosis, but provide very specific information that indicates the need for (or unsuitability of) a particular therapy. This type of test is known as a **theranostic**. The development of theranostics is of particular interest to funders of healthcare because they have the potential to ensure that treatments are targeted specifically at the patients who will benefit most from them.

The terminology used in relation to tests that aid diagnosis lacks clarity; terms are often used interchangeably

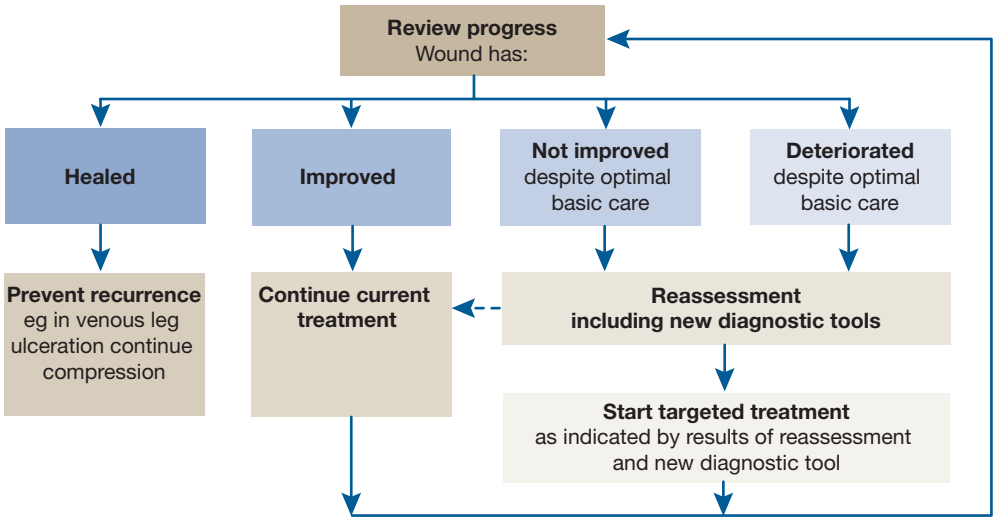
Figure 2 | Clinical or laboratory test types



ROLE OF NEW DIAGNOSTIC TOOLS

It is essential that new diagnostic tools are used as part of an integrated, structured approach to patient management that is designed to ensure that appropriate treatment is provided at all times. Ideally, new diagnostic tools will indicate specific modifications to practice or treatment that will move the wound towards healing (Figure 3).

Figure 3 | Potential role of new diagnostic tools in wound management



There may be instances when the use of these new diagnostic tools is appropriate at initial assessment and diagnosis, eg they may be appropriate in a patient whose initial presentation is complicated by immunosuppression or an unusual aetiology.

As diagnostic tools increase in number and complexity, clinical experience will determine the timing, relevance and optimal frequency of use of each. The technology must be used appropriately and tests should be performed only if it is possible to react to the result, ie to change patient management.

In reality, it is unlikely that a diagnostic tool for one specific marker will be identified as the key to determining appropriate treatment for **all** non-healing wounds. It is more probable that a number of markers (and related diagnostic tools) will be identified and that sequential use of several diagnostic tools will be most practical and appropriate.

In addition, protocols will be needed that specify which tests can be applied routinely, are appropriate to specific wound types, or should be used selectively in order to be cost-effective.

The use of comprehensive diagnostic technologies should not be regarded as an alternative to thorough clinical assessment and monitoring of the patient and the wound by an experienced clinician

DIAGNOSTICS IN PRACTICE

Tests should be performed only if the results will influence patient management

The complexity of wound healing means that it is unlikely that there is a single marker for identifying problems with wound healing

Ultimately, it is likely that a range of new diagnostic tools will be required and that these may be applicable at different stages of healing. Some tools may include testing for several linked or related markers

THE IDEAL DIAGNOSTIC TOOL

In patients with wounds, new diagnostic tools are most likely to be used to detect (and probably quantify) substances (such as molecules involved in healing) or biological factors (such as infecting micro-organisms).

To maximise their usefulness and potential for improving the treatment of wounds, new diagnostic tools must be:

- clinically relevant
- appropriate for use by clinicians with different skill sets, from the specialist physician to the community nurse or, in some instances, perhaps the patient/carer
- accurate, reliable, sensitive to change and with reproducible results in normal use, unaffected by other substances present in the test sample, and easily correlated with reference test methods
- quick and easy to use
- easy to interpret – ie capable of providing unambiguous guidance on the significance of the result and the need to initiate or continue treatment
- cost-effective – eg reduce time taken to heal, staff time, hospital or clinic costs and/or need for interventions
- produced and disposed of after use in ways that minimise environmental impact.

Ideally, these diagnostic tools will also:

- measure a single marker or molecule (or a set of markers) and present a single result
- predict healing
- clearly indicate the need for (or inappropriateness of) a specific therapy
- be non-invasive and make use of a consistent (non-variable) sample that is easy to collect, permits repeat testing if required and requires no (or minimal) sample preparation
- provide an electronic read-out (which is preferable to visual detection or colour-based systems)
- be used at the point of care (ie near the patient rather than in a laboratory – Table 2, see page 10)
- be sufficiently cost-effective to encourage widespread adoption into everyday practice
- be self-contained and not require expensive dedicated hardware.

If insurmountable problems are encountered in developing a point-of-care test, a new laboratory-based diagnostic tool could still have the potential to make a significant contribution to the management of wounds

COST-EFFECTIVENESS

Diagnostic tools that indicate appropriate treatment may trigger a change to a more effective form of therapy and so shorten treatment time by promoting healing. In this way, they have the potential to reduce staffing and infrastructure costs. Diagnostic tools may also prove useful in demonstrating the futility of expensive treatments for patients with wounds that have no prospect of healing.

Wounds that are slow-to-heal are a major healthcare cost and are likely to be a focus for the development of new diagnostic tools

DIAGNOSTICS IN PRACTICE

By providing specific information that indicates whether or not a particular intervention is suitable or is being effective, the ideal diagnostic tool may promote more accurately timed and targeted care

POTENTIAL MARKERS

Several markers that could form the basis of new diagnostic tools for use in wound care are currently under investigation (Box 1); ongoing research is likely to identify others. Future diagnostic tools may involve examination of systemic markers, eg those present in blood, urine or sweat, as well as those present in wound fluid or tissues (Box 2).

BOX 1 | Markers under investigation for use in wounds

- Bacterial load/specific microbial species/biofilms
- Cytokine release in response to specific microbial antigens
- DNA – eg gene polymorphisms to indicate susceptibility to disease, poor healing or infection
- Enzymes and their substrates – eg matrix metalloproteinases and extracellular matrix
- Exposed bone
- Growth factors and hormones – eg platelet-derived growth factor (PDGF), sex steroids (androgens/oestrogens), thyroid hormones
- Immunohistochemical markers – eg integrins, chemokine receptors and transforming growth factor beta II receptors to monitor healing status
- Inflammatory mediators – eg cytokines and interleukins to monitor healing status and guide use of anti-inflammatory treatments
- Nitric oxide
- Nutritional factors – eg zinc, glutamine, vitamins
- pH of wound fluid
- Reactive oxygen species
- Temperature
- Transepidermal water loss from periwound skin

BOX 2 | Potential sample types for analysis

- Wound fluid*
- Tissue from the wound bed, wound margin or normal skin adjacent to the wound
- Blood
- Samples from used dressings
- Urine
- Sweat
- Saliva
- Hair/nails

*Collection of adequate amounts of wound fluid and standardisation of collection present a challenge

Before any potential marker can be developed into a diagnostic tool, the relationship between the marker and wound/patient outcomes will need to be established and validated (Figure 6, see page 10). This will itself require improved methods of evaluating the impact of interventions on patients and wounds, including the development of validated surrogate endpoints for use in place of the conventional endpoint of wound closure/healing.

Research will also be necessary to characterise the relationships between some of the potential markers. For example, variations in wound pH may influence enzyme activity (eg of proteases), and so measurements of enzyme activity may not be relevant unless corrected for pH.

Considerable research is required before validated diagnostic tools for use in wound care can be fully developed

Infection can delay healing and possible approaches to diagnostic tools for its detection are described below. Also discussed are the rationale and implications of diagnostic tools that analyse enzyme activity or nitric oxide levels.

POTENTIAL MARKERS OF INFECTION

In addition to the pathogenic potential of a given micro-organism, the bacterial load of a wound can have a major impact on its rate of healing. Even so, many wounds heal satisfactorily despite containing significant numbers of bacteria. The ability of the patient's immune system to deal with bacteria in the wound (host response), and the number and type of bacteria involved are the major determinants of whether clinical problems develop.

Current practice

The diagnosis of infection is usually made on the basis of the clinical signs/symptoms and is often supported by the results of laboratory-based tests (which may take hours or days to report results)[5]. These tests help clinicians to identify the organisms present (Box 3, see page 8) and their particular antibiotic susceptibilities.

There are delays inherent in using laboratory-based tests. For patients requiring urgent antibiotic treatment for life- or limb-threatening wound infections, this means that

5. Sibbald RG, Orsted H, Schultz G, et al. Preparing the wound bed 2003: focus on infection and inflammation. *Ostomy Wound Manage* 2003; 49(11): 24-51.

empirical, probably broad-spectrum, antibiotics are necessary until the results are available. This may have implications for the development of antibiotic resistance and the emergence of healthcare-associated infections. For other patients with less serious problems, the delay in reporting may mean that treatment – and therefore healing – continues to be delayed.

A diagnostic tool for infection

The major issues relating to diagnostic tests for clinicians in the management of wound infection are currently the inevitable delay involved in laboratory test reporting and issues with sampling. Therefore, a diagnostic tool that has the potential to prove useful in the management of wound infection would:

- be simple, rapid and used at the point of care
- not require invasive sampling
- provide quantitative (ie about amount) and/or qualitative (ie about type and/or toxin production) information on a range of micro-organisms, including bacteria.

Particular challenges for such a diagnostic tool include:

- ensuring sampling provides an accurate reflection of what is happening within the wound and any biofilm (Box 4) present, and not just on the surface of the wound
- determining the threshold values that should be assigned to each marker and that indicate the need for intervention.

Other approaches to the development of diagnostic tools for use in wound infection could involve detection of biofilms and evaluation of host response.

Even when new diagnostic tools for wound infection become available, it is likely that microbial culture will still be needed for determination of antibiotic susceptibilities or for genotyping of micro-organisms for infection control purposes.

BOX 3 | Current laboratory methods for identifying and quantifying bacteria

- **Gram stain** – a staining technique used in the preparation of specimens for microscopic examination that may give clues to the preliminary identification and clinical significance of the micro-organisms; may provide a very rough guide to numbers
- **Semi-quantitative analysis** – cultures and identifies bacteria but provides limited information on numbers, eg growth may be reported as light, moderate or heavy
- **Quantitative analysis** – cultures and identifies bacteria and quantifies the number of colony forming units (CFU) (ie bacteria) per gram of tissue or mm^3 of pus

BOX 4 | Biofilms

Once mobile (planktonic) bacteria have attached to a surface, eg in a wound, they may surround themselves in a protective coating called a glycocalyx and form a biofilm. The biofilm protects the bacteria from antibacterial agents and the immune system[6].

Scanning or electron microscopy of wound biopsies has revealed biofilms in 60% of those examined[7]. It has been speculated that removal of biofilms might facilitate healing and explain why debridement may 'kick-start' healing in chronic wounds.

At present, there is no routine way of detecting biofilms: they are not visible to the naked eye and culture techniques cannot confirm whether any bacteria grown have formed a biofilm. Further research is required to establish and characterise the link between bacteria, biofilms and wound outcomes.

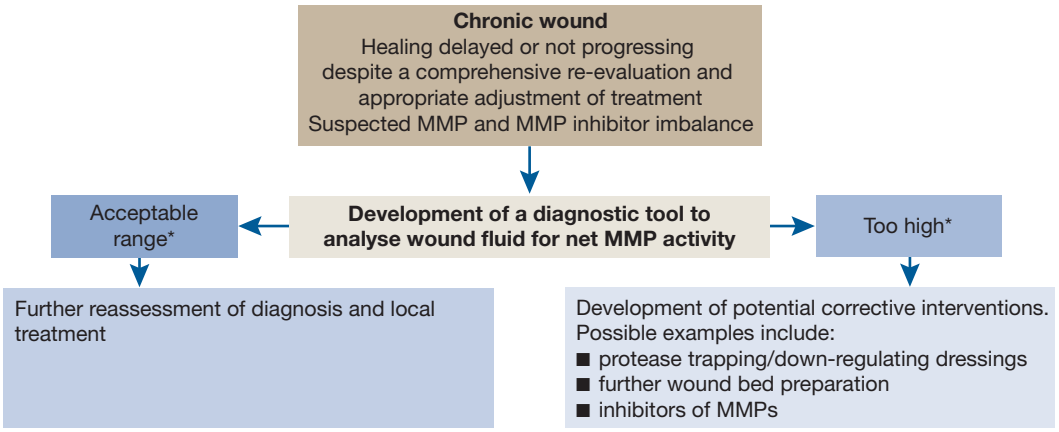
POTENTIAL DIAGNOSTIC BASED ON ENZYME ACTIVITY

Some of the many enzymes involved in wound healing remodel the extracellular matrix – the scaffolding that supports the cells. These include the matrix metalloproteinases (MMPs).

Studies have indicated that the rate of wound healing appears to be linked to the interaction of MMPs and inhibitors of these enzymes in wound fluid. The research suggests that wounds that heal well have a lower overall MMP activity than those that heal poorly[8]. As a result, a test that readily provides this information might be clinically useful in predicting how well a wound is likely to heal and whether an intervention that modifies net MMP activity may be useful (see Figure 4 for a hypothetical example).

6. Percival SL, Bowler PG. Biofilms and their potential role in wound healing. *Wounds* 2004; 16(7): 234-40.
7. James GA, Swogger E, Wolcott R, et al. Biofilms in chronic wounds. *Wound Repair Regen* 2008; 16(1): 37-44.
8. Ladwig GP, Robson MC, Liu R, et al. Ratios of activated matrix metalloproteinase-9 to tissue inhibitor of matrix metalloproteinase-1 in wound fluids are inversely correlated with healing of pressure ulcers. *Wound Repair Regen* 2002; 10(1): 26-37.

Figure 4 | Hypothetical diagnostic tool that analyses net MMP activity in wound fluid
NB: This is a hypothetical example ONLY. The interventions mentioned require substantial further investigation to explore and clarify their role in this context.
*These ranges are still to be fully determined.

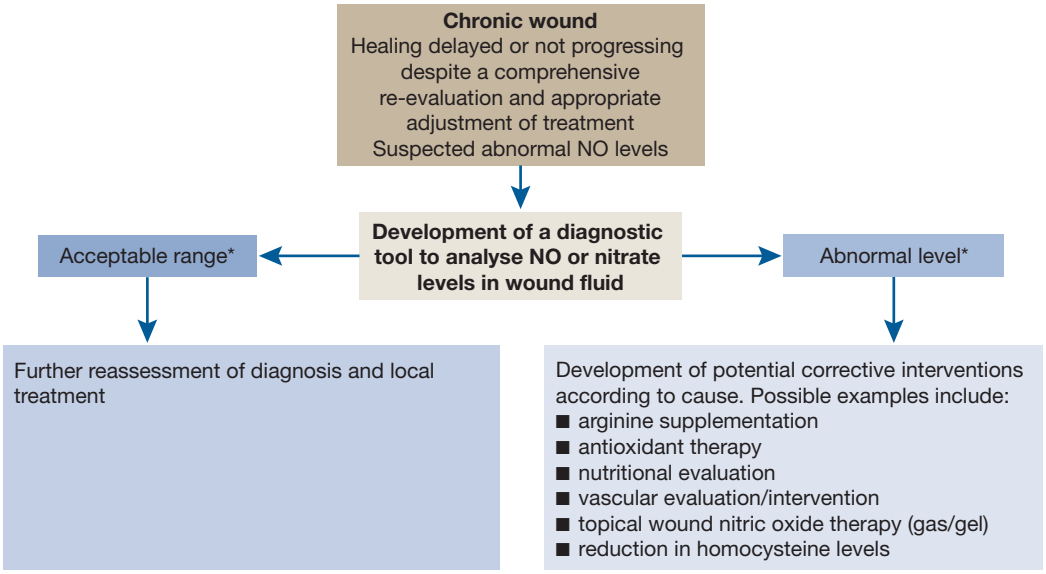


POTENTIAL DIAGNOSTIC BASED ON NITRIC OXIDE LEVELS

Nitric oxide (NO) is produced in the body from the amino acid arginine. It is involved in numerous physiological processes, including wound healing[9]. Abnormal NO levels are associated with some factors that themselves are known to be associated with impaired wound healing, eg malnutrition, diabetes mellitus, corticosteroid therapy, ischaemia and smoking. If further research confirms that NO or metabolites of NO (nitrates) are important in wound healing, a diagnostic tool that measures NO or nitrates in wound fluid could be clinicially useful in predicting wound outcomes, and interventions to alter wound NO levels may be of benefit (see Figure 5 for a hypothetical example).

9. Schultz G, Stechmiller J. Wound healing and nitric oxide production: too little or too much may impair healing and cause chronic wounds. *Int J Low Extrem Wounds* 2006; 5(1): 6-8.

Figure 5 | Hypothetical diagnostic tool that analyses nitric oxide levels in wound fluid
NB: This is a hypothetical example ONLY. The interventions mentioned require substantial further investigation to explore and clarify their role in this context.
*These ranges are still to be fully determined.



DIAGNOSTICS IN PRACTICE

A vital factor in the development of new and useful diagnostic tools will be the ability to demonstrate that intervention-induced alterations in the markers examined correlate with meaningful clinical benefits

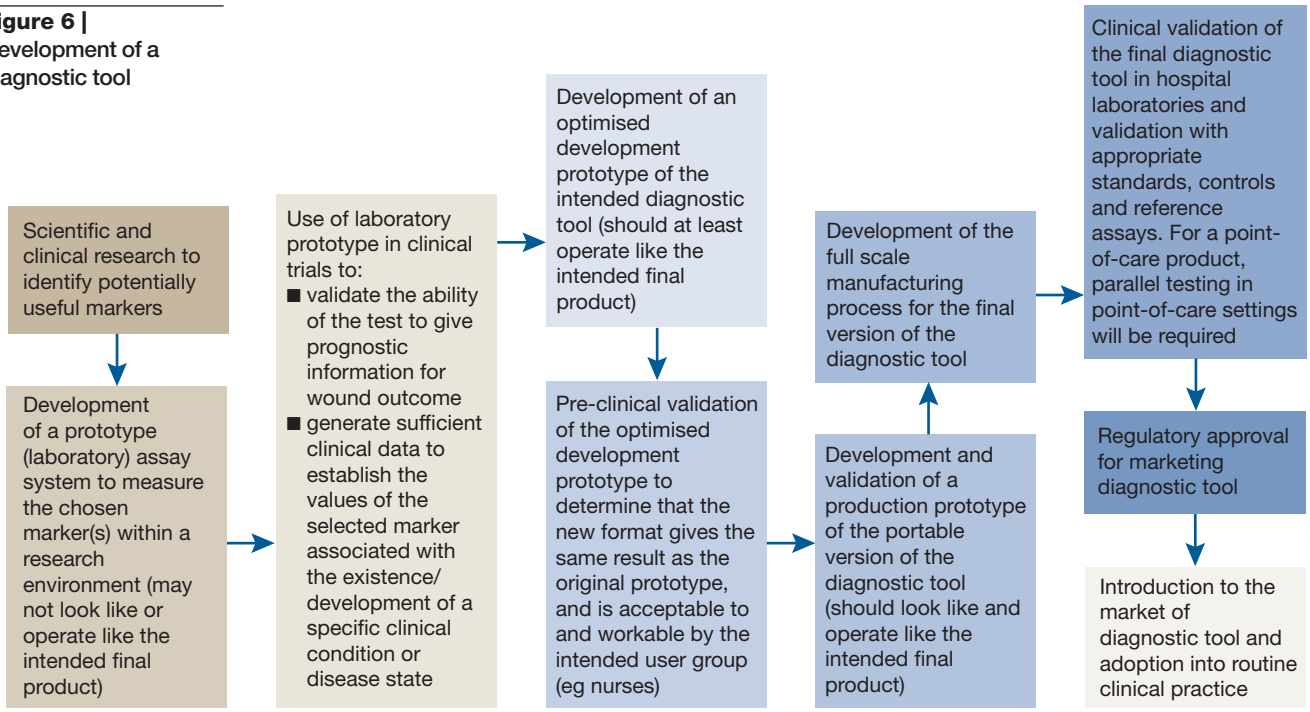
Table 2 | Comparison of test locations
The location of a test, ie where it is conducted, will be determined largely by its complexity, the need for specialised equipment and the time taken to obtain a result. A diagnostic tool that can be used easily by a non-specialist in a community setting offers many practical advantages to the patient and clinician. For example, it could eliminate the need to transport clinical samples (or the patient) and overcome potential problems such as the relatively unstable nature of some of the markers to be measured.

Characteristic	Test location		
	Central laboratory	**Clinic or point of care**	**Consumer (patient) use**
Operator	Highly skilled and trained	Minimally trained	Untrained
Hardware	Complex, sophisticated	Limited	Very basic (if any) Integrated into device
Test menu	Potentially very extensive	Limited	None – single analyte; integrated result for a single indication
Data reporting	Data reported only, no diagnosis offered or treatment proposed	Data report closely linked to a limited set of diagnoses	No raw data output, just basic result or diagnostic conclusion
Turnaround time	Variable – hours or days	Rapid – no substantial wait for result	Fast – instant or within 15 minutes
Sample type	Potential to analyse different sample types	Limited sample types	Single non-invasive sample, eg urine/saliva
Sample preparation	Some manual possible, emphasis on automation	Limited	None possible, unless integrated into device

DEVELOPING A DIAGNOSTIC TOOL

Development of a diagnostic tool (Figure 6) represents a huge challenge for all those involved and is potentially very expensive. Industry will need to ensure that commercially available systems build confidence and credibility by producing clear, meaningful results. The cost of the device will be important and will heavily influence its uptake into clinical practice.

Figure 6 | Development of a diagnostic tool



The simpler the diagnostic system, the more likely it will be widely used. As far as practicable, diagnostic tools need to be moved into the clinic or the patient's home to ensure optimal care is provided for patients with wounds