



australasian society of clinical immunology and allergy inc.

Unorthodox Testing and Treatment for Allergic Disorders

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Allergy is a science-based speciality, which relies on understanding the biological mechanisms underlying allergies such as asthma, allergic rhinitis (hay fever), food allergy, insect allergy and anaphylaxis. Accurate diagnosis requires an examination of the history to determine whether an immune/allergic condition is likely to be the cause of symptoms, combined with reliable allergy testing to confirm the diagnosis.

Advice needs to be evidence based

When considering testing and treatment, advice needs to be evidence based. In other words, there needs to be evidence that a particular test or treatment is reliable, based on studies of other patients with the same condition. Reliable tests need to be able to distinguish between those with illness and those without. Therapeutic trials are designed to show that any improvement seen is due to the treatment, and not just due to chance or coincidence. Such studies also examine whether a particular treatment may also cause harm as well as benefit. Levels of evidence have been developed to rate the quality of published evidence, with Level I being the highest quality of evidence, and level IV being of lesser quality. These levels assist doctors to more readily select a test and/or treatment for their patient that is most likely to help. An example of the 2006 Australian NHMRC Levels of Evidence are shown in the table on the following page, and Levels of Evidence for the unorthodox approaches to allergy testing and treatments are also listed in the text.

Use of unproven so called allergy tests is common

Despite advances in scientific knowledge about allergic disorders, around half of all people with allergies consult alternative practitioners each year for diagnosis and treatment. Some will undergo unproven diagnostic so called allergy testing or treatments. Incorporation of traditional eastern health care philosophies into western culture and uncritical media attention to claims of new "cures" for allergy may all contribute to the uptake. This topic is reviewed in greater detail at Unorthodox Testing and Treatment for Allergic Disorders (www.allergy.org.au/content/view/262/1/)

Unproven allergy testing and treatments are not regulated

Unlike claims to "cure" cancer, unsubstantiated claims to be able to detect or "cure" allergic or immune disorders are only stringently regulated by government, medical boards or advertising regulators if the practitioner is a registered medical practitioner. There is also currently no stringent regulation of unproven diagnostic techniques or devices. These devices and tests can be listed in Australia without having to prove that they work.

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Table 1. Designations of levels of evidence^a according to type of research question (including tablenotes)

Level	Intervention ^b	Diagnosis ^c	Prognosis	Aetiology ^d	Screening
I*	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies
II	A randomised controlled trial	A study of test accuracy with: an independent, blinded comparison with a valid reference standard, ³⁸ among consecutive patients with a defined clinical presentation ³⁹	A prospective cohort study ⁴⁰	A prospective cohort study	A randomised controlled trial
III-1	A pseudorandomised controlled trial (i.e. alternate allocation or some other method)	A study of test accuracy with: an independent, blinded comparison with a valid reference standard, ³⁸ among non-consecutive patients with a defined clinical presentation ³⁹	All or none ³⁸ⁱ	All or none ³⁸ⁱ	A pseudorandomised controlled trial (i.e. alternate allocation or some other method)
III-2	A comparative study with concurrent controls: <ul style="list-style-type: none"> • Non-randomised, experimental trial⁴ • Cohort study • Case-control study • Interrupted time series with a control group 	A comparison with reference standard that does not meet the criteria required for Level II and III-1 evidence	Analysis of prognostic factors amongst untreated control patients in a randomised controlled trial	A retrospective cohort study	A comparative study with concurrent controls: <ul style="list-style-type: none"> • Non-randomised, experimental trial • Cohort study • Case-control study
III-3	A comparative study without concurrent controls: <ul style="list-style-type: none"> • Historical control study • Two or more single arm study⁷ • Interrupted time series without a parallel control group 	Diagnostic case-control study ¹¹	A retrospective cohort study	A case-control study	A comparative study without concurrent controls: <ul style="list-style-type: none"> • Historical control study • Two or more single arm study
IV	Case series with either post-test or pre-test/post-test outcomes	Study of diagnostic yield (no reference standard) ⁴¹	Case series, or cohort study of patients at different stages of disease	A cross-sectional study	Case series

Allergy redefined

Some unorthodox practitioners claim that conventional allergy testing only detects some types of allergies. They state that conditions such as headaches, migraine, irritable bowel, muscle tension, pain, addiction, premenstrual syndrome, fatigue or depression are due to hidden allergies, yet there is no evidence for these claims. Instead of relating allergy to components of the immune system, disease is attributed to either (a) a disturbance of vital life force or energy ("Qi", yin-yang), or (b) are secondary to noxious external triggers such as environmental toxins and chemicals, food allergens / additives, or chronic infection with organisms like *Candida albicans*. It is stated that the body can generally cure itself if given the opportunity to correct these imbalances on the one hand, or avoid/eliminate environmental toxins, allergens or occult infection on the other. These philosophies use terminology loosely, blur and confuse the distinction between the terms "fatigue" and "immunity", and blend concepts of immunology, neurology and spirituality to explain the nature and causes of disease.

There are many types of unproven tests

A multitude of tests have been proposed to detect "hidden allergies", based on concepts of disease pathogenesis very different to those underlying Western medicine. These have no scientific basis, and have not been shown to be reliable or reproducible when subjected to formal study. Not only are such tests unreliable in diagnosing allergic disease, they are also increasingly being promoted for the diagnosis and management of disorders for which no evidence of immune system involvement exists. ASCIA strongly advises against the use of these tests for diagnosis or to guide medical treatment. No Medicare rebate is available in Australia for these tests, and their use is not supported in New Zealand.

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Vega (electro-diagnostic) testing (Evidence Level II: inaccurate test)

Vega testing claims to detect disease by measuring changes in body electrical currents using a "Vega machine". The patient holds one (negative) electrode in one hand, and the positive electrode is applied to acupuncture points over fingers or toes. An allergen (such as food extract) in a sealed glass container is brought into the electrical circuit. An alteration in current is interpreted as meaning the person is "sensitive" to that substance. Formal examination of this technique shows that practitioners are unable to distinguish between healthy and allergic individuals, and between responses using allergens as well as "dummy" control solutions. Results also don't correlate with those obtained using conventional allergy testing.

Cytotoxic testing ("Bryan's test") and the Alcat test (Evidence Level II: inaccurate test)

In cytotoxic food testing ("Bryan's test"), the size and shape of white cells is assessed after incubation with food extracts on a microscope slide. These results have been shown to not be reproducible, give different results when duplicate samples of the same blood are analysed repeatedly, and "diagnose" food allergy in people with symptoms that do not actually suggest food allergy. The Alcat test is a variant on a theme; the results are analysed on an expensive laboratory machine instead of under the microscope. Results from these techniques don't correlate with those obtained using conventional allergy testing.

Iridology (Evidence Level II: inaccurate test)

Iridology claims to diagnose disease by examining iris patterns. Its theoretical basis, however, is undermined by the fact that iris patterns (like fingerprints) are so unique and unchanging, that they can be used as "biometric identification markers" to distinguish one person from another. Studies of iridology have also demonstrated that practitioners are unable to distinguish healthy from sick individuals, and even give different diagnoses using iris photographs from the same patients taken minutes apart.

Kinesiology (Evidence Level II: inaccurate test)

Kinesiology is based on the concept that exposure to exogenous toxins or allergens will be reflected in a reduction in muscle strength. Muscle strength is measured before and after exposure to food. "Provocation" to food occurs by having drops of food extracts given under the tongue or by holding a vial of food extracts in one hand. Children are assessed by testing the parent's strength first and again while holding the child's hand. The two test results are then subtracted to give the final results. Controlled study has shown that kinesiology results are not reproducible and are no more accurate than guessing. Unfortunately, kinesiology and other unproven diagnostic techniques are used as the basis of unorthodox treatment techniques as well.

IgG food antibody testing and other techniques (Evidence Level II: inaccurate test)

IgG antibodies are proteins produced by the immune system in response to exposure to external triggers, like pollens, foods or insect venoms. Their presence reflects exposure to these triggers, not disease that results from exposure. IgG antibodies to food are commonly

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detectable in healthy adult patients and children, whether food-related symptoms are present or not. There is no credible evidence that measuring IgG antibodies is useful for diagnosing food allergy or intolerance, nor that IgG antibodies cause symptoms. (The only exception is that gliadin IgG antibodies can be used to monitor the success of avoiding gluten in people with proven celiac disease.). Despite studies showing the uselessness of this technique, it continues to be promoted in the community.

VoiceBio® (Evidence Level: no evidence)

This technique is based on the concept that internal organs communicate with each other via sound waves, with each organ vibrating at certain frequencies, and with organ dysfunction being detectable by analysis of such frequencies using a computer assisted analysis of the patient's voice. There is no scientific rationale for this technique, and no evidence that results are useful for diagnosing any disorder, including allergies.

Other techniques

Other techniques such as pulse testing, stool or hair analysis or oral provocation/neutralisation have no scientific basis and no proven role in the diagnosis or management of any medical condition.

Unorthodox therapies are unproven

Claims of "breakthrough treatments" continue to appear at regular intervals in the media, often accompanied by testimonials and usually generally variations of other unorthodox treatments. These treatments have either not been subject to careful study or shown to be unhelpful when carefully examined. Unorthodox treatments pander to a common but unfortunately unrealistic desire to cure disease rather than simply control symptoms. Unfortunately, there are actually very few cures for disease, other than those that can be eliminated with antibiotics, removed with a surgeon's knife or sometimes eliminated by cancer chemotherapy. Treatments usually centre around one or more of (a) dietary manipulation, (b) diet supplements (eg. herbal remedies, anti candida supplements) to strengthen the immune system, or (c) techniques to "cure" or "eliminate allergy", even when the patient has no evidence of immune mediated disease.

Allergy elimination techniques (Evidence Level: no published studies)

At the present time, the only proven technique which is close to being a "cure" for allergy is allergen immunotherapy, when there is clear evidence of an immune mediated allergic reaction to inhaled allergen, or to stinging insects. Both sublingual/oral and systemic/injectable immunotherapy have been shown in controlled studies to reduce the severity and frequency of symptoms in the majority of patients. This form of therapy is the closest thing to cure for proven allergic disease. In recent years however, unorthodox "allergy elimination techniques" have also become popular. Also known as advanced allergy elimination and Nambudripad's allergy elimination in some countries, practitioners claim to treat a range of conditions (not necessarily with evidence of an immune basis), as well as symptoms attributed to inhalant allergens, or perceived chemical or environmental triggers.

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This treatment is based on the concept that "allergen" is perceived by the nervous system as a "threat" to the body's well being. Exposure to allergen disrupts the flow of nervous energies from the brain to the body via "meridians", resulting in symptoms. The technique seeks to "re-programme" the brain by applying acupressure applied to both sides of the spinal column (where energy flowing along meridians intersects with nerve roots) while the patient is in direct contact or close proximity to purported allergen. While proponents claim to be able to "eliminate" almost any allergy or sensitivity, this approach lacks any scientific rationale or physiological basis, and there is not a single published study demonstrating its effectiveness for any medical condition.

Adverse outcomes from unorthodox testing and treatments may arise

The potential for adverse outcomes following some unorthodox diagnostic techniques and treatment is not always obvious, but potentially more serious than the commonly debated issues surrounding adverse reactions to herbal medicines.

- Misleading results may result in advice to undergo major dietary restrictions. These have the potential to impair growth and even cause malnutrition, particularly in more vulnerable groups such as young children.
- Access to more effective diagnostic techniques and treatments may be delayed, with lost productivity from inadequately controlled disease.
- Substitution of homoeopathic vaccines for those with proven effectiveness (or even discouragement to undertake vaccination at all), has individual and public health implications.
- Unnecessary environmental and chemical avoidance, creating a perception of allergic or other organic illness when there are other explanations for their symptoms, can impact on employment and social functioning.
- So-called "allergy elimination techniques" have the potential to cause particular harm, if those with a potential dangerous allergy consider themselves protected from exposure.

Unproven diagnostic techniques and treatments are not inexpensive

The costs incurred are not insignificant, and amount to over \$600 million per year in consultations, and over \$1.5 billion per year in complimentary medicines in Australia alone, greater than the out of pocket contribution by the community to the PBS system. While it can be argued that this is a cost borne by individuals rather than the public purse, this claim is undermined by the cost implications of:

- Adverse outcomes with assessment by the conventional medical community, resulting in costs borne by the community,
- Lost income and productivity results from inadequately controlled disease,
- Private funds are directed into non-productive areas and are not available for more useful activities, and
- Private health insurance funds being similarly misdirected into unproven endeavours, diverting resources away from cost-effective medical treatments and indirectly, raising the cost of private and publicly funded health care.

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Evidence, claims and counterclaims

There are only two types of therapies for disease; those that have been proven to be effective, and those that are unproven. The plural of anecdote or testimonial is not good clinical evidence. The medical literature is littered with the corpses of treatments previously claimed or thought to be effective on theoretical grounds, later discarded as unproven when subjected to careful study.

Questions to ask unorthodox practitioners

In the absence of effective advertising or government regulation for unsubstantiated claims for unorthodox allergy testing or treatments, and to minimise the chance that patients may inadvertently harm themselves or their children patients should be encouraged to ask the same questions they pose for any form of treatment before going ahead:

- What is the evidence it works?
- Has such evidence been published? If so, can I find it on Medline/Pubmed?
- What are the risks and benefits?
- What might happen if I do not undertake this form of treatment?
- How much does it cost?
- Are there any side-effects?
- Why doesn't my own doctor suggest this type of treatment?
- What are the qualifications of the practitioner recommending the treatment?
- Why can this one test of treatment detect or treat so many different problems?
- Why don't I get any Medicare (Australia) rebate for this type of test or treatment?

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The Australasian Society of Clinical Immunology and Allergy (ASCIA) is the peak professional body of Clinical Immunologists and Allergists in Australia and New Zealand.

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