

Herbal Medicines; the professionals' questions

An approach for primary care

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**National Institute for
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The practice of evidence based medicine is central to the College's development.

EQUALLY

**Doubt is not a pleasant
condition but certainty
is absurd.**

Voltaire

Primary care clinicians
make most of their
professional decisions in
the context of universal
uncertainty.

The usual suspects

- Is it safe?

(The Pharmacoepidemiology)

- Is it effective?

(Does it work pragmatically)

- Is it efficacious?

(Versus placebo)

- Where do I get it?

(In the UK)

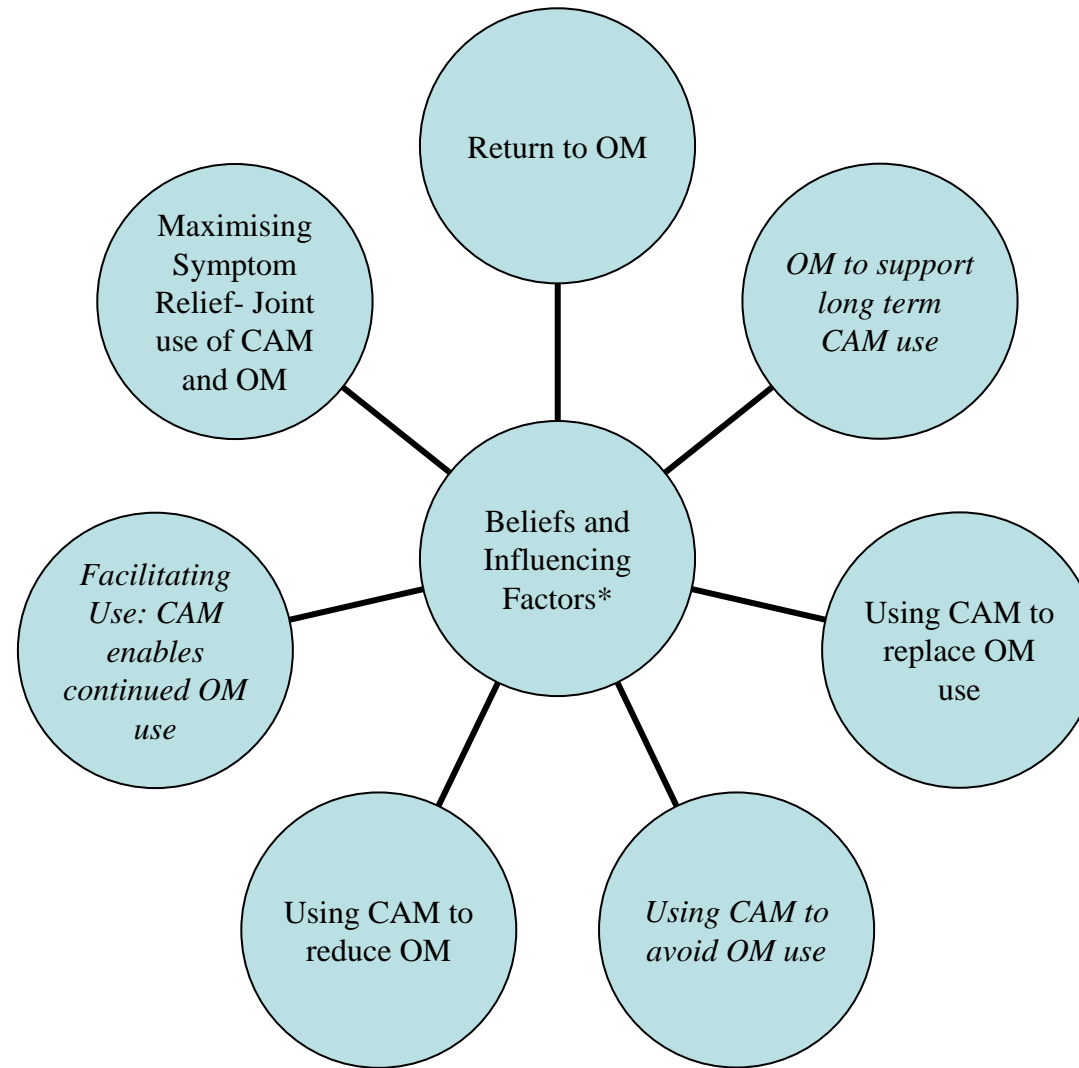
- What dose do I use?

(Phase 2 studies)

- How long should I suggest it should be used?

(Dose and response)

How do our patients use
herbs (CAM) in the UK?



The management of chronic ill health; balancing CAM and OM healthcare systems

Note: Italics indicate that this type of use was first identified in Stage 1 of data collection and analysis.

Beliefs and influences

- *Beliefs* about Treatment, Practitioner and Therapy; Philosophy of healthcare system;
- *Influenced* by; Perceived **effectiveness** of CAM and OM; **Side effects** of OM; Seriousness of **medical condition**; Medical or CAM practitioners **recommendations**, knowledge and qualifications; Personal treatment **preference**; **Availability**; **Cost**; Gaining control of treatment; Previous experience of CAM; Desperation.

Herbs will tend to be used

- In chronic long term conditions.
- In some acute conditions.
- Where there are effectiveness gaps.
- In relation to peoples beliefs, experience and sometimes desperation.

St John's Wort (Hypericum);

Linde 2005

Use

Depression but wider traditional use.

Probable mechanism (Hyperforin)

Affects a variety of neurotransmitters including blocking serotonin uptake and metabolism.

Dose

240-1800 mg of herbal extract.

Safety

- Fewer withdrawals in clinical trials than placebo (4925 patients, Linde 2005).
- 34,804 patients safety data indicate: GI symptoms, light sensitivity and skin reactions.
- *Toxicity*: mania, photosensitivity, neuropathy.
- *Drug interactions*: oral contraceptive pill and HRT, anticoagulants, HIV protease inhibitors, Triptans and SSRIs.

Therapeutic effects in major depression (Linde 2008)

- Systematic review (5489 people).
- 29 trials (18 placebo, 17 comparing antidepressants).
- Significantly improved depression:
 - Over placebo
 - Similar to Tricyclics, Tetracyclics and SSRIs
 - Fewer dropouts for Hypericum.

Hypericum is superior to placebo, similar to conventional antidepressants in major depression and appears to have fewer side effects.

**Saw Palmetto
(*Serenoa repens*);**

Wilt 2002

Use

BPH although wider urinary uses traditionally.

Probable mechanism

Blocks the production of 5-dihydrotestosterone (mainly).

Dose

Saw Palmetto extracts of 320mg daily but inconsistent information about dose extract and dose response.

Safety

- As safe as placebo (Avins 2007).
- 3139 participants agree (Wilt 2002).
- High dose extracts maybe cytotoxic.
- May interact with oral contraceptives and HRT.

Therapeutic effects (Avins 2006, Wilt 2002)

- Systematic review (3139 people).
- 21 trials (18 DB, 13 PC).
- Significantly improved:
 - Urinary symptom score
 - Nocturia
 - Self rated symptoms
- Equivalent to Finasteride.

Saw Palmetto produces mild to moderate benefit for BPH

BUT

Blinding maybe compromised
More studies needed to prove specific efficacy

Pelargonium Sidoides
(Koloba);

Conrad 2008

Timmer 2009

Use

Upper and lower respiratory tract infections.

Probable mechanism

Immunomodulation, cytoprotection (interferon and cytokine induction) and inhibition of bacterial adhesion.

Dose

A liquid containing 80mg of herbal extract per 50mls.

Safety

- 1994-2003 109 million daily doses sold with 73 adverse events reported.
- Adverse events marginally more common in placebo groups (hypersensitivity, gastrointestinal upset).
- Interactions – none known.

Therapeutic effects in respiratory infection (Timmer 2009)

- Systematic review of RCTs only (746 adults and 819 children).
- 6 double blind RCTs
- Significant efficacy demonstrated in 2 of 3 adult trials.
- No pragmatic studies comparing Pelargonium to conventional symptomatic treatment or antibiotics.

Pelargonium *maybe*
effective in acute
respiratory infections ?

Hawthorne for Heart Failure;

Guo et al 2008

Use

Heart failure.

Probable mechanism

Positive inotropic effects, decreasing atrioventricular conduction time, and increases coronary blood flow.

Dose

900 mg daily.

Safety

- Postmarketing surveillance studies report only mild and infrequent adverse events in patients receiving Hawthorn extract in a study of 1011 patients.

Therapeutic effects (Guo 2008)

- Ten trials including 855 patients with chronic heart failure (NY classes I - III).
- Significantly better than placebo for exercise and cardiac O₂ consumption.
- Works effectively with conventional medication.

Hawthorne is safe and effective for heart failure and can be used with conventional medication.

How do I get the remedy?

- Through a UK or EU GMP supplier.
- Perhaps through the internet OR via a reputable pharmacy OTC.
- With the knowledge of my physician (interactions) .
- When I have read the data sheet!
- Remember to report ADRs!

And we could consider

- UTIs
- IBS
- Insomnia
- Anxiety
- Arthritis
- Diabetes

And more with similar data.

So what does this tell us?

- Does evidence make a difference?
- There is a lot we know but do not act on.
- There is a lot more that we need to understand (dose, duration, cost effectiveness, etc).
- There is little good evidence of harm when herbs are prescribed for chronic conditions or cancer.

Conclusions

- The data is probably better than we deserve from our limited investment.
- Issues of national legislation, intellectual property, product production, professional liability and clinical competence limit development .
- More research is needed particularly with respect to dose and duration.


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