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Partners in practice: Practitioners' perceptions of herbal medicine manufacturers revealed through dispensary decisions

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Abstract:

The dispensary of professional herbalists and naturopaths, with its stock of herbal products, provides a window into their relationships with both herbal manufacturers and patients. This research aims to examine their decision-making process in relation to dispensary stock.

Method: A survey was developed in the Qualtrix platform to gather the perceptions of practitioners of Western herbal medicine in Australia who are responsible for herbal dispensary decisions. Links to the survey were disseminated through major professional bodies and a hard copy was distributed at the NHAA International Conference in 2015.

Results: One hundred and sixty-seven surveys were completed by decision-making initial respondents who tended to be in their forties and in practice for over 10 years. Herbal tinctures were ranked by 71% as their most frequently prescribed herbal product, followed by herbal tablets (23%). Eighty-five percent purchased stock from two or more suppliers and/or manufacturers. The range of herbal products (both plant species and preparations) and perceptions of manufacturers 'standards and practices' drove decisions about purchases. Clinicians' textual responses reveal high expectations of manufacturers beyond manufacturing

standards, including ethical practices, honesty, sourcing of herbal raw materials, investment in research and customer support.

Conclusion: Practitioners rely on manufacturers to provide clinically effective herbal products, to disseminate research summaries and to provide continuing professional education. This gives manufacturers great responsibility and influence. Australian herbalists need to be aware of the importance of access to independent, non-commercial advice regarding all aspects of the clinical encounter.

Keywords: Western herbal medicine, herbalist, naturopath, complementary and alternative medicine

Introduction

Professional herbalists and naturopaths typically hold a dispensary within their clinic, from which individual mixtures of herbal liquids are extemporaneously prepared for patients. These are dispensed along with tablets, capsules and other herbal products manufactured by herbal suppliers.[1]

Practitioners of Western herbal medicine (WHM) in Australia rely on a *materia medica* of plants that are almost invariably foreign to Australian flora. Many are native to Europe, North America and Asia, but all continents are represented. The vast bulk of the medicinal plant raw material used in Australia is imported, as this country has no substantial commercial herb-growing industry. While some species are cultivated overseas, many are wild-harvested, principally in developing countries.[2] Cultivation, particularly in developed countries, facilitates traceability. In contrast, wild harvesting involves long supply chains where cultures of secrecy impede transparency.[3] With few exceptions, Australian practitioners use medicines made from

raw materials grown and harvested overseas, sometimes prepared as extracts overseas, and their provenance is rarely transparent. Global population pressures on land, both wild and agricultural, already acutely impact the sustainable use of some medicinal plants.[4] Meanwhile, consumers in developed countries continue to adopt WHM, increasing the demand for raw materials.[5, 6]

Practitioners purchase dispensary supplies either directly from Australian herbal manufacturers, who must comply with stringent government regulation including the Code of Good Manufacturing Practice (GMP), or from distributors who provide products from a number of manufacturers. We suggest a range of drivers influence practitioners in their purchasing decisions about herbal products, which may include scientific evidence, traditional use, professional experience, price, availability, source and sustainability. Our aim was to gain a better understanding of decision drivers, and their relative importance.

This study contributes to the growing body of literature that describes aspects of the professional experience and behaviour of Australian herbalists and naturopaths.[1, 7-10] We note that there are differences in nomenclature when discussing liquid herbs, and we have used the term 'tincture' to cover tinctures, liquid extracts and fluid extracts.

Method

A survey was developed in the Qualtrix platform to gather the perceptions of practitioners of WHM in Australia who are responsible for herbal dispensary decisions. The survey was pilot tested by four herbalists who reviewed structure and content. The final survey consisted of 17 questions. The first question separated herbalists responsible for decisions about dispensary stock from others, inviting only the former to complete the survey. Demographic information about the herbalist/naturopath (age group, years in practice, education level, state and setting of practice) was gathered. Participants were asked to rank a range of herbal products in order

of the frequency with which each is dispensed. Product options were herbal tinctures, teas, glycetracts, herbal capsules, tablets, and mixed herbal and nutritional preparations in liquid, capsule or tablet form. Participants were asked to what extent they contributed to their dispensary by growing, harvesting and/or manufacturing herbal products and to comment on this practice. Three questions gathered information about ordering herbs from manufacturers or suppliers and what factors influenced their decision to order from a particular source: perceptions of the manufacturers' standards and practices, range of herbal or herbal and naturopathic products, the availability of standardised extracts, value for money, convenience, reliability and speed of delivery, availability of products with organic certification, identified country of origin with identified harvesting (wildcrafting) or cultivation practices. Other factors and comments were invited. Three questions collected information about perceptions of the quality of herbal tinctures: variability between brands and within a brand, and how an assessment of quality is made (observation, clinical experience, manufacturer information, other).

Perceptions about the origins, cultivation and harvesting practices of the herbs in their dispensary products were also gathered (were stocked herbs thought to be certified organic; cultivated or wild-harvested in Australia or overseas; sustainably wildharvested; subject to Fairtrade agreements and/or threatened species?). Participants were asked whether the addition of more information about herbal medicine sourcing on product labels would be likely to influence stocking decisions or not.

The president and/or the head of research of the following professional herbal and naturopathic organisations were contacted: the National Herbalists Association of Australia (NHAA), the Australian Traditional Medicine Association (ATMS), the Australian Natural Therapists Association (ANTA), the Complementary Medicines Association (CMA) and the Australian Naturopathic Practitioners Association (ANPA). They were invited to disseminate the survey to their membership, by posting information and an invitation to participate with

the link to the survey, or by emailing members individually. Additionally, a hard copy version of the survey was made available to delegates to the NHAA International Conference 2015, and the link was posted via social media on at least two sites. The survey was available from March 2015 to June 2015. The research was approved by the Human Research Ethics Committee, Southern Cross University, approval number: ECN-15-037.

Results

These results are descriptive in nature. Since not all respondents answered all questions, results are expressed as a percentage. Numerical values including the total number of respondents to a particular item are also provided. Two hundred and eleven people started the survey, with 144 (68%) using the online format and 67 completing paper surveys (32%). A research assistant transferred these data to Qualtrix. The majority of respondents (n=198/211, 94%) were in clinical practice. Of these, one hundred and ninety five continued the survey. Eighty four percent (164/195) had sole responsibility for decisions regarding which herbal products are stocked in their dispensary, while a further 30 (15%) shared that decision-making and one respondent had no responsibility in this area. This respondent was excluded from the results. Surveys were completed by 82% (n=167) of the 194 decision-making initial respondents.

Demographics

Among the respondents those aged between 40 and 49 years of age constituted the largest age bracket (63/169, 37 %) and those who had been qualified for 10-20 years were in the largest years-since-first-qualification bracket (67/150, 45%). Only 2% (n=4/169) respondents were aged under 30. The greatest number live in NSW (69/171, 40%), with 25% (n=42) in Victoria and 17% (n=29) in Queensland. Sixty nine percent (119/172) of practices were considered urban. Over half the respondents (88/172, 51%) have a bachelor's degree, master's

degree or PhD qualification in herbal medicine or naturopathy, while 30% (n=52) have a three- or four-year diploma. A total of 19% of respondents (n=32) indicated a professional qualification that is neither naturopathy nor herbal medicine. Details of the demographic information are available in Table 1.

Prescribing practices

Respondents were asked to rate eight categories of herbal products in order of 'most frequently prescribed'. The frequency with which each choice was ranked first or second is illustrated in Table 2. In the interest of reliability lower rankings are not included as seven participants provided feedback that they only ranked three out of the eight products.

The majority of respondents (120/168, 71%) identified herbal tinctures as their most frequently prescribed herbal product. Herbal tablets ranked the second most common prescription, being chosen by 38 (23%), with herbal teas preferred by 20% (n=33). Herbal capsules and glycetracts were ranked most commonly prescribed by the fewest participants (n=3, 2% and n=1, 1% respectively). Table 2 includes practitioners' rankings of their first two most commonly dispensed forms of herbal preparations and confirms that practitioners dispense a variety of herbal products.

Sourcing herbal products

Seventy-one percent (119/168) of respondents sourced their herbal products from both manufacturers and distributors, while 27% (n= 45) sourced only from distributors and 3% (n=5) only directly from manufacturers (data not shown). Thirty-three percent of participants (56/170) reported purchasing herbal supplies from four or more manufacturers and only 15% (n=25) restricted the majority of their dispensary purchases to one manufacturer.

Provisioning the dispensary

To explore the influences that contribute significantly to decisions about ordering herbal supplies, respondents were invited to rank a range of factors from most to least important and to describe other influences and comment on decision making.

Forty-five percent of respondents ranked manufacturers' practices and standards as the most important factor in their decision making (76/168), while 29 % (n=49) ranked the range of herbal and naturopathic products as of most significance (as shown in Table 3).

The textual responses indicate that the category of 'practices and standards' was interpreted widely, going beyond manufacturing practices (such as compliance with GMP). Rather, it included the perceptions of a broad range of behaviours related to ethics and honesty, which we have labelled as 'trustworthiness'. Practitioner expectations of company practices were far-reaching, as demonstrated in the following:

> *'The ethical stance of the company is also important. This covers sustainable sources (of medicinal plants), no animal testing, organic (supplies) wherever possible, good practitioner support, support for natural medicine research and support for the natural medicine industry.'*

Other respondents focused on similar issues, emphasising the importance of:

> '*Openness and honesty in communications around source of raw materials, manufacturing processes'* and '*how accessible, approachable, transparent and helpful they (the manufacturers) are when contacted about their products.'*

For some, brand loyalty is, by their own statements, 'rusted on'; for others, more of a moveable feast. Contrast these two responses:

'Once I would never use any herbs in a bottle or tablet unless it came from Mediherb as Kerry Bone's ethics guaranteed that the herbs were the best quality, sustainability, ethical etc., so I never thought too much about it.' This respondent goes on to explain that, as the ownership of Mediherb has now changed, '*I should pay more attention*.'

A second respondent has a less fixed attitude: '*I like Optimal herbs at the moment, not only do they work really well they look lovely in my dispensary.'*

Practitioners stated that clinical efficacy was an important factor in their decision-making, as was quality. While this was often undefined, some equated it with traditional assessments such as taste.

'Our assessment of quality is by organoleptic means and our experience of efficacy.'

The attitude of the manufacturer in regard to support for natural medicine, particularly as evidenced by their support for natural medicine research, as exemplified earlier, was another recurring theme.

The 'range of naturopathic products' was interpreted by respondents as covering both the range of plant species and the type of preparations available. Some respondents indicated they prefer to use extracts made from fresh rather than dried plants, others prefer tablets over tinctures, or pre-formulated prescriptions, and the availability of these preferences influenced their choice of manufacturer. This respondent considered:

'…the actual strength of the extract formula or dried encapsulated or tablet form, so that I can offer the person a smaller dose and hopefully also be able to offer a savings: as a simple example, a blend of say 5 herbs saves them rather than having to purchase and take 5 separate herbs.'

Twenty people identified the source of the raw material used in the manufacture of the products including organic cultivation, whether the plant was wild-harvested and country of origin as most important influence on their decision making (12% 20/168). It was the second most important factor in the decisions of a further 36 respondents. Pragmatic choices, including price, the flavour of the extract, convenience and the reliability of delivery were the most important factor in the decisions of 2% of respondents (4/168).

However, as one respondent remarked, priorities in decision-making are not always fixed:

'When ordering, there is a complex mental 'dance' that occurs and depends on patient needs, time and timing, response by suppliers and finances. What is no 1 on one day might be no 3 on another.'

Quality

A total of 169 respondents answered a question about how they assess the quality of the herbal products they prescribe in clinical practice (data not shown) and clinical experience. Patient feedback was ranked first with manufacturer information regarding the constituent profile of the herb ranking second. Fewer practitioners used organoleptic observations of smell, taste and appearance as an indicator of quality. Herbal product quality was reported as variable both between and within brands (93%, 156/167 and 40% 67/167 respectively).

Growing herbs, making medicines

While most respondents rely completely on manufacturers for the herbs they prescribe for their patients, a sub-group reported being involved in the growing, collecting and/or manufacturing of one or more of their own remedies (42/169, 25%). Details of this aspect of the research will be reported at a future date.

Exploratory questions

An exploratory question about product labelling indicated that respondents believe increased information about the following would all influence their decision making: organic certification, cultivated rather than wild-harvested, sustainably wild-harvested, of Australian or overseas origin, subject to a Fairtrade agreement, and threatened species status. Labelling about wild harvesting and organic cultivation were seen as being most likely to influence decisions.

Discussion

The sample of herbalists who responded to the survey are demographically similar to those of two other recent surveys of Australian naturopaths and Western herbalists, tending to be in their 40s and living in the Eastern states in urban settings.[9, 10] While just over half of our respondents have professional qualifications at bachelor level or above, 17% of respondents dispense herbal medicines without a qualification in either naturopathy or herbal medicine, and are qualified in other health professions, reflecting the unregulated status of the profession in Australia. Further research is required to ascertain the consequences of this lack of specific herbal/naturopathic training in areas such as patient safety, the philosophical underpinnings of practice and approaches to dispensing.

For over 70% of respondents, herbal tinctures – typically 'the mix', which is an individually prescribed mixture of single herbs in liquid form – are the preferred form of herbal prescribing, and all respondents use them. A small number of respondents (20%) preferred to

prescribe herbal tablets and capsules, which may represent a change in prescribing habits. Almost a decade ago, Casey et al[1] found that a larger percentage (91%) of practitioners identified herbal liquids as their preferred form, with a smaller number of practitioners (4%) preferring tablets and capsules. Further, this study found 40% of practitioners included tablets and capsules as part of their dispensing practice. Lin et al did not collect data about preferred forms of herbal medicines, and her team found that 81% of naturopaths prescribed tinctures, and 68% prescribed tablets and capsules.[10]

Tablets and capsules have advantages over tinctures in terms of palatability, the absence of alcohol, and convenience. Implications of their increased popularity go beyond the pharmaceutical form. Tablets are pre-formulated, either as single herbs or as combinations, so their prescription can represent a compromise of convenience over specific therapeutic appropriateness. Variation in dose is limited to multiples of the tablet, as opposed to liquids, which afford greater flexibility in dosage. In addition, when combinations of herbs/nutrients are given, further restrictions on dosage occur because safe limits for the minerals need to be observed. The starting material for tablets is generally more concentrated than that of liquids, and more processing is involved in production.[11]

A further issue regarding dose can be associated with tablets and capsules. Evidence-based practice recommends reference to clinical trial data for dose and form. However, clinical trials of herbal medicines rarely have the funding to test more than one dose, so they standardise a dose that is generally quite substantial, one that is hypothesised to enable clinically measurable end-points achievable in a fairly short timeframe in a carefully defined clinical population. The interpretation of evidence-based practice may mean that practitioners use a specific tablet that has been trialled, and not experiment with lower doses and other preparations, even those whose therapeutic use is well documented. In turn, higher doses become the norm: a further pressure on an already strained supply chain.

Access to quality medicines directly affects the practitioner's ability to succeed in practice – their personal skills only go so far and good quality herbal remedies are required in order for patients to achieve positive clinical outcomes. The dispensary stocks are the herbalist's tools of trade. These natural products are complex substances that require very specific preparation and handling so that their final form is appropriate and effective. Manufacturers can be seen then as an intermediary between the herb, the herbalist/naturopath and their patients.

Practitioners rely on manufacturers for the products that ensure clinical success. Manufacturers also provide practitioners with a range of other services including technical support, either personally (usually via a practitioner-support advisory phone line, where advice is provided regarding the application of herbal medicines) or via written summaries of recent research findings and product development. In addition, manufacturers are major providers of continuing professional education. Given the structure of the profession, its unregulated status and the lack of government and other independent resources, practitioners rely on manufacturers to provide these. This is an environment in which most practitioners, even those trained in critical analysis of research literature, receive much of their up to date information about developments in herbal/naturopathic practice, through the filter of commercial interest.

Practitioners in our survey demonstrated a high level of emotional attachment and trust in the honesty and ethical behaviour of the manufacturer, going beyond objective practices and standards. This translates into high expectations of the manufacturers and covers not only the quality and clinical efficacy of their products, but also the quality of the support they provide practitioners. Our research found that there is a level at which manufacturers are understood to be partners in the practitioner's clinical work.

Trust in manufacturers is seen again with regard to perceptions of quality. While the respondents' major determinant of the quality of the medicines they dispense was clinical efficacy as evidenced by patient feedback, manufacturer information regarding the constituent profile of the herb was the second most important factor, above their own observations of the plant's characteristics. Many products used by Australian herbalists today are not easily assessed organoleptically i.e. involving use of the senses, particularly smell, taste, sight and touch.[11] In particular, herbal tablets and capsules, as well as liquid combinations of herbs and nutritional supplements, do not lend themselves to this type of assessment. Nonetheless, 93% of respondents stated that the quality of herbal products varies between brands. This perception of variability both within and between brands requires further clarification. The notion of quality is a vexed one, and can be in the eye of the beholder. While we did not specifically ask respondents for their understanding of the term, it was clear from the textual responses that for some of our respondents, quality was equated with GMP compliance, whereas for others it encompassed specific levels of active constituents, and for yet others organic status or the vitality of the starting material.

Two decades ago, providers of naturopathic and herbal education, and manufacturers of naturopathic and herbal products in Australia, were small to medium sized businesses founded and operated by individuals passionate about herbal medicine and naturopathy. Often these founders and directors were themselves practitioners. This is no longer the case. These companies have now grown and are attractive to institutional investors and may be bought and sold as global commodities. Manufacturers may be small parts of large corporations whose core business may be oil and gas or pharmaceuticals, and global education providers may own colleges. Two examples illustrate this point: in manufacturing, Mediherb, strongly associated since its inception in 1986 with founding herbalist Kerry Bone, was sold in 2008, and since 2010 its parent company has been the New Zealand oil and gas company, Todd Corporation.[12] In education, the Southern School of Natural Therapies, established by

naturopath Alf Jacka in 1961, was bought in 2010 by Think Education which, in turn, is part of the global education conglomerate Laureate International Universities.[13] Decisions about the priorities, policies and direction which affect the education of herbalists/naturopaths and the production of their medicines, are thus not only made in an increasingly stringent regulatory environment, but also by boards of directors who may be answerable to shareholders and whose priorities may differ to those of Australian herbalists and naturopaths.

During the last decade, herbal medicine education in Australia has moved out of universities and is once again exclusively available within private colleges. Private education providers are without the research responsibilities associated with public universities and largely without institutional cultures supportive to research, with appropriate resources and infrastructure. Consequently, future development of research capacity within the profession is constrained. It is noteworthy that Endeavour College of Natural Health has responded to this situation by establishing an Office of Research and introducing an honours programas a step in the direction of training in research.

Limitations

Employing both online and paper questionnaires complicated the data collection process and made it impossible to report the results of a question about practitioner understanding of plant sources, as online and hardcopy versions differed slightly but significantly. Thirty-seven people (18%) did not complete the survey after commencing, suggesting a more succinct questionnaire would have been more appropriate. We suggest a more extensive and critical piloting procedure to address some of these problems in the future.

Conclusions

The role of herbal manufacturers as providers of herbal information has become more significant in recent years as a result of changes in the educational and research environment of Australian herbal medicine and naturopathy. These changes impede both the development of non-industry funded clinical research and the opportunity for herbalists to play an active part in independent research into the discipline. In such an environment, the need for Australian herbalists and naturopaths to have access to independent, non-commercial advice regarding all aspects of the clinical encounter is paramount, especially for therapeutic approaches and dosage considerations, as is the need for critical thinking to become second nature to all practitioners. It is appropriate that manufacturers provide good herbal information and practitioner support. However, when they are the only or major source of such information and support, independent practice is compromised. Innovative approaches are required if herbalists and naturopaths are to have the capacity to provide optimal clinical care.

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Table 1: Demographic characteristics of participants

Age bracket in years (n=169)	**n (%)**
20-29	4 (2)
30-39	33 (20)
40-49	63 (37)
50-59	48 (28)
60+	21 (12)
Years since first qualification in herbal medicine or naturopathy (n=150)	**n (%)**
Under 2	13 (9)
Between 5 and 10	39 (26)
Between 10 and 20	67 (45)

Over 20	29 (19)
Currently studying	2 (1)
Highest professional qualification in herbal medicine or naturopathy (n=172)	**n (%)**
Naturopathic diploma – 3 years	12 (7)
Naturopathic diploma – 4 years	29 (17)
Herbal diploma – 3 years	6 (4)
Herbal diploma – 4 years	5 (3)
Bachelor of Naturopathy	67 (39)
Bachelor of Herbal Medicine	10 (6)
Master of Herbal Medicine (coursework)	7 (4)
Master of Herbal Medicine or Naturopathy (research)	0 (0)
PhD in herbal medicine, naturopathy or related field	4 (2)
Other qualification Includes health science, sports therapy, nutrition, community health, pharmacy, medicine, nursing	29 (17)
Location (n=171)	**n (%)**
ACT	4 (2)
NSW	69 (40)
NT	1 (1)

Queensland	29 (17)
South Australia	5 (3)
Tasmania	4 (2)
Victoria	42 (25)
Western Australia	17 (10)
Setting (n=172)	**n (%)**
Urban	119 (70)
Regional	37 (22)
Rural/Remote	16 (9)

Table 2: The two herbal products ranked first or second from eight products as 'most frequently prescribed' and the frequency with which each product was ranked either first or second (n=168)

Herbal Products	**Ranked first Frequency (%)**	**Ranked second Frequency (%)**
Herbal tinctures	120 (71)	15 (9)
Mixed herbal and nutritional tablets	15 (9)	24 (14)
Herbal tablets	9 (5)	38 (23)
Mixed herbal and nutritional liquids	7 (4)	16 (10)
Mixed herbal and nutritional capsules	7 (4)	21 (13)
Herbal teas	6 (4)	33 (20)
Herbal capsules	3 (2)	10 (6.0)
Glycetracts	1 (1)	11 (7)

Table 3: Ranked factors influencing decisions about ordering herbal dispensary supplies (n=168)

Influences on ordering herbal supplies	**Ranked first Frequency (%)**	**Ranked second Frequency (%)**
Manufacturers practices and standards	76 (45)	27 (16)
Range of herbal and naturopathic products	49 (29)	56 (33)
Organic cultivation, harvesting and or country of origin	20 (12)	36 (21)
Standardised extracts	8 (4)	22 (13)
Personal recommendation	4 (2)	7 (4)
Price, convenience, reliability of delivery	4 (2)	17 (10)
Other	7 (4)	3 (2)