RURAL INDUSTRIES RESEARCH
& DEVELOPMENT CORPORATION

# Medicinal Herbs & Pharmaceutical Plant Extracts

## R&D Opportunities

**Proceedings of a workshop held in Sydney on 8 July 1997**

Coordinated by
Professor Ron Wills, University of Newcastle
and Dr David Evans, RIRDC

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*Medicinal Herbs and Pharmaceutical Plant Extracts – R&D Opportunities*
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**Researcher Contact Details**
Professor Ron Wills
Department of Food Technology
University of Newcastle,
Central Coast Campus
PO Box 127
OURIMBAH NSW 2258

Phone: 043 484140
Fax: 042 484 145
Email: ftrbhw@cc.newcastle.edu.au

**RIRDC Contact Details**
Rural Industries Research and Development Corporation
Level 1, AMA House
42 Macquarie Street
BARTON ACT 2600
PO Box 4776
KINGSTON ACT 2604

| | |
|---|---|
| Phone: | 02 6272 4539 |
| Fax: | 02 6272 5877 |
| Email: | rirdc@netinfo.com.au |
| Website: | http://www.rirdc.gov.au |

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# Foreword

There is growing interest in Australia in the production of medicinal herbs and plant-based pharmaceuticals. These commodities present opportunities for diversifying farm businesses, for adding value, for import substitution and for export.

This report provides an overview of a workshop aimed at:
- Outlining the current status of the Australian industry;
- Determining the potential for future development;
- Examining where impediments to development exist; and
- Identifying R&D strategies to overcome these impediments.

The report should be read in conjunction with RIRDC's R&D Plan for the Essential Oils and Plant Extracts Program 1996-2001, available from the Corporation and on the Internet at http://www.rirdc.gov.au.

**Peter Core**
Managing Director
Rural Industries Research and Development Corporation

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# 1. Introduction

RIRDC has supported development of the Australian medicinal herbs and pharmaceutical plant extract industries for a number of years through its Essential Oils and Plant Extracts R&D Program. The rapid development of these products in the market place in recent years prompted RIRDC to seek an industry-driven view of where R&D priorities should be focused.

This workshop was therefore convened by RIRDC in July 1997 to bring together about 20 persons prominent in the production, processing, trading, usage or research of medicinal herbs and pharmaceutical plant products in Australia with the aim of:

- Outlining the current status on the Australian industry,
- Determining the potential for further development,
- Examining where impediments exist to development, and
- Identifying R&D strategies to overcome these impediments.

This report provides:

- outlines of brief overview papers presented to highlight the position of various industry segments, and
- summarises output of the subsequent plenary sessions on industry conclusions of the potential for industry development and recommendations for R&D to support this development.

# 2. Industry Overviews

## Medicinal Herb Crops: An Overview

*Denis Stewart*
*Gosford Natural Health Centre, Gosford, NSW*

**1. Rationale and need for a serious medicinal herb industry in Australia.**

- The herbal renaissance,
- Herbs, the fastest growing commodity in retail history,
- Recent development of North American herbal product manufacturers, many Utah based, has placed unsustainable demand on wildcrafted herb supplies in the United States and elsewhere,
- Developing Australian herbal product manufacturers are restricted by dependence on overseas herbal starting material,
- Australia has never been a major player in natural drug cultivation and therefore is arguably behind in the serious cultivation of conventional medical/pharmaceutical herbs as well as other levels of medicinal herbs,
- Pressure on conventional Australian crops now forces reappraisal of this disregard.

**2. Three levels of medicinal herb crops.**

- Major recognised medical/pharmaceutical herbs from which alkaloids, glycoside etc are extracted e.g. opium poppies. Other possible are Madagascar periwinkle, foxglove, henbane, belladonna, datura,
- Popular medicinal herbs usually not components of medical/pharmaceutical drugs but popular over-the-counter or retail commodities e.g. dandelion, valerian, chamomile, red clover,
- Medicinal herbs to support the herbal renaissance particularly American herbs e.g. the echinaceas, golden seal, the unicorn roots, wild indigo.

**3. Important texts to govern the selection and cultivation of medicinal plants:**

*The Potential of Herbs as a Cash Crop* by Richard Allen Miller
*Major Medicinal Plants – Their Cultivation* by Dr Julia Morton

## Processing and Products: a Manufacturer's Perspective

*Lee Carroll*
*MediHerb, Warwick, Qld*

### 1. Issues concerning manufacturers

• Manufacturing covers a broad range of product types including, retail, practitioner/doctor and bulk concentrates or processed herb, with each area having potentially different requirements from the grower. • All herbs can be sourced from abroad. • Manufacturers are not dependant on Australian grown herbs. • As demand increases opportunities arise for Australian growers. • Growers need to proactively market to manufacturers. • Marketing position needs to be quality oriented at both ends of the spectrum. • Manufacturing costs are higher in Australia, therefore need to produce better quality extracts to compete. • With global retail sales for herbal remedies estimated at US$14 billion for 1997 and growth estimated to average 15%, large opportunities exist for manufacturers.

### 2. Advantages for manufacturers using Australian grown herbs

• Potential for working closely with the grower in selecting better seed/plant breeding, and for selecting optimum growing conditions for each herb species. • Better quality of herb is available due to greater ability to influence growing conditions. • Perceived market preference for an Australian grown herb. • Greater potential for sourcing organically grown herb. • Where quantitative quality parameters are defined it is easier dealing with an Australian grower or wildharvester.

### 3. Disadvantages for manufacturers using Australian grown herbs

• The industry is 'very young' and does not have a lot of experience. • This often results in unreliability of supply and variable quality. • Many small growers are often unable to supply in the quantity or the price required.

### 4. What is needed from an R & D perspective to help the industry

• Development of production techniques to help reduce costs and increase capacity. • Strong focus on the development of herb varieties with increased or standardised levels of active components.

**Pharmaceutical Plant Products: An Overview**

*Dr Reg Smith*
*Phytex Australia, Sydney*

• Plant extracts represent the pure fine chemicals or active pharmaceutical ingredients segment of the natural products industry.

• In excess of 25% of proprietary medicines contain plant-derived active components • These are represented by classes of organic compounds such as:

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|---|---|---|
| • Alkaloids | morphine, codeine | painkillers |
| | scopolamine, atropine | anticolinergics |
| | castanospermine | antivirals |
| • Coumarins | esculin | sunscreens |
| • Diterpenoids | taxol | anti-tumour |

• Herbal extracts were known and used for over 5000 years whereas use of plant secondary metabolics in pure forms began to develop only as recently as the early $19^{th}$ century along with the emergence of study of organic chemistry, • Morphine the first secondary plant metabolic to be isolated in pure form heralding pharmaceutical chemistry as an exact science.

• Australian natural product research became active in late 1800s but sthe mall population base affected the potential for a finished form pharmaceutical industry prior to WWII.

• During WWII shipping routes from Europe to Australia disrupted, • Need for essential drugs morphine, scopolamine, esculin, • Task undertaken by Sir Russell Grimwade with the help of CSIRO set up an emergency supply of these drugs, • Commercial plant cultivation and drug extraction established byDHA, • Decline in local pharmaceutical manufacture after WWII when embargo on export of raw materials (eg Duboisia) lifted.

• Nowadays, morphine, codeine and scopolamine produced locally in substantial quantities for export, • Raw materials supplied by vigorous local agricultural industries based on plantation-grown native plants.

• Competitive edge in production of actives dependent upon use of indigenous raw materials, • Cheap labour rate countries make it uncompetitive to grow and use raw materials originating overseas, e.g. Vinca for antitumour alkaloids, Digitalis for cardiac glycosides.

• Biological screening now used to direct the source of prospective new drugs, • Extended beyond plants to marine and fungal sources.

• Gestation periods for new drug development candidates can be long (8-10 years) with low success rates, e.g. castonaspermine developed to Stage II clinical trials over 8 years and then rejected, • High risk factor in growing raw materials and isolating the active ingredients.

• Problem with complete lack of government support in preventing raw materials, containing active ingredients, from being taken out of Australia for value-adding overseas.

## Wholesale Market Trends for Medicinal Herbs

*Warren Morey*
*Hobler-Mann, Melbourne*

• Market for medicinal herbs in Australia is growing at a phenomenal rate, • Most Australian manufacturers are growing at a minimum 25% pa, • Growth is consumer-driven as people focus on health maintenance using natural products, • Herbal medicines are well suited to the treatment of chronic illnesses which allopathic medicine often finds difficult to treat,• Australian herbal manufacturers are regulated by TGA standards therefore quality standards are equivalent to pharmaceuticals, • Gives herbal products status as premium quality, • Manufacturers are making excellent progress in the export of finished products, • Market in Australia for rough cut herb has been limited to manufacturers of liquid extracts as tablet manufacturers generally need powdered extracts, • One Australian company, Mediherb, now has capacity to manufacture spray dried powder extracts which generate tablets, • Will increase market as tablet manufacturers had to purchase starting materials from overseas.

• Hobler-Mann is still in a development phase, • sales doubled in last 12 months as more Australian growers reached a commercial level, • currently supply 2-10t Echinacea pupurea, Hypericum perfoliatum, Scutellaria lateriflora, • 0.2-2t Inula helenium, Crataegus monogyna, Hyssopus officinalis, Marrubium vulgare, Ruta graveolens, Rosmarinus officinalis, Salvia officinalis, Verbena officinalis, Agrimonia eupatoria, Taraxacum officinale, Urtical dioica, Filipendula ulmaria, Rumex acetosella, Achillaea millifolium, Galium aparine.

• RIRDC could sponsor the sourcing of unavailable plant material for distribution to allow broadening of herbs grown, • Could source Indian and Chinese herbs, • India may prohibit export of all herbal raw materials to force value adding in India, • industry needs planting material of wild yam, gotu kola, feverfew, golden seal and false unicorn root.

• Market: Organic V Trade, • 30% herbs used in Australia of organic or wildcrafted origin, 70% from trade, • May underestimate importance of growing trade quality herb in Australia, • Not feasible to have organic competing against trade herb, • two distinct markets, Organic for traditional herbalists using liquid extracts, trade herb for retail outlets.

• World Herb Markets: USA top 10 herbs, echinacea, garlic, golden seal, ginseng, ginkgo, saw palmetto, aloe, ephedra. Siberian ginseng, cranberry, • Delivery: 53% capsules. 15% tablets, 7.3% tinctures, • 1995 value US$ 1.5 billion, • German top 10, ginkgo, horse chestnut, hawthorn, yeast, St John's wort, myrtle, stinging nettle, echinacea, saw palmetto, milk thistle, • In Germany circulatory stimulants and tonics are very popular followed by antidepressants, urinary tonics and immunostimulants, • In USA immunostimulants are the most popular, followed by energy enhancing and circulatory tonics.

• Prices for most herbs rising due to increased demand and decreased availability of quality products, • Affected by supply reduction from Eastern Europe of subsidized herb, • As buyers become more sophisticated in quality and botanical medicine market becomes more popular, quality considerations will become paramount, • If quality is not addressed, consumers will be disillusioned with products and lack industry self policing, • Bacterial contamination needs carefully monitoring , • Use of manure adds significantly to risk.

## Retail Market Trends for Herbal Medicines

*Paul Mannion*
*Bullivants Natural Health Products, Sydney*

### 1. General market trends

• Interest in herbal medicine is high and sales as a proportion of the total health supplement market are increasing steadily both domestically and worldwide. This is due to: • Public disillusionment with orthodox medical system and its therapies • Increasing levels of research into herbal activity and clinical usage • Word of mouth • Ethnic backgrounds of migrants to Australia familiar with herbal medicines • Effective marketing.

### 2. Retail trends in herbal medicines

• The use of bulk herbs and herbal teas, traditionally the mainstay of herbal medicine has been in decline for some time. Tablets and capsules are by far the most popular format of herbal medicine, together comprising 46% of the US market for herbs in 1996. The change is most likely due to: • unpleasant taste of many herbs, • the ability to combine herbs with vitamins, minerals and food supplements to give more 'complete' supplements, • greater convenience.

• Capsules are often preferred to tablets due to: • Ease of swallowing, • Perceived to have improved absorption over tablets, • Ability to open capsules (2 piece) to mix contents with food or liquid for children, • Lack of fillers and tabletting aids.

• Liquid preparations are the flavour of the month, and seem to be increasing in prevalence. This is due to: • Perceived to be more natural then tablets or capsules, • Perceived to have enhanced absorption and speed of action over tablets or capsules.

• Liquid extracts made with glycerol are much more popular than alcoholic extracts. This is due to: • Improved taste, • Soothing action on throat and gut, • More acceptable for use in alcoholics, children and people with liver damage.

• Some other important features of medicinal herbs in the market at present are:

- Organic Herbs: This is not considered to be highly significant at a retail level, however, it does become a highly significant feature if selling to practitioners.
- Standardization: This appears to be here to stay in the market. It is not considered to be a huge issue in the mind of the consumer at present, but will become increasingly important as herbs begin to be recommended by more orthodox practitioners.

### 3. Retail trends in herb species

• The two largest selling herbs at present are garlic and echinacea, • Other popular herbs include celery seeds, valerian, ginseng and ginkgo biloba, • Indian and Asian herbs are growing in popularity, • herbs with a strong research support base are also growing in popularity, • Some other herbs which we consider may be prominent soon are cat's claw, saw palmetto, Eiplobium and Kava kava, • Herbs which are in short supply worldwide are a good opportunity eg golden seal and echinacea.

**Production Issues on Broadacre Cultivation**

*Phillip Brown*
*Subiaco Herbs, Walcha, NSW*

• Subiaco Herbs commenced cultivation of medicinal herbs in 1996-97 on a broadacre scale, • Area under cultivation 130 acres with a number of other district farmers growing under contract, • Major crops echinacea, skullcap, valerian, • Production based on organic principles, • Aim is to market high quality, organically-grown herbs.

• Costs are considerable to set up growing of medicinal herbs on a broadacre scale with many problems that are easily overcome on smaller coastal holdings, • problems are exacerbated when grown under organic farming principles, • Research is needed into organic production of medicinal herbs, • Of the many problems, weed control is considered the major threat in organic production, • Improved techniques for weed control are needed in the nursery as well as in the field.

• Research that develops new farm machinery or nursery techniques would have considerable flow-on benefit to other sectors of the organic farming industry both locally and internationally, • Such equipment could be a valuable export earner for Australia.

• Strongly support Australia developing its medicinal herb industry for organic production, • Believe we will compromise our international strength base if fail to promote organic, • There are price premiums in the international market to justify the additional costs and effort, • Growers need to be more aware of international pricing and be more aggressive in obtaining the best price.

• Organic production needs a strong quality accrediation base, • Installation of a quality management system is essential to ensure organic practices are followed and provide proof to the market, • Testing for quality in the form of active constituents in herbs and freedom from chemical residues will also be essential.

• Additional threats to the industry can come from increasing government regulation, • Involvement by multinational pharmaceutical companies is also seen as a threat, • Many already have taken equity positions in medicinal herb manufacture, • The threat could come from many aspects depending on how the pharmaceutical companies choose to wield their undoubted market power.

## Organic Production Issues

*Howard Rubin*
*Organic Herb Growers of Australia, Lismore, NSW*

• Organic Herb Growers of Australia formed North Coast NSW from 15 growers, now 500 members nationwide, • Fully accredited organic certification for herbs, • Member federal government Organic Producers Advisory Committee, • Publish bimonthly magazine Herb Grower, • Instill professionalism in members.

• If industry to avoid boom/bust syndrome common all other primary sectors, need to develop industry plan covering import replacement of exotic herbs plus use of indigenous plants, • Differ other primary producers as growing medicines not just cash crops, • Cannot rely on following USA and hope produce cheaper product, • Strategy not sustainable, • Will be defeated by developing countries at half our price.

• Production of crops not the problem, • personally trialed >60 species, confident all commercially viable, • Traders need be more explicit in dealings with growers, • major deterrent to development is unscrupulous buyers who do not honour promises to purchase after growers generate crop, or only pay unfair low market price, • Australian traders and manufacturers should be purchasing Australian-grown herbs in preference to imported.

• Personal experience overseas indicates buyers want either cheap herbs or certified organic herbs, • Australian cost structures demand our future is in organic production, • Australian clean green image not enough to support a traditional farm practice industry, • Seen recent failure of beef industry with residue problems, • Organic certification only answer.

• Growing regime influences the medicinal properties of herbs, • Need to be grown under optimal conditions of light, temperature and soil, • When plants moves from wildcrafting to cultivation, need to preserve natural growing conditions, • Application of synthetic chemicals absorbed and difficult to remove from plant, • Safety a paramount public concern, • Certified organics only reliable source of pure pesticide-free crops with Maximum active constituents, • Quality testing for actives and residues important public safeguard.

• First priority of manufacturers is to use organically-grown herbs, • Not good enough to rely on farmer's word, should insist on organic certification, • Organic Herb Growers of Australia able to provide this certification under federal legislation, • Certification will give manufacturers the sustainable marketing advantage cheap prices never will, • Competing solely on price on the world stage is invitation to disaster for Australia.

• Current R&D focused on Western herbs often duplicating overseas, • Whatever work is done in Australia, they remain American herbs, • Our industry needs to go further, • Suggest R&D monies be spent identifying indigenous herbs, determining their active constituents, establishing their efficacy and toxicology, understanding their cultivation techniques and eventually market these products, • We live in a vast continent with much as yet unexplored flora, • Requires a multi-disciplinary team of scientists and industrialists to bring new indigenous crops to a commercial reality, • Not a short term venture, but only through such action will Australia become a true market leader in medicinal herbs.

# 3. Opportunities for R&D

The R&D issues that were highlighted during the industry overviews and the subsequent plenary session are summarised below.

**Compendium of crop production in Australia**

Growers interested in growing medicinal herbs were considered to need assistance in determining those crops with market potential and guidance in cropping practices. This support is currently being provided on an *ad hoc* basis by various groups and individuals. Development of a publication which acts as an entry document and encapsulates the questions being asked by prospective growers would be of considerable value to an efficient industry expansion. The diverse position of prospective growers ranging from backyard hobbyists to broadacre companies was noted with differing information requirements between groups.

**Weed control**

The most pressing farm issue for both small and large farms operating on organic principles was considered to be weed control. There does not appear to be any alternative to physical removal of weeds but no appropriate farm equipment exists to perform the task in an economical manner. Development of such equipment was considered to have considerable commercial potential across many industries around the world. Alternate procedures such as physical methods of weed suppression are also of interest particularly in nursery situations.

**National development plan**

The need for a national industry development plan was raised with an important issue being whether the future of the Australian industry should be as a supplier of high quality products. Due to the relative cost structures between Australia and developing countries, there was general agreement for Australia to focus on generating high quality products. There was, however, no consensus on the need for developing a coordinated industry plan.

**Marketing information**

It was agreed that the success of industry development will depend on individual operators having access to reliable international market information on prospective crop prices and trading volumes. Growers in particular need to know which crops to produce. However, many felt that the generation of marketing information was the responsibility of individuals and not government agencies.

**Cropping options**

Traders generally considered producing a wide range of crops in Australia provided flexibility in meeting market demand which was unpredictable from year to year. There was, however, a counter view that to be successful internationally, Australia needed to be able to be a high volume supplier particularly in the substantial US market.

Crops with current or potential commercial value include:
- current Australian-grown crops such as echinacea, skullcap, valerian, and ginseng,
- popular international crops such as dandelion, St John's wort, golden seal, chamomile, red clover, and St Mary's thistle,
- mixed culinary/medicinal herbs such as thyme, sage and celery, and
- pharmaceutical herbs such as duboisia.

**Varietal development**

An important element in being a supplier of high quality products was seen to be the development of cultivars with a high level of active constituents when grown under Australian conditions. The effect of agronomic practices on crop yield and concentration of actives would need study as there was some anecdotal support for the proposition that the level of actives would decrease as crop yield increased.

**Planting material**

The cost-effective development of a high quality Australian industry requires that planting material of uniform quality be available to growers at a reasonable price. Encouragement of larger nurseries to be involved in the trading of medicinal herbs would be advantageous. Tissue culture was considered a propagation technique with potential for the industry. While there is some activity is the use of tissue culture for medicinal herbs in Australia, this aspect needs further development.

**Organic cropping**

The question of Australia concentrating its efforts to only export raw material or processed products obtained from certified organically-grown crops found no general agreement. Some of the trading representatives considered there to be no substantial price premium in the market for organic products. The related question of only marketing products that are residue-free was not contested.

**Indigenous plants**

The potential for Australian indigenous plants as medicinal herbs and pharmaceutical plant extracts on the international market was canvassed. There was general agreement that there are undoubtedly indigenous crops of considerable health benefit but many considered the cost of commercialising these crops was extremely high with a high element of risk. The ability and willingness of Australia to protect planting material from foreign exploitation through an embargo on export was doubted.

**Plant extracts**

Opportunities for the Australian pharmaceutical plant extracts industry was considered to be in niche marketing to avoid competing directly with the large multi-national pharmaceutical companies. While there are opportunities for developing local industries such as has already been done with *Duboisia,* most projects will need to be developed with considerable secrecy with an assured flow of intellectual property to a designated manufacturer.

**Quality testing**

If Australia is to become an international marketer of high quality medicinal herbs, it was recognised that there was a need have independent laboratories able to certify the quality of crops and possibly also of processed products. The potential for analysis being for the level of active constituents, pesticide residue and heavy metal compliance, and microbial status. Considerable research will be required to develop satisfactory cost-effective analytical methods for active constituents across a range of crops although methods for residue and microbial testing currently exist.

**National quality standards**

The desirability of having national quality standards that would be used on crop trading and processed products in both domestic and international trade was discussed. Standardisation of labeling was considered to have importance in the retail trade in generating consumer confidence. While there was no disagreement with the proposition, it was unclear who had responsibility for such development.

# 4. Recommendations for R&D

## Objectives for a targeted R&D program

- Determine which medicinal herbs are most appropriate for production in Australia
- Improve yield and the quality of active constituents
- Provide cost effective production systems
- Achieve high quality Australian products with national and international acceptance

## Strategy

Identified project areas which will promote the objectives are:

- Support research across a wide range of medicinal herbs for which commercial interest exists from Australian growers or processors.
- Generate an entry document appropriate for distribution to potential growers of medicinal herbs.
- Develop and evaluate high yielding cultivars with high levels of active constituents under Australian growing conditions.
- Provide cost effective mechanised implements and physical practices for the control of weeds and other farm-related problems in organic farming systems.
- Devise and establish improved postharvest handling and drying procedures.
- Develop cost effective quality testing and certification systems for active constituents in crops and processed products.

# 5. List of Workshop Participants

| | Name | Organisation | Phone | Fax |
|---|---|---|---|---|
| 1. | Dr David Evans | RIRDC | 06 2725472 | 06 2725877 |
| 2. | Prof Margaret Britz | RIRDC Board | 03 96519267 | 03 96519861 |
| 3. | Phillip Brown | Subiaco Herbs | 067 777444 | 067 777454 |
| 4. | Kati Brown | Subiaco Herbs | 067 777444 | 067 777454 |
| 5. | Prof Cliff Ellyett | Ellyett Herb Farm | 043 621626 | 043 621433 |
| 6. | Howard Rubin | Organic Herb Growers of Australia | 066 291057 | 066 291057 |
| 7. | Dr Graham Michael | Greenleaf Extracts | 076 981176 | 076 981755 |
| 8. | Peter Johnson | Ginseng Growers Association | 035 4446674 | 035 4446688 |
| 9. | Denis Stewart | Gosford Natural Health Centre | 043 252461 | 043 243352 |
| 10. | Lee Carroll | MediHerb | 076 610700 | 076 610788 |
| 11. | Warren Morey | Hobler-Mann | 03 97690155 | 03 97690166 |
| 12. | Paul Mannion | Bullivants Natural Health Products | 015 372394 | 02 98948495 |
| 13. | Dr Reg Smith | Phytex | 02 95331324 | 02 95331500 |
| 14. | Dr Erich Lassak | Phytochemical Services | 063 733539 | 063 733437 |
| 15. | Phillip Daffey | Blackmores | 02 99510111 | 02 99491954 |
| 16. | Nicholas Langdon | HJ Langdon | 02 96721677 | 02 96721505 |
| 17. | Dr Alex Shamgar | NSW State&Regional Development | 02 92426671 | 02 92426676 |
| 18. | Prof Ron Wills | University of Newcastle | 043 484140 | 043 484148 |
| 19. | Doug Stuart | University of Newcastle | 043 484140 | 043 484145 |