

Social pharmacy

Collaborators from the Research Group in Social Pharmacy at the **University of Bergen** discuss their studies into the treatment of vulnerable patients and the safety of herbal medicine



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What do you consider to be a vulnerable patient group?

In our research we have chosen to work with elderly people and pregnant women, but the work could be easily extended to other groups, such as children or patients with porphyria. We consider these groups to be vulnerable for various reasons. First of all, medicines are not normally tested in those groups before marketing authorisation is given. This means that close follow-up of treatment is necessary. Persons in those groups metabolise medicines differently to adults in general, which means that effects can vary and there is a greater risk of side effects. Elderly patients, especially those suffering from dementia, may have difficulties understanding why, when and how to use their medications. Pregnant women are often worried about the teratogenic potential of medicines – the risk of harming the unborn baby. Essentially, a 'vulnerable patient group' is a group with a higher risk of side effects or other unwanted effects of medicines than experienced among the general population.

For what reasons are you primarily investigating elderly people in nursing homes?

Firstly, elderly people living in nursing homes are patients with severe functional and/or cognitive impairment who are in need of

continuous care. Drug therapy is especially challenging in this patient group, because of advanced age, several co-morbidities and multiple drugs, but also due to scarce resources to provide medical care. Normally, a GP works in the nursing home one or two days a week. The GP often needs to rely on the information provided by the nurses in aspects of initiation and adjustment of drug therapy.

Secondly, this has been, and still is, a focus area for research in Bergen. Our department has been especially involved and now has a great deal of competence in this area. Recently, the Centre for Elderly and Nursing Home Medicine (SEFAS) was established at the University of Bergen. Researchers from several backgrounds contribute to this, which gives opportunities for high-impact multidisciplinary projects.

Why is it important to focus on the prescription and use of herbs in pregnant women and medicines in elderly patients?

As pharmacists we naturally focus on all aspects of medicines – from research and development to safe use, via production. Patient safety is essential in the healthcare system because of the cost to individuals as well as society when errors occur. Both elderly and pregnant patients have special challenges as mentioned earlier. It is essential that choice of medicine is considered

closely for those groups in order to avoid unnecessary treatment, administer correct doses and provide the most suitable medicine when there is a choice.

What do you consider to be your greatest challenge and achievement in the project so far?

The biggest challenge in our studies with elderly patients has been to choose areas of focus, since there are so many problems that need addressing. The choice was made based on the main competence of the primary supervisor and the network already established. For our research on pregnant women we have had two main challenges: recruiting people to

Scrutinising safety

Has there been a systematic failure of drug trials in addressing the needs of minority or particularly vulnerable patient groups? Are there hidden risks underlying age-old natural remedies? The **Research Group in Social Pharmacy** in Bergen hopes to shed light on such questions

TRADITIONAL APPROACHES TO providing therapeutic care focus on isolating the appropriate treatment based on the patient's condition, and direct evidence of symptoms and laboratory test results, with only a cursory glance to the broader context of the patient – which generally constitutes a few short questions on family history. This model of medicine has indeed proven extremely successful over the past century: significant advances in terms of the treatments available, and the spectrum of conditions which are now curable, have been made possible thanks to an understanding of which are the right questions to ask.

Despite this progress, the medical community has increasingly recognised that it is not only knowledge of the ailment which is important in selecting the most effective treatment: the unique details of the individual being considered also play a significant role. At the high-technology end of the research spectrum, such efforts are being realised through detailed analyses of the patient's genetic makeup to help inform treatment selection. This allows doctors to draw on the growing wealth of knowledge in molecular biology, proteomics, metabolomic analysis, genetic testing and molecular medicine.

However, such approaches remain in their infancy and are still far from reaching a wider audience. In addition, there are more factors than just genetics that can be considered when assessing the suitability of a treatment to a patient. In particular, if patients are elderly, pregnant, or suffer from any comorbid conditions, significant adverse reactions or side effects can occur. By using knowledge which takes into account the specific needs of such patient groups, one can arrive at a more robust and safer selection procedure for treatments. However, despite this fact, phase I clinical trials – in which procedures are tested for adverse reactions – continue to make use of only fit and healthy subjects. Such a methodology seems necessary in order to easily identify adverse effects, but has the unfortunate consequence that there is a lack of understanding of the frequency or severity of adverse effects in vulnerable patients. It is the study of effects in such patient groups that constitutes one important line of inquiry for the Research Group in Social Pharmacy at the University of Bergen, Norway.

DIABETES EPIDEMIC

The group has explored several avenues of investigation in this area. For instance, in addition to the recent establishment of a Centre for Elderly and Nursing Home Medicine (SEFAS) in Bergen, they have fruitful collaborations with NOKLUS, an organisation that conducts assessments of laboratory analyses in primary healthcare, and the University of East Anglia in Norwich, UK. As a focus for one set of initial studies the group has chosen to look more closely at the care of elderly patients with diabetes mellitus, a disease whose incidence is showing growth of epidemic proportions among adults worldwide. The most significant rise has been among people aged 65 years and above, but despite the rapid growth of this group, there are currently no specific guidelines or treatment goals for their care. Research has suggested that there is a need for better management of diabetes in nursing homes, particularly in regard to providing adequate glycaemic control. A lack of understanding of the specific needs of elderly patients has resulted in nursing home residents suffering from hypoglycaemia caused by overmedication, which in cases can lead to serious clinical outcomes.

APPROPRIATE GOALS

A study into care of nursing home patients with diabetes is currently being conducted to assess whether the current prevailing practices are providing suitable care for these patients. Preliminary results indicate that diabetes care in these nursing homes is kept simple and non-invasive in aspects of drug therapy and blood glucose monitoring, though we must wait before a conclusion can be reached regarding the degree and quality of care being provided. As the study continues the group hopes that, by investigating the quality of drug regimens and

survey, and finding out what the used herbal remedies actually contain in terms of herbs and amounts of possible active ingredients.

The greatest achievement is actually being awarded the grant from the Norwegian Research Council as a joint project with the University of Oslo. We are a little research group and would have been even smaller without the grant. We have now been able to establish ourselves as a group and start connecting with others both within and beyond our department. The department is multidisciplinary, which is a great advantage and gives us a unique opportunity to work with other healthcare personnel for the benefit of patients.

Do you have any plans to change the focus of your work within the Research Group in Social Pharmacy in the foreseeable future?

We have no plans to change our focus, but to develop it – for instance, by looking at medicines in nursing homes more generally, or to study patients with porphyria. We are in the process of employing a new part-time associate professor, who will bring his/her areas of interest to the group.

INTELLIGENCE

RESEARCH GROUP IN SOCIAL PHARMACY

OBJECTIVES

The main objective is to improve patient safety by creating knowledge about diabetes care in Norwegian nursing homes, and by examining the safety of ginger and other herbs used during pregnancy, in terms of congenital malformations and selected pregnancy outcomes.

RESEARCH GROUP

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LONE HOLST, pharmacist, PhD, has been Associate Professor at the University of Bergen since 2011. Her main research interest is in the use of herbal remedies in general and especially among pregnant women. She is the main supervisor for PhD student, Kristine Heitmann.



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blood glucose monitoring, they will be able to contribute knowledge that can be used to develop appropriate treatment goals and guidelines for these vulnerable patients. The implementation of such findings would offer the possibility of improved quality and safety of drug prescription and administration.

HERBAL MEDICINES

A parallel study the group has been undertaking in collaboration with Professor Nordeng is into the public perception and safety of herbal medicines. One thread of this research has focused on examining the safety of selected herbs frequently used during pregnancy. This recently culminated in the publication of an article scrutinising the safety of use of ginger among pregnant women. The researchers are also investigating the safe use of raspberry leaves and cranberry in pregnant women, and the use of black elder and other herbs against respiratory tract infections. As with elderly patients, pregnant women undergo changes to their metabolic rate, necessitating a careful study of their particular treatment case. Moreover, pregnancy also leads to the additional risk of teratogenic effects. Ginger, cranberry and raspberry leaves were chosen based on their frequent use among pregnant women and their use as remedies for common maladies experienced during pregnancy. Ginger is believed to combat nausea and vomiting; cranberry to prevent recurrent urinary tract infections; and raspberry leaves are often said to induce or ease labour.

POTENTIALLY UNSAFE

Herbal remedies are of concern since most are sold as food supplements which do not require marketing authorisation, and as such there is no guarantee for quality, safety or efficacy of the products and no demand from authorities ensuring proper understanding of adverse effects. As a result, sparse documentation

exists about any possible risks or how they adversely affect particular special cases, such as pregnant women.

The study into the safety of ginger looked for a link to congenital malformations or selected pregnancy outcomes, such as preterm delivery, low birth weight, low Apgar score and perinatal death. In this case, the use of ginger was not associated with any increased risk of congenital malformations or the selected pregnancy outcomes. However, earlier studies into the use of cranberry to treat urinary tract infections (UTIs) concluded it to be a potentially harmful practice. Cranberry has not been shown to be effective in treating UTIs, and as a result the untreated asymptomatic bacteriuria may be allowed to progress into pyelonephritis, which has been associated with preterm delivery and low birth weight.

MIXED MESSAGES

These scientific studies have complemented the broader descriptive studies undertaken by the group, which focus on understanding which herbal remedies are used and why. Surveys among pregnant women uncovered that 58 per cent of respondents had used herbal remedies during pregnancy and that ginger, cranberry and raspberry leaves were the most common. Focus groups found family and friends to be the principal source of information about herbs, and that patients would not inform doctors or midwives about their usage. This is for a variety of reasons, including the expectation that herbs are natural and thus inherently safe, and/or because patients expect healthcare personnel will lack knowledge about herbal remedies, will ridicule the use, or will send mixed messages, ie. professionally disapproving – but personally recommending – the remedies. Navigating this complicated social landscape and tackling such misconceptions are but two of the many challenges the group faces in harnessing a better understanding of the care of these unique and vulnerable patient groups.

