

Paper Reference(s) 31494H

Pearson BTEC Level 3 Nationals Diploma

Health and Social Care

**Unit 4: Enquiries into Current Research in Health and
Social Care**

Part B

STIMULUS MATERIAL BOOKLET

**DO NOT RETURN THIS STIMULUS
MATERIAL BOOKLET WITH THE
QUESTION PAPER.**

ARTICLE 1: HEALTH RESEARCH

NEW DRUG FOR SEVERE ASTHMA ‘SHOWS MASSIVE PROMISE’

Monday August 8 2016

THE DRUG HELPS KEEP THE AIRWAYS FREE FROM INFLAMMATION

“Asthma drug ‘gamechanger’ could revolutionise treatment,” The Guardian reports after a new drug called fevipirant showed promising results in a small study of 61 people with moderate to severe asthma.

Asthma is a lung condition that can cause inflammation of the airways, which can lead to breathing difficulties. While many people can control the condition with existing drugs, a minority of people only have a partial response to treatment, so their quality of life can be adversely affected.

This trial aimed to investigate whether fevipirant reduced airway inflammation in people with moderate to severe asthma associated with raised levels of eosinophils, the particular white blood cell linked to asthma. The 12-week trial compared fevipirant with placebo in 61 adults. The drug was added to any medication they were already taking.

The main outcome was on the percentage of eosinophils in their sputum, which did decrease by a greater amount in the fevipirant group. It also had a beneficial effect on quality of life, but no effect on overall asthma control or symptoms.

(Continues on next page)

(Turn over)

The potential implications of the research were summed up succinctly by Dr Samantha Walker, Director of Research and Policy at Asthma UK, who said: “This research shows massive promise and should be greeted with cautious optimism.” These initial findings are promising, but more studies will be needed to confirm that the drug is safe and has a definite effect on asthma control compared with other treatments.

WHERE DID THE STUDY COME FROM?

The study was carried out by researchers from a variety of institutions, including the University of Leicester and the University of Oxford in the UK, and Novartis in Switzerland. It was jointly funded by the UK National Institute for Health Research, the EU AirPROM project, and Novartis Pharmaceuticals, the Swiss drug company behind fevipiprant. Industry funding is not unusual, but four of the researchers were employed by Novartis. This represents a potential conflict of interest that was clearly stated in the study. The study was published in the peer-reviewed journal, *The Lancet – Respiratory Medicine*.

This study was widely reported on by the press. While the coverage was generally accurate, much of it was arguably overoptimistic. Claims that fevipiprant is a “wonder drug” that could mark “the end of the inhaler” verge on hype. Cautious optimism is probably a better approach.

(Continues on next page)

(Turn over)

WHAT KIND OF RESEARCH WAS THIS?

This randomised controlled trial (RCT) aimed to investigate whether fevipiprant (currently unlicensed in the UK) reduced inflammation in patients with moderate to severe eosinophilic asthma. This is asthma characterised by increased levels of eosinophils – the particular type of white blood cell known to be associated with asthma and allergies. White blood cells are used by the immune system to combat infections.

There are currently 5.4 million individuals receiving asthma treatment in the UK alone, representing a large burden on the NHS. A double-blind placebo-controlled trial like this one is one of the best ways of investigating the safety and effectiveness of a potential new treatment. However, several stages of testing can be needed before we know whether this could lead to a new licensed treatment.

WHAT DID THE RESEARCH INVOLVE?

The trial was carried out at Glenfield Hospital in Leicester in the UK, and involved 61 patients (mean age 50) with persistent moderate to severe asthma and an increased sputum eosinophil count (more than 2%). Individuals with other serious coexisting conditions were excluded.

Between 2012 and 2013, the participants were randomly assigned (1:1) to receive either fevipiprant tablets or a placebo for 12 weeks. Thirty individuals were given fevipiprant (225mg twice a day) and 31 were given the placebo.

(Continues on next page)

(Turn over)

Fevipiprant was added to any medication participants were already taking. The two groups were matched for baseline characteristics.

Patients had a variety of measurements taken at the start of the study, including eosinophil sputum count, scores on the Asthma Control Questionnaire (ACQ) and Asthma Quality of Life Questionnaire (AQLQ), and FEV1, the amount of air that can be forcibly exhaled in the first second of breathing out. Patients were assessed again at weeks 6 and 12.

The main outcome of interest was changes in sputum eosinophil levels between the start and end of treatment. Changes in asthma symptoms and FEV1 were compared, and the safety and tolerability of the drug was also assessed throughout the trial.

WHAT WERE THE BASIC RESULTS?

Fevipiprant gave greater reduction in eosinophil count compared with placebo. In the fevipiprant group, the mean percentage of eosinophils in sputum decreased 4·5 times from 5·4% to 1·1%. It decreased by only 1·3 times in the placebo group from 4·6% to 3·9%.

The difference between groups was statistically significant (3·5 times greater reduction, 95% confidence interval [CI] 1·7 to 7·0). Looking at other outcomes, fevipiprant had no significant effect on asthma symptoms. In the fevipiprant group, the symptom score decreased by a mean 0·18 points (95% CI –0·54 to 0·18) and in the

(Continues on next page)

(Turn over)

placebo group it increased by a mean 0·14 points (95% CI –0·22 to 0·49). This made a non-significant 0·32-point reduction with treatment (95% CI –0·78 to 0·14).

The change in quality of life score on the AQLQ was thought significant. In the fevipirant group, it increased by 0·27 points (95% CI –0·07 to 0·61) between week 0 and week 12, and decreased by 0·33 points (95% CI –0·06 to 0·01) in the placebo group. This was a significant 0·59-point increase with treatment (95% CI 0·16 to 1·03).

Treatment also significantly improved FEV1, with a difference between the groups of a 0·16 litre increase (95% CI 0·03 to 0·30).

Overall, fevipirant had a favourable safety profile – no deaths or serious adverse events were reported in the group.

Three patients in the fevipirant group and four in the placebo group withdrew from the study because of asthma complications, but these were not judged to be related to the study drug.

HOW DID THE RESEARCHERS INTERPRET THE RESULTS?

The researchers concluded that, “Compared with placebo, fevipirant significantly reduced eosinophilic inflammation in the sputum and bronchial submucosa in patients with persistent moderate to severe asthma and sputum eosinophilia. “Fevipirant reduces eosinophilic airway inflammation and is well tolerated in patients.”

(Continues on next page)

(Turn over)

CONCLUSION

This study aimed to investigate whether the new drug fevipiprant reduced inflammation in patients with moderate to severe eosinophilic asthma.

It found the drug had a significant effect on the main outcome being studied – compared with the placebo group, the mean percentage of eosinophils in sputum decreased by a greater percentage in the fevipiprant group.

It also gave improvements in asthma quality of life and FEV1, though the drug didn't have a significant effect on overall asthma control.

Although these findings show potential promise for the future, there are a few points to bear in mind:

- **The trial had a small sample size of 61 patients and only a 12-week testing period. Longer follow-up would be ideal to test whether the drug remained efficient and complication-free in the long-term.**
- **The mean age of participants was 50, and the study did not look at the effects in children or young people aged under 25.**
- **The researchers only compared the drug with placebo and not other active treatment, though people in both groups continued to take their standard asthma treatments.**

(Continues on next page)

(Turn over)

- The main outcome the study was designed to assess was the effect on eosinophil numbers, not asthma symptoms or asthma control. This means it doesn't provide strong evidence at this stage that the treatment wouldn't definitely improve a person's day-to-day symptoms and reduce the risk of asthma attacks.

Dr Samantha Walker, Director of Research and Policy at Asthma UK commented: “More research is needed and we’re a long way off seeing a pill for asthma being made available over the pharmacy counter, but it’s an exciting development and one which, in the long term, could offer a real alternative to current treatments.” She also noted that this finding should be “greeted with cautious optimism”.

Analysis by Bazian. Edited by NHS Choices. Follow NHS Choices on Twitter. Join the Healthy Evidence forum.

(Continues on next page)

LINKS TO THE HEADLINES

Asthma drug ‘gamechanger’ could revolutionise treatment. The Guardian, August 6 2016

Asthma pill ‘promising’ for people with severe symptoms. BBC News, August 6 2016

Could this be the end of the inhaler? ‘Game-changing’ pill for asthma can cut lung inflammation by 80 per cent. Mail Online, August 5 2016

Asthma pill could prove ‘game-changer’ for people with severe symptoms. The Independent, August 6 2016

Scientists Hail ‘Exciting’ New Asthma Drug. Sky News, August 6 2016

First new asthma pill in 20 years hailed as ‘wonder drug’ by sufferers. The Telegraph, August 5 2016

Scientists welcome ‘gamechanging’ asthma drug. ITV News, August 6 2016

LINKS TO THE SCIENCE

Gonem S, Berair R, Singapuri A, et al. Fevipiprant, a prostaglandin D2 receptor 2 antagonist, in patients with persistent eosinophilic asthma: a single-centre, randomised, double-blind, parallel-group, placebo-controlled trial. The Lancet – Respiratory Medicine. Published online August 5 2016

(Article 2 begins on next page)

ARTICLE 2: SOCIAL CARE RESEARCH

IMPROVING EFFECTIVE INTEGRATED HOME SUPPORT FOR PEOPLE WITH DEMENTIA AND THEIR CARERS

KEY POINTS FROM THE RESEARCH

A robust Fidelity Index tool and associated Service Template developed to assess the quality of home care for people with dementia had generally been seen by services as useful as a means of self-assessment, focusing attention on how services might be improved, in a setting where providing good service is evidently most difficult, which in turn makes engagement of services with research very challenging.

While homecare is an important Government priority, services appeared to operate within significant ‘structural’ constraints, deriving from partnership issues and commissioning policies and practices, that appear to mitigate the application of many of the best practice standards set out in the Service Template. This includes disincentives for staff remaining in-post and developing in their role, as the result of a ‘market place’, based upon generally poor pay and conditions, and commissioning practices that can impact on the delivery of person-centred care.

A significant finding of the research, and one that would benefit from further, more detailed work, is the area of partnership working, or collaboration, between home care services and their NHS colleagues. This was a recurrent theme in interviews with service managers, and during conferences designed to explore the Service Template in more detail. While everyone would agree that good

(Continues on next page)

(Turn over)

communication and cooperation between the different providers of health and social care are important, there would appear to be cultural and structural impediments to its realisation, that suggest the need for further research.

Proper resourcing of services is essential and seeking more evidence, to weigh the relative importance of the key ingredients of good services and how they may best be combined, is crucial. The project team have continued to work to seek more such evidence and to 'validate' the Service Template, particularly with carers and those using the services.

BACKGROUND

This project aimed to create and test an evidence-based tool designed to allow services to critically self-assess the application of good practice standards in good home care for people with dementia (PWD).

The first stage of the project was to map from the literature the key ingredients, or enablers, that facilitate good care. The themes arising from this were then used, to develop an evidence-based 'Service Template' (shown in Table 1 on pages 12–13), listing items regarded as central to the delivery of good services. This process suggested that a 'good' service is commissioned to be person-centred, rather than service-centred, is effectively planned and coordinated with other services, delivered consistently by sufficient numbers of well trained and supported staff, who are empowered to work in a flexible and responsive way, and which involves the principal carer.

(Article continues on page 14)

TABLE 1. THE SERVICE TEMPLATE

Theme	Elements of practice
1 Commissioning	Person-centred / outcome-based commissioning that focuses on the client, as opposed to the level of service, is deemed appropriate.
2 Integration, coordination and care management	‘Joined-up care’, i.e. activities between multiple stakeholders should be effectively coordinated.
3 Person- and relationship-centred care	The person with dementia and their carer are the explicit focus of the process, achieved by involving them and valuing their opinion.
4 Continuity of care	Allocation of the same care worker(s) to the client in order to build trusting relationships. The service should have sufficient numbers of staff to facilitate this.
5 Support for carers	Carers are integral to the support process and should therefore be considered as partners and service users in their own right.
6 Care planning	Effective, appropriate and realistic written plans of care that focus on the client’s / carer’s biography, reflect choice and promote (safe) independence. Plans should be accurate, fit for purpose and used as a tool for information, communication and monitoring.

7 Training	Staff working with PWD should have access to suitable dementia-care training and skill development appropriate to their role and responsibilities.
8 Support for staff	Staff should have access to a manager / supervisor who will assess and meet their training needs, monitor their performance and support them in their duties.
9 Flexible and responsive services	Flexibility of response – care available according to the needs of the client and their carer. Staff have the necessary time and flexibility to meet the needs of clients and carers.
10 Organisational factors	Provider facilitates person-centred care services via clear organisational (dementia oriented) policies. Procedures that reflect the elements of effective communication and person-centred care. Processes that facilitate cooperation and coordination of activities with care managers and other service providers. Adequate systems, resources, staff training and supervision. A culture that engages in audit and service improvement, including evidence that complaints are acted upon.

(Article continues on next page)

FIDELITY INDEX SELF-ASSESSMENT

The second stage of the project involved translating the Service Template into a series of interlinked self-assessment questions (a Fidelity Index), and then testing the usefulness of this tool with 32 managers of homecare for people with dementia from the public, private and voluntary sectors. The tool comprised 42 questions, each scored on a five-point (Never, Seldom, Half the Time, Usually, Always) scale. Service managers were also asked to distribute a questionnaire to key stakeholders (carers, staff and professionals), containing equivalent questions to those used in the Fidelity Index, for later comparison.

RESEARCH FINDINGS

For simplicity, we have chosen ten representative questions, linked directly to the Service Template, and showed the percentage of services answering 'Always' or 'Usually' to the ten questions and the percentage of care workers and principal carers 'Agreeing' or 'Strongly agreeing' to a similar range of questions (Table 2 on pages 15–16). From this, it appeared that those managing services provided positive responses to most questions within the Fidelity Index, i.e. they had generally indicated that a particular area of good practice 'Usually' or 'Always' happened within their service. The most noticeable exception related to the flexibility of the service, where under half indicated that their care workers would 'Always' or 'Usually' be able to use their time with the

(Article continues on page 17)

(Turn over)

TABLE 2. REPRESENTATIVE FIDELITY INDEX QUESTIONS MATCHED TO SERVICE TEMPLATE

Answers: ‘Always’ or ‘Usually’ and ‘Agree’ or ‘Strongly agree’

Service Template	Question area	Manager (n = 32)	Care worker (n = 21)	Principal carer (n = 17)
1 Commissioning	Can change the way that the service is provided or organised.	81·3%	85·7%	64·7%
2 Coordination and Care Management	Services for the client (e.g. district or nurses) are effectively coordinated.	81·3%	52·4%	35·30%
3 Person-centred care	Service takes into account the client’s unique background and circumstances.	81·3%	100%	58·80%
4 Continuity of care	Allocation of same care workers for most visits.	90·7%	95·2%	35·2%

(Table 2 continues on next page)

(Turn over)

5 Support for the principal carer	Talking to the principal carer about their care and support needs.	84·4%	85·8%	23·5%
6 Care planning	The client has a written care plan that care workers follow.	65·6%	66·6%	52·9%
7 Training	Care workers are knowledgeable about the care needs of PWD.	93·8%	76·2%	41·2%
8 Support for staff	Workers have access to support from their managers when they need it.	96·9%	76·2%	58·8%
9 Flexible and responsive services	Time allocated to the client can be used flexibly and as needed.	46·9%	80·9%	58·8%
10 Organisational factors	The service's written policies and procedures are dementia friendly.	78·2%	76·2%	No equivalent question

(Article continues on next page)

(Turn over)

client flexibly. A similar pattern of positive responses emerged from care workers; with the exception of 'coordination and care management' (52% 'Agreeing' or 'Strongly agreeing' that services are effectively coordinated). A possible explanation for this arose in the interviews with service managers, who suggested that the relationship between home care providers and some (district) nursing staff was not always good, leading to occasional operational issues for staff, such as being delayed between calls. Although only small numbers, positive responses from principal carers' were generally much lower across the range of questions, dipping to around 23% 'Agreeing' or 'Strongly agreeing' that someone from the service talked to them about their care needs. One independent sector manager explained that it was difficult to 'support' the principal carer, when the local authority was paying for a discrete client-focussed service.

INTERVIEWS WITH SERVICE MANAGERS

Semi-structured interviews were conducted with service managers to understand how they had used the Fidelity Index tool, and the context within which it had been completed. It was evident that the service managers worked pragmatically and extremely hard to ensure the best possible service and outcomes for their clients. This often included a lot of (unpaid) networking with different stakeholders and occasionally, due to local need, delivering care to their clients in person. The principal message was that managing homecare can be complex and challenging: "Unless you work in the business, you

(Continues on next page)

(Turn over)

don't understand the constraints, the financial constraints, the regulations we have to work by. It's hard work, you are swimming in treacle, basically" (manager, medium size private sector organisation).

A significant finding suggested that different health and social care providers do not operate in a 'joinedup' manner, for example, there were several references to poor relationships between home care and district nursing staff: "We find a lot of aggression from the NHS, not so much from the NHS as a Trust, but from the district nurses... They really, really don't like us for some reason..." (private sector provider). Of equal significance and consistency were issues of communication and collaboration when clients required in-patient care: "They're sending them home [from hospital] and then assuming that we will be going, but we don't even know that they've gone home" (large private sector provider). These factors placed additional pressures upon clients and stakeholders, leading to inefficient and possibly unsafe service delivery.

Structural factors, over which the service could exercise little control, were consistent themes of the interviews, for example, the manager's ability to recruit and retain a suitable workforce: "I take on eight care workers and lose four – each month". This meant that agencies: "are always recruiting, because we never have enough carers" (large private sector provider). Some attributed such problems to salary, where pay levels may be fixed for years by tendering
(Continues on next page)

arrangements: “The poor pay...is the one thing that underlies all of our difficulties” (large private sector provider). Tendering arrangements and ‘minute-by-minute commissioning’ tended to fix the price for care – in turn dictating the staffing and remuneration structure of the service, and the level of choice available to the client. “It’s all paid for by the electronic monitoring, so it’s not a case of them actually choosing the kind of care, but with our private service users, we tailor the package to them” (medium size private sector provider); “We seem to get a lot of 15 minute calls now. By the time the carer has logged in, taken their coat off, you haven’t got a lot of time left have you – and then when you’ve done what you’ve got to do, you have all of the notes to write...” (private sector provider).

CONCLUSIONS AND FUTURE RESEARCH

The findings appear to comprise two distinct themes:

- (i) the generally positive messages regarding the Fidelity Index tool, its utility and application, juxtaposed with feedback from the stakeholder’s equivalent questions; and
- (ii) contextual data, from the semi-structured interviews, suggesting a sector under significant pressure.

It was interesting that the care workers’ assessments of the service were closely aligned with those of the service managers. However, assessments by the principal carers were consistently lower across the range of themes. This might suggest a disconnection between the providers’

(Continues on next page)

(Turn over)

perspectives on their services and the actual experience of this key group. One of the Care Quality Commission's outcome measures is how providers assess and monitor the quality of services they deliver. A potentially useful aspect of the Fidelity Index tool was the use of these equivalent stakeholder questionnaires, with the theoretical potential to allow services to compare the manager's perception of the service with those of key stakeholders.

ABOUT THE STUDY

The study was conducted between November 2010 and May 2013 by researchers at the University of Nottingham. For further information contact Professor Rob Jones, University of Nottingham, Rob.jones@nottingham.ac.uk.

ACKNOWLEDGEMENTS:

Jones, R., et al. (2014) Improving effective integrated home support for people with dementia and their carers, London: NIHR School for Social Care Research.

NHS Choices (2016) New drug for severe asthma shows massive promise, NHS.

Every effort has been made to contact copyright holders to obtain their permission for the use of copyright material. Pearson Education Ltd. will, if notified, be happy to rectify any errors or omissions and include any such rectifications in future editions.