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NIHR CLAHRC West Midlands News Blog

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Welcome to the latest issue of your NIHR CLAHRC West Midlands News Blog.

In the latest issue of our News Blog we argue that caution should be exercised when synthesising evidence for policy. We take a look at papers on changing views on addiction; moving to patient-controlled electronic records; a review of operations research; more on the risk of medico-legal claims; and using immunotherapy to treat multiple sclerosis.

Further, we bring you the latest news; profile Lee Gunn; highlight upcoming events; feature some recent Tweets; and have our CLAHRC WM Quiz. Finally, we list some of our latest publications.

We hope that you find these posts of interest, and we welcome any comments. You can find previous issues of our News Blog here.

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Director's Blog

Caution should be Exercised when Synthesising Evidence for Policy

Policy should be formulated from all the available evidence. For this reason systematic reviews and meta-analyses are undertaken. However, they are often not conclusive. Indeed, there have been notable articles published in the *BMJ* over the last two years which are critical of the evidence or conclusions of reviews that have been conducted to inform important contemporary public health decisions.

A key theme that often emerges from articles critical of reviews is that only evidence from randomised controlled trials (RCTs) is strong enough to support policy decisions. For example, Teicholz [1] claimed that a number of important RCTs were ignored by a recent report explaining changes in dietary guidance in the US. This claim has since been refuted by a large number of prominent researchers.[2] Kmietowicz [3] argued that there were flaws in a meta-analysis of observational patient data that supported the stockpiling of anti-flu medication for pandemic influenza, casting doubt on the decision to stockpile. An upcoming analysis of clinical trial data was instead alluded to, despite these trials only examining seasonal flu. Recently, McKee and Capewell,[4] and later Gornall,[5] criticised the evidence underpinning a comprehensive review from Public Health England [6] on the relative harms of e-cigarettes. They noted that it “included only two randomised controlled trials” and that there were methodological weaknesses and potential conflicts of interest in the other available evidence. McKee and Capewell make the claim that “the burden of proof that it is not harmful falls on those taking an action.” However, this is illogical because any policy choice, even doing nothing, can be considered an action and can cause harm. This claim therefore merely translates to saying that the policy chosen should be that best supported by the evidence of its overall effects.

Public health decisions should be made on the basis of *all* the currently available evidence. What then are reasons one might write off a piece of evidence entirely? One might object to the conclusions reached from the evidence on an ideological basis, or one might view the evidence as useless. In the latter case, this opinion could be reached by taking a rigid interpretation of the ‘hierarchy of evidence’. RCTs may be the only way of knowing *for sure* what the effects are, but this is not tantamount to concluding that other evidence should be rejected. RCTs are often, correctly in our view, regarded as an antidote to ideology. However, it is important

not to let matters get out of hand so that RCTs themselves become the ideology.

In a recent paper, Walach and Loef,[7] argue that the hierarchy of evidence model, which places RCTs at the top of a hierarchy of study designs, is based on false assumptions. They argue that this model only represents degrees of internal validity. They go on to argue that as internal validity increases, external validity decreases. We don't strictly agree: there is no necessary decoupling between internal and external validity. However we do agree that in many cases, by virtue of the study designs, RCTs may provide greater internal validity and other designs greater external validity. Then how could we know, in the case of a discrepancy between RCTs and observational studies, which results to rely on? The answer is that one would have to look *outside* the studies and piece together a story, i.e. a theory, and not ignore the observational evidence as recognised by Bradford-Hill's famous criteria.

The case of chorion villous sampling, a test to detect foetal genetic abnormalities, serves as a good example of how different forms of evidence can provide different insights and be synthesised. Observational studies found evidence that chorion villous sampling increased the risk of transverse limb deformities, which was not detected in any of the RCTs at the time. To make sense of the evidence and to understand whether the findings from the observational evidence were a result of random variation in the population or perhaps poor study design, knowledge of developmental biology, teratology, and epidemiology were required. It turned out that the level of the transverse abnormality – fingers, hands, forearm, or upper arm – corresponded to the embryonic age at which the sampling was conducted and also to the development of the limb at that point. This finding enabled a cause and effect conclusion to be drawn that explained all the evidence and resulted in recommendations for safer practice.[8] [9]

Knowledge gained from the scientific process can inform us of the possible consequences of different policy choices. The desirability of these actions or their consequences can be then assessed in a normative or political framework. The challenge for the scientist is the understanding and synthesising of the available evidence independently of their ideological stance. There often remains great uncertainty about the consequences of different policies. In some cases, such as with electronic cigarettes, there may be reason to maintain the current policy if, by doing so, the likelihood of collecting further and better evidence is enhanced. However, in other cases, like stockpiling for pandemic influenza, such evidence depends on there being a pandemic and by then it is too late. Accepting only RCT evidence or adopting an ideological stance in reporting may distort what is reported to both key policy decision makers and individuals wishing to make an informed choice. It may even be potentially harmful.

-- Richard Lilford, CLAHRC WM Director

-- Sam Watson, Research Fellow

Leave a comment

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CLAHRC WM Quiz

Which parasitic disease is able to avoid the host's immune system through the parasite rearranging its own DNA?

Email CLAHRC WM your answer.

Answer to our previous quiz: The Zika virus is named after the **Zika Forest of Uganda** where the virus was first isolated from a rhesus macaque monkey. Zika means 'overgrown' in the local dialect.

Congratulations to Sam Watson, Alan B. Cohen, Barry Clarke and Jonathan Reinarz who were first to answer correctly.

Many thanks to Jonathan Reinarz for sending this classic paper from 1952: Dick GW, et al. Zika virus. I. Isolations and serological specificity. *Trans R Soc Trop Med Hyg* 1952;**46**:509–20.

Director's Choice - From the Journals

Addiction as a Brain Disease

News Blog readers know that the CLAHRC WM Director is a completely unapologetic advocate of Enlightenment values. Sciences does not just provide information *about* nature. It also changes our world view *of* nature. Since we humans are part of nature, it has the potential to change how we think about ourselves. A natural, but untutored, view of addiction is that it is a moral failure – a lack of personal responsibility leading to voluntary indulgence in hedonistic pursuits. However, addiction is a neuro-physiological condition with an organic basis – just like other psychological phenomena.[1] The clue was always there – the condition affects some people but not others, and applies to behaviours such as video-gaming, not just toxic substances. Activation of specific neurobiological circuits is associated with:

1. Intoxication
2. Withdrawal
3. Craving.

Intoxication leads to a learned response so that, over time, dopamine cells start firing, not in association with the reward, but in *anticipation* of it – the classical mechanism in learning. The CLAHRC WM Director does not think of alcohol until dinner-time. The dinner is activating his dopaminergic neurons and creating craving. Fortunately, they stop firing when he has a glass of wine so he can stop drinking (most days). But a person predisposed to addiction would not experience satiation. Worse, dopaminergic responses to the stimulus attenuate over time so that more of the agent is required to produce the same gain. Worse still, dopaminergic responses to other (non-addictive) positive stimuli – say from getting a paper published in a high-ranking journal – are also attenuated. So the addicted person enters a downward spiral. Compensatory down-regulation of dopamine signalling elsewhere in the brain leads to dysphoria (depression) and a drop in motivation. An afflicted person's life thus descends into further chaos.

Why are some people more susceptible than others? Here are risks:

1. Genetic predisposition; a number of specific genetic polymorphisms predisposing to addiction have been found.
2. Early exposure – the adolescent years especially, as this is a time of high neuroplasticity.
3. Poor familial and social support.
4. Restricted alternatives – sport should be encouraged.

This deeper knowledge of the molecular and neuro-anatomical basis of addiction is leading, not just to new pharmacological and neuro-biological treatments, but a profound change in social attitudes. This is manifest in, for example, more lenient sentencing for non-violent offences perpetrated by people with addictions. Science is a civilising process that does not just inform how to reach an objective, but also colours our choice of objectives.

-- Richard Lilford, CLAHRC WM Director

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Reference

If the Electronic Notes Belong to the Patient,
then Health Care Providers Can Update Them

As an Obstetrician (alright, ex-Obstetrician), the CLAHRC WM Director is familiar with the patient acting as custodian of her medical notes. Maternity care has used a patient-based paper note system for four decades. Now Rupert Fawdry has suggested a patient-based booklet, WISDAM, for all health care needs (as mentioned in a previous blog). But Mandl and Kohane think we can move to a patient-controlled electronic record,[1] which various health care providers would top

up as necessary from their electronic systems, using information formats compliant with inter-operability standards. The record would also be topped up with the patient's data from any study in which they have participated. Patients would record their own thoughts. Data from all sorts of physiological recording devices would be streamed into the electronic record. The electronic note would accumulate data anamnestically over a life-time and, of course, it would include the owner's full gene sequence. Presumably dental records, social work reports, community nurse reports, etc. would all go into the cloud-based archive. Some record this! How quickly we can move to such a record, whether we should use a paper-based patient-held booklet in the meantime, and how to stop the whole thing becoming an impersonal monster that will drive everyone mad – these are big problems to solve.

-- Richard Lilford, CLAHRC WM Director

Leave a comment

Reference

From the South-West Peninsula and Wessex CLAHRCs

A nice review of operations research (systems modelling and *in silico* simulation) uses access to thrombolysis for stroke as its example.[1] They identified where the snarl ups arose (e.g. the ambulance needs to radio ahead) and predicted that they could improve thrombolysis rates from about 5% to 15% of strokes. By Jupiter that is what they achieved! The article contains a nice review of OR methods.

-- Richard Lilford, CLAHRC WM Director

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Reference

More on Risk of Medicolegal Claims

Everyone knows that neurosurgery, orthopaedic surgery and plastic surgery are the specialities with the highest risk of medicolegal claims, with obstetrics and gynaecology hot on their heels. Psychiatry and paediatrics have the lowest risks. Also well known is the lower risk for female than male doctors (though this might be an artefact of number of patients cared for, as women see less patients per week on average than men). A recent study [1] went further and examined how risk changes according to number of previous cases of litigation claims. The answer: after controlling for age, speciality and sex, the risk rises with increasing number of previous claims. As with drivers, previous record is a good index of future risk. The CLAHRC WM Director believes that psychological testing cannot identify this risk, but welcomes comments. Interestingly, the increased risk with multiple previous cases of successful litigation diminishes gradually as time passes. Maybe the high-risk practitioners gradually improve their performance or restrict their range of practice.

-- Richard Lilford, CLAHRC WM Director

Leave a comment

Reference

Immunotherapies for Multiple Sclerosis

Tramacere and colleagues boldly conducted a network meta-analysis of no less than 39 individual RCTs of immunotherapy for Multiple Sclerosis.[1] The treatments as a class both prevent deterioration (measured by EDSS [Expanded Disability Status Scale] score) *and* reduce the frequency of relapses. Some of the medicines within the class appear significantly better than others. But the trials are of only moderate quality on the GRADE score, and the follow-up is limited, mostly to two years. The really important data will come with the ten year follow-up results from the English Risk-Sharing Scheme, which is due to report imminently.

-- Richard Lilford, CLAHRC WM Director

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News

Early Intervention in Youth Mental Health is Key to Improving the Lives of Young People

CLAHRC WM are hosting an event on Tuesday 7 June 2016 around youth mental health. It will be an opportunity to share views on youth mental health and how services may be improved, as well as getting the latest information about the on-going transformation of youth mental health services in Birmingham and West Midlands. There will be live entertainment, guest speaker Rt Hon Norman Lamb, and ample opportunities to network with people passionate about youth mental health.

For more information, and to book a free ticket, please visit: https://shoutoutfymh.eventbrite.co.uk

Or for enquiries email: shoutoutfymh@warwick.ac.uk

CLAHRC WM Co-Director's Inaugural Lecture

Prof Tom Marshall, CLAHRC WM Co-Director, will be giving his inaugural lecture on Wednesday 2 March, 16:30-17:30, at the Leonard Deacon Lecture Theatre, University of Birmingham – '*The Knowable and the Unknowable: Reflections on Health Services Research*'.

A fundamental difference exists between clinical practice and science. Clinicians diagnose, make prognosis and decide on treatment, generating apparent certainty from uncertain symptoms and situations. But science is driven by doubt. In this lecture, Professor Marshall will explore some of the paradoxes of knowledge and its absence in relation to his own research.

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Personality of the Issue

Lee Gunn

Lee Gunn is a Research Fellow in Patient and Public Involvement (PPI) with CLAHRC WM Theme 5, Implementation and Organisational Studies, as part of a job shared post with Alison Hipwell, who was profiled in the blog a few months ago. She studied sociology before learning from a wide variety of jobs, including youth work, writing, program management and usability engineering. Then, after a few years teaching communication design to undergraduates at Coventry University, she decided to become a student again herself. She gained a masters degree in social research methods, and followed this with a series of funded research studies in the health service, based mostly on interviews and focus groups with patients, family carers, and health professionals.

Lee enjoys finding out about people's experiences and their different kinds of expertise. She hopes that collaborative research can improve mutual understanding and, eventually, help to alleviate distress. She is a member of the Royal College of Nursing Research Institute (RCNRI), and her current post is jointly managed by Sophie Staniszewska of the RCNRI and by Graeme Currie of Warwick Business School. Over the last year, Lee has been investigating the conceptualisation of patient and public involvement in the implementation of evidence. She is also preparing a study of parents' and carers' involvement in young people's mental health services, in collaboration with Theme 2 of CLAHRC WM and with PPI advisors.

Lee reads voraciously, visits the north east coast whenever she can, and tries to make time for both academic and creative writing.

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Selected Replies

Re: How Many Doctors Do We Really Need?

Interesting article, and I tend to agree with the premise that we probably do not need more doctors, and there is a large amount of care (procedures, notably) that could probably be provided by appropriately trained practitioners, but I do disagree with some of our points.

In particular, back pain in primary care is a hard problem: it's very common, very likely benign, and has a few serious causes. The only investigation of significant worth is MRI (which numerous studies have shown has a high FP rate and is often abnormal in asymptomatic patients), a high cost investigation.

'Red flag' features unfortunately don't work (link). Algorithmic management of problems like pain doesn't work particularly well, because it's just too common and the history and examination findings too broad. The same holds true for many common problems - the sensitivity and specificity of the protocols are not good

enough.

The other key problem is multi-morbidity. There's a neat paper in the BMJ i'm sure you've seen (link) that shows that guidelines for common, often co-existing, conditions often interact. Guideline or algorithmic management for these patients, particularly in primary care is difficult. Should I stop the beta blocker as there is some evidence of airways obstructive disease? (probably not). Those are the decisions that are hard, and require complex thinking and high level doctor skills. I particularly like this example: (link)

Primary care has both the most amount of low risk, simple patients that are ideal to be managed without complex management, but also has a large number of complex, multi-morbid, vague patients - and you don't know which one you're going to see!

I do agree that a huge number of technical hospital work could be replaced, especially in elective surgery, but I certainly think that primary care (and probably internal medicine/hospitalism) is the place I want the high level care and skills.

-- Gus Hamilton

Thank you CLAHRC WM team for another entertaining blog. Really enjoyed reading the article on "HOW MANY DOCTORS DO WE REALLY NEED?". I think that medicine can take inspiration (again) from aviation, where the pilots only need to take over from the auto-landing system during landing in extreme weather conditions. Routine procedures can be conducted by an on-board computer.

Thank you to Tom Marshall for providing insight around national screening programmes. I think even a lay person would recognise the national diabetes prevention programme as public screening. Why can't policy makers? If you are going to expense of funding and effort of setting up a public health intervention, it needs every chance of being successful in its primary objective.

I look forward to the next blog.

-- Max Feltham

I should like to bring the ideas from two different areas where I have some experience.

1. It is not true that pilots use autolanding routinely. Even on the modern aircraft they do it mostly 'by hands', and employ the auto-landing only in special circumstances (very low visibility). I believe that if to learn from aviation, doctors may be relaxed: while many specific task are shown may be done by 'technicians' successfully, the whole system of care (including the patient as a subsystem) is so complicated that doctor is needed. And will be needed for a long time.

2. There are not only countries who want more doctors and who want less doctors. There are some, like Russia, where there are plenty of Drs in the big cities, and Drs are almost not available in the desert areas. It is impossible to arrange the medical care provided by Drs, if you have the population density like 2 people per square kilometer. USSR did try to arrange the care for such

areas by nurses, trained for independent practice. But even this model failed (my opinion) because of the same problem - long distances, rare population. Now, in 21st century Russia is develping the model of care provision for sparcely populated areas by lay care providers.

-- Vasiliy Vlassov

Re: Screening That Dare Not Speak its Name

Emphasis has been put on obesity but as became clear at the recent conference in Solihull this is not the only symptom for diabetes risk. Stress may be another. For some years now I have been I point below the risk level for diabetes and the cut-off would seem to be rather arbitrary. I have recently brought this up with my doctor and the only solution would seem to be for a blood test, though I appreciate it is far too cumbersome to do this for the whole population, which appears ultimately to be what is being asked for here.

-- Duncan Purslow

It is screening, and the screening doesn't work. The best evaluated programme was DESMOND from Leicester. A negative trial, spun by the authors using secondary outcomes and wishful thinking as a positive one. And no-one called them out. Keep up this battle.

-- Jim Thornton

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Events

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23 Feb 2016
Patients Bereaved by Suicide (PABBS) Workshop
Britannia Stadium, Stoke-on-Trent

The West Midlands AHSN Person-Centred Care Theme are hosting a one-day workshop to offer health professionals an opportunity to build their confidence and skills in caring for those bereaved by suicide.

For more information, please click here. To book a place please contact Emily Brayford on e.c.brayford@keele.ac.uk

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24 Feb 2016
ePrescribing: Looking to the Future
Royal College of General Practitioners, London

The Centre for Research on Families and Relationships (CRFR) are holding an event on ePrescribing, from implementation and adoption to organisational transformation

and patient benefits, which will look forward from 5 years of ePrescribing research. There will be discussions focussing on lessons learned and implications for the NHS, and maximising benefits and realising returns on investment through technologies. International experts include Prof David Bates (Harvard Medical School), and Prof Denis Protti (University of Victoria).

For more information, and to book a place, please click here.

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01 March 2016, 17:00-18:00
Evaluating Integration: Unlocking the Mysteries
University of Birmingham

Whilst integrated care is a priority of health and care systems across the UK and internationally, our understanding of how to best achieve integrated care in different contexts and for particular populations is far from perfect. One of the reasons behind this patchy evidence base is the complexity of researching such a wide variety of mechanisms and expected outcomes within different organisational and professional settings.

In this research seminar international expert Professor Bert Vrijhoef will share his experience of undertaking such research – the methods that work and the pitfalls to avoid.

For more details, please visit the HSMC website. If you are planning to attend, please email e.balandyte@bham.ac.uk.

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01 March 2016, 15:30-19:00
WMAHSN Meridian Launch event
The Vox Conference Centre, Birmingham

The West Midlands Academic Health Science Network (WMAHSN) are holding an event to officially launch Meridan, their online health innovation exchange. It has been specifically designed to support the West Midlands' innovation ecosystem by providing industry with an opportunity to showcase their innovations and performance-enhancing products, services and technology. This platform also facilitates the NHS and academia to formulate campaigns which address service delivery and medical challenges that require creative and innovative solutions via collaborative development with industry.

For more details, and to book a place, click here.

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06 April 2016
CAT in a Day
Primary Care Sciences Building, Keele University

Health Professionals working with patients with musculo-skeletal disease are invited to attend a CAT in a day workshop - '*Your Clinical Question Answered in a Day*' - at Keele University. The workshop will be focused around exercise and is free to attend, but places are limited. To secure a place, please contact Emily Brayford on e.c.brayford@keele.ac.uk by 31 March 2016.

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Fortnight's Publications

Farre A, Cummins C. Understanding and evaluating the effects of implementing an electronic paediatric prescribing system on care provision and hospital work in paediatric hospital ward settings: a qualitatively driven mixed-method study protocol. *BMJ Open*. 2016; **6**: e010444.

Jones E, Taylor B, MacArthur C, Pritchett R, Cummins C. The effect of early postnatal discharge from hospital for women and infants: a systematic review protocol. *BMC System Rev*. 2016; **5**: 24.

Lamont T, Barber N, de Pury J, Fulop N, Garfield-Birkbeck S, Lilford R, Mear L, Raine R, Fitzpatrick R. New approaches to evaluating complex health and care systems. *BMJ*. 2016; **352**: i154.

Oyebode O, Oti S, Chen Y, Lilford RJ. Salt intakes in sub-Saharan Africa: a systematic review and meta-regression. *Popul Health Metr*. 2016; **14**: 1.

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Tweets

Public satisfaction with the NHS in 2015 fell to 60%. Dissatisfaction rose to 23%. More [online]
-- @TheKingsFund, 9 Feb 2016

NHS Mental Health Apps Library; directory of #NHS endorsed digital #mentalhealth services. Have you seen this yet? http://ow.ly/XZB3u
-- @NHS England, 6 Feb 2016

@CLAHRC_WM applications are open for the NIHR Infrastructure Doctoral Training Exchange Scheme [link]

-- @NIHR_Trainees, 5 Feb 2016

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