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Pragmatic randomised controlled trials of professional behaviour change interventions: how far can you go?

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Credits

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Implementation Research

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- "Implementation research is the scientific study of methods to promote the systematic uptake of clinical research findings and other evidence-based practices into routine practice, and hence to improve the quality (effectiveness, reliability, safety, appropriateness, equity, efficiency) of health care. It includes the study of influences on healthcare professional and organisational behaviour."
  - (adapted from Implementation Science http://www.implementationscience.com/info/about/ accessed 10/03/08).

Implementation Research

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- Implementation research centrally involves the study of changing behaviour and maintaining changed behaviours
  - of and in organizations and the groups and individual healthcare professionals within them
- It concerns:
  - The study of behaviour
  - The determinants of behaviour
  - How to change and maintain behaviour
- All with due cognisance of the organisational context within which behaviours are enacted

Why is Implementation Research important?

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- There are important gaps in applying clinical evidence in routine healthcare
- Healthcare professionals and organisations are unlikely to innovate systematically and reliably
- The health gains from successful implementation can exceed those of enhancing current technologies

Implementation Research – a sizeable evidence base but …

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- Over the past 15-20 years a body of implementation research has developed
  - Cochrane Effective Practice and Organisation of Care Review Group
  - Interventions can be effective
  - The effects are “worth having”
    - Effectiveness of interventions varies across different clinical problems, contexts and organizations

More informative trials

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- Beyond 2 arm intervention v control
  - Multi arm trials to explore different levels of intervention
  - Factorial designs to explore synergistic effects of interventions
- Pragmatic trials with broad inclusion criteria
  - Allowing exploration of whether variations in subjects modifies effects
  - Allowing exploration of whether variations in method of delivery modifies effects

More informative trials

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- Trials with replicated interventions across different behaviours
- Process evaluations
  - Intervention fidelity (as delivered)
  - Intervention uptake (as received)
  - Causal mechanisms
  - Mediators and moderators
  - Unintended consequences
- Temporal evaluations

- Scale of ambition
- Programmes of trials

COGENT: 2x2 balanced incomplete block cluster RCT

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- Objectives
  - To develop guidelines; interactive computerised prompts
  - To measure process and outcome of care before and after the implementation; to perform an economic evaluation
- Power
  - 80% power to detect 10% change in adherence, 5% sig
  - powered as two RCT's
- 203 practices using AAH Meditel and EMIS in the former Northern Region
  - need to recruit 60 practices
    - pattern of computer use; size
    - 60 patients/condition/practice

COGENT: 2x2 balanced incomplete block cluster RCT

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	Angina	Asthma
Group A	*Intervention*	*Control*
Group B	*Control*	*Intervention*

- Equalises Hawthorne Effects
- Two trials for the price of one

Results

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- No effect of CDSS on consultation patterns
- No effect of CDSS on drug prescribing
- No effect of CDSS on other aspects of process of care
- No effect of CDSS on patient outcomes

- Why? What happened?

Temporal analysis - COGENT

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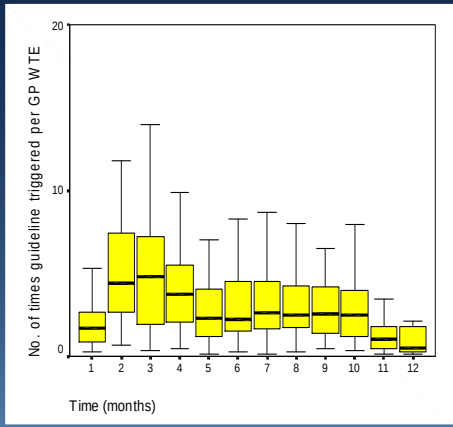
- Number of times guideline triggered per whole time equivalent GP by month



Process evaluation - COGENT

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- Nested case study – 6 family practices receiving intervention
- 19 semi structured interviews with 13 key informants
- Interviewees were largely enthusiastic and optimistic about the benefits of computing BUT…
  - System was felt by most general practitioners to be difficult to use and unhelpful clinically
  - System did not activate at an appropriate time within the general practice consultation

NEXUS: a pragmatic 2x2 factorial cluster RCT

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- Evaluated effects of
  - Audit and Feedback on GPs' x-ray referral patterns
  - Brief educational messages appended to x-ray reports
- Lumbar spine and knee x-rays
- 240 general practices, NE England and NE Scotland
- Intervention delivered by 6 radiology departments (teaching and non-teaching hospitals)
  - Intervention embedded into routine reporting systems in 4 departments, stickers manually placed in 2 departments

Audit and feedback

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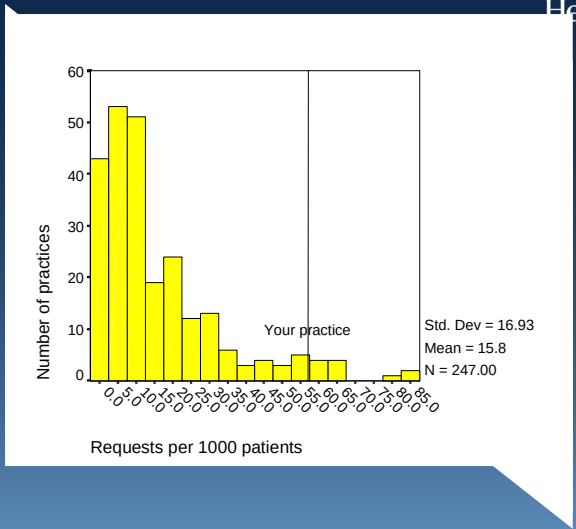

Requests for knee x-rays

Second intervention

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- NE**X**US EDUCATIONAL MESSAGE
  - In either acute (less than 6 weeks) or chronic back pain, without adverse features, x-ray is not routinely indicated
  - In adults with knee pain, without significant locking or restriction in movement, x-ray is not routinely indicated

Results

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- Over the 12 months of the intervention period
  - – Audit & Feedback
    - No effect
  - – Brief educational messages
    - 20-30% relative reduction in x-ray requests
    - No difference in effects across condition, radiology departments in different settings or by method of delivery
- When did this happen? Was it sustained

Temporal analyses - NEXUS

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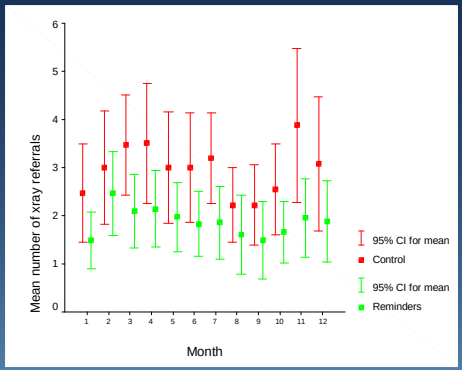
- The effect of educational reminder messages was produced as soon as the intervention was delivered and maintained throughout the intervention period
- There was no evidence of the effect of the intervention wearing off

Mean number of knee x-rays by month



DRAM : 2 x 2 factorial cluster RCT

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- Evaluated effects of
  - Audit and feedback on GPs' lab test ordering
  - Brief educational messages
- 9 biochemistry, haematology and immunology tests
- 85 primary care practices (350 GPs) served by a single laboratory service in the NE Scotland
- Data collected from routine sources 12 months pre and 12 months post intervention
- Post intervention survey based on Theory of Planned Behaviour

DRAM educational messages

Report (for message to appear in)	Trigger for Message	Message to add
Follicle Stimulating Hormone (FSH)	FSH	CPD Note: In general, FSH testing is of limited value in the assessment of menopausal status in women over 40 years of age.
Thyroid Function Tests (TFTs)	TSH	CPD Note: TFTs are not indicated as a screening procedure in young, clinically euthyroid patients.
CEA	CEA	CPD Note: CEA should not be used to screen, diagnose or exclude malignancy.
CA-125	CA-125	CPD Note: CA125 should not be used to screen, diagnose or exclude malignancy.
FBC	Request for FBC with a MCV > 95	CPD Note: Macrocytosis without anaemia is unlikely to be due to B12 deficiency (thus should not be requested). Thyroid or liver function tests may be helpful.
FBC	Request for FBC with a MCV < 80	CPD Note: Ferritin measurement is generally unnecessary in caucasians with hypochromic microcytic anaemia as the underlying cause is almost always iron deficiency.
B12	B12 request	CPD Note: B12 levels are of no value and should therefore not be requested in patients undergoing parenteral B12 therapy.
Helicobacter Pylori serology	Helicobacter Pylori serology request	CPD Note: Helicobacter Pylori serology should not be used to assess the efficacy of antibiotic eradication therapy as antibody levels may remain positive for some time after eradication.
IgE RAST Test	IgE RAST Test request	CPD Note: General allergen 'screening' is unhelpful. Allergen testing requests should instead be specific as directed by the history.
Autoantibodies report	any autoantibody request	CPD Note: Autoantibody 'screen' requesting is inappropriate for investigation of non-specific illness. Requests should be test-specific.

DRAM audit and feedback

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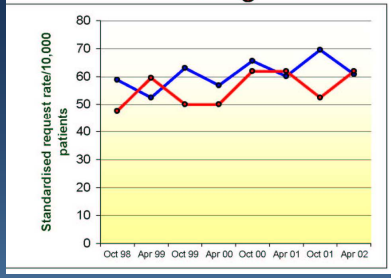
Follicle Stimulating Hormone



Grampian Average 60.7

Your Practice 61.9

Follicle Stimulating Hormone (FSH) is released by the pituitary gland and acts to stimulate sex hormone production and reproductive processes. In general, FSH testing is of limited value in the assessment of menopausal status in women over 40 years of age, and so should not be requested for this purpose. Menopausal/Peri-menopausal status is best confirmed retrospectively based on clinical symptoms, signs and frequency or absence of menstruation. Biochemical measurement adds little to this classification, and may mislead.

Results

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	Feedback	Educational messages	Feedback and messages
Number of tests with positive direction of effect	8/9	6/9	9/9
Median odds ratio risk (range)	0.84 (0.51 – 1.07)	0.88 (0.41 – 1.01)	0.79 (0.46 – 0.89)
Number of tests with statistically significant results	3/9	3/9	6/9

Theory of Planned Behaviour

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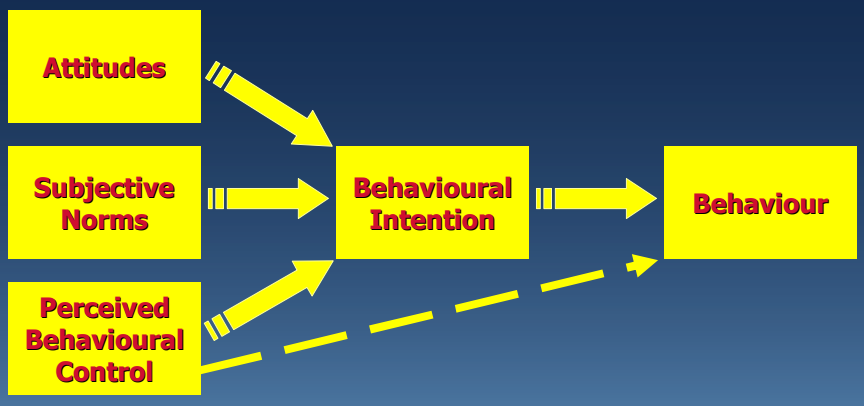

Ajzen & Madden, (1986), *Journal of Experimental Social Psychology*, 22, 453

Causal mechanisms
FSH

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	Intention (1-7)	Attitudes (1-7)	Subjective norms(1-7)	PBC (1-7)
Control	4.3	4.2	4.2	2.0
Feedback only	5.6	5.2	4.9	1.5
Educational messages	6.0	5.5	5.2	1.5
Feedback and messages	6.0	5.7	5.2	1.5

Causal mechanisms
Helicobacter pylori

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	Intention (1-7)	Attitudes (1-7)	Subjective norms(1-7)	PBC (1-7)
Control	6.3	7.0	6.0	2.2
Feedback only	7.0	7.0	6.0	2.2
Educational messages	7.0	7.0	6.2	1.2
Feedback and messages	7.0	7.0	6.3	2.0

Causal mechanisms
DRAM

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- Possible causal mechanism
  - FSH
    - Interventions enhanced attitudes and subjective norms resulting in improved intention and behaviour change
  - Helicobacter
    - High baseline attitudes, social norms and intentions
    - psychological ceiling effect?

Buchan et al. Implementation Science 2009, 4:68

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- Effectiveness of seven different interventions designed to increase the proportion of GPs accepting an offer of free access to online BMJ Clinical Evidence
- 14,000 Australian GPs
  - Group 1: No experimental demands
  - Group 2: Standard invitation
  - Group 3: Tutorial
  - Group 4: Opinion leaders
  - Group 5: Acquisition of professional development points
  - Group 6: Eligibility for a prize ($500 Conference Registration)
  - Group 7: Combination intervention

Buchan et al. Implementation Science 2009, 4:68

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- In the group with no research demands, 27% accepted the offer
  - Average acceptance across all other groups was 10%
  - There was no advantage in using additional strategies
- “If we are to improve care and encourage evidence-based practice, we need to find effective ways of motivating doctors and other health professionals to take part in research that can inform our implementation efforts”

Zwarenstein et al. Implementation Science 2007, 2:37

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- Large (1250 practices per arm), simple, factorial, cluster RCTof effectiveness of printed educational messages
- Control versus Three intervention groups
  - Informed with an attached postcard-sized, short, directive "outsert"
  - Informed with a two-page explanatory "insert" on the same topic
  - Informed, with both outsert and insert.
- Three replicates
  - 1) angiotensin-converting enzyme inhibitors, hypertension treatment, and cholesterol lowering agents for diabetes
  - 2) retinal screening for diabetes
  - 3) diuretics for hypertension

Bhattacharyya et al. DESH

Otolaryngology- Head and Neck Surgery
2010; 143: 1S1, p66.

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- 2 arm RCT
- All 594 districts in India randomized
  - Mailed information package
  - No intervention
- Intervention targets key district-level actors:
  - Politicians, bureaucrats, including CMOs
- Outcome data
  - Sequential surveys on prioritization and implementation of health interventions by CMOs
  - Review of administrative databases for budgetary and health service measures

TRiaDS: a programmatic approach to guideline development and implementation

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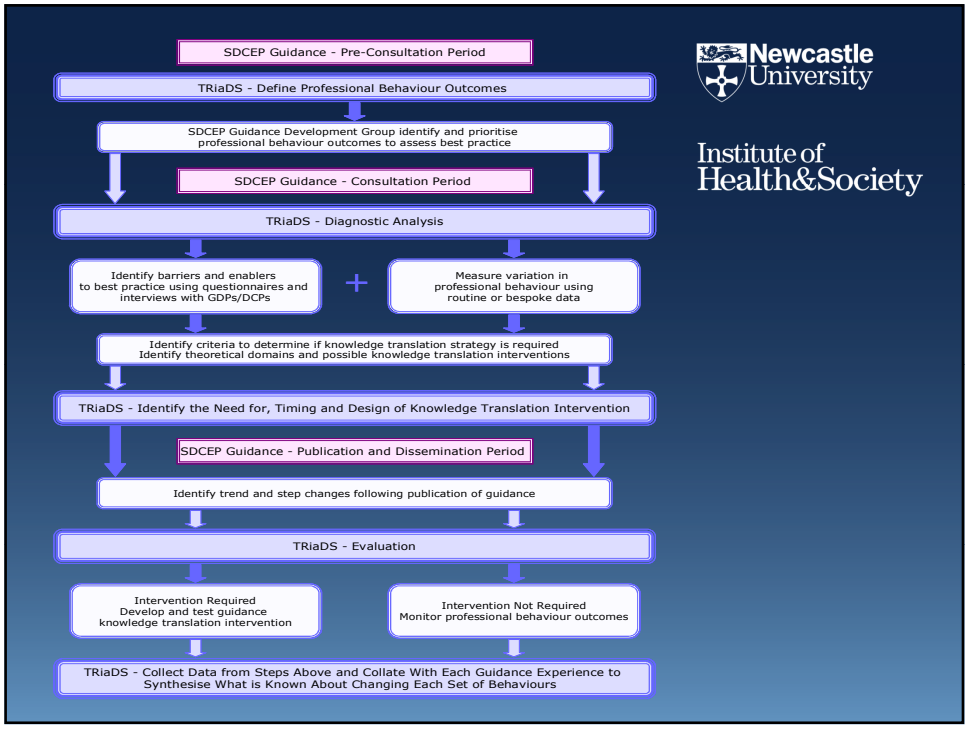
- For dentistry in Scotland, the production of clinical guidance is the responsibility of the Scottish Dental Clinical Effectiveness Programme (SDCEP)
- TRiaDS (Translation Research in a Dental Setting) is a multidisciplinary research collaboration, embedded within the SDCEP guidance development process
- Aims to conduct and evaluate a programme of integrated, multi-disciplinary research to enhance the science of knowledge translation

Clarkson JC, Ramsay CR, Eccles MP, et al. The translation research in a dental setting (TRiaDS) programme protocol. *Implementation Science* 2010, **5**:57



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TRiaDS Process and Activity

	Define professional behaviour outcomes	Diagnostic analysis	Decide on the need for and design of knowledge translation intervention	Evaluation
Conscious Sedation				
Decontamination	✓	✓	✓	CRCT
Emergency Dental Care	✓	✓		
Drug Prescribing	✓	✓	✓	ITS
Oral Health Assessment	✓	✓		
Dental Caries in Children	✓	✓		
Practice Support Manual	✓			

Conclusions

- Pragmatic “real world” trials are informative and feasible
  - Need a good multi-disciplinary team
- Need to move beyond small, two arm, intervention versus control trials
  - More complex designs
  - Additional elements to studies
  - Programmes of evaluation
- Scale of ambition

Implementation Science:
Impact Factor 2.49

Implementation Science

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Scope

All aspects of research relevant to the scientific study of methods to promote the uptake of research findings into routine healthcare in both clinical and policy contexts

www.implementationscience.com

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