Final protocol

PROJECT TITLE:

The effectiveness of patient initiated clinics in patients with chronic or recurrent conditions managed in the secondary care setting

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1.1 Decision Problem

Many chronic conditions with fluctuating levels of disease severity are managed traditionally by regularly scheduled appointments at outpatient clinics. Often this leads to a mismatch between clinical need and clinical input and can create an outpatient service that is unwieldy and unresponsive to requests for help during periods of exacerbated disease. Evidence from several disease areas (e.g. rheumatoid arthritis, inflammatory bowel disease, diabetes, various cancers) suggest that open-access, patient-led clinics may have positive effects in terms of patient care and satisfaction, cost-effectiveness and efficiency.

1.1.1 Purpose

The purpose of this systematic review is to help to clarify the effectiveness of patient initiated or open access clinics in patients with chronic or recurrent conditions managed in the secondary care setting.

1.1.2 The interventions

Patient or carer initiated, open access, follow-up clinics in the secondary care setting.

1.1.3 Population

Patients with long-term, chronic or recurrent conditions managed in secondary care for whom patient or carer initiated, open access, follow-up clinics may be appropriate.

1.1.4 Comparators

Standard/usual care in which regular follow-up clinics are initiated by the clinical team.

1.1.5 Outcomes to be examined

If possible outcome measures will include:

- Frequency of visits contacts with secondary care by type (including accident and emergency)
- Cost to the patient and the service
- Quality of life
- Clinician satisfaction
- Patient and carer satisfaction
- The proportion of the reference population included in the trial
- Measures of health status or disease control
- Failures of the 'system' e.g. how long are patients able to initiate clinic visits before the clinical team need to re-instigate regular follow-up clinics

1.2 Methods of synthesis of evidence of clinical effectiveness

We will conduct a systematic review of the evidence for the effectiveness of patient initiated or open access, follow-up clinics in patients with chronic or recurrent conditions managed in the secondary care setting. The review will be undertaken following the general principles published by the NHS Centre for Reviews and Dissemination.

1.2.1 Search strategy

Refer to Appendix 1 for details of the sources to be searched and the draft search strategy for MEDLINE.

The search strategy will comprise the following main elements:

- Searching of electronic databases, including MEDLINE, Pre-Medline, and EMBASE
- Scrutiny of bibliographies of included studies
- Contact with experts in the field

- Current research will be identified through searching the Current Controlled Trials Register and the MRC Clinical Trials Register
- Hand searching of relevant journals from inception
- Any other sources?

1.2.2 Study selection criteria and procedures

1.2.2.1 Types of study to be included

Randomised clinical trials and other controlled trial data will be included. These study design criteria may be relaxed to include other comparative study designs depending on the availability of more methodologically robust evidence.

Studies will only be included if they describe the effects of patient initiated clinics and report data on one or more of the required outcome measures.

Any associated process evaluations identified through this search strategy will also be retrieved and studied.

Criteria	Specification	Notes
Population	Patients with long-term, chronic or recurrent conditions managed in secondary care for whom patient or carer initiated, open access, follow-up clinics may be appropriate	Adults only
Interventions	Patient or carer initiated, open access, follow-up clinics in the secondary care setting.	
Outcomes	Frequency of visits – contacts with secondary care by type (including accident and emergency)	
	Cost – to the patient and the service	
	Quality of life	
	Clinician satisfaction	
	Patient and carer satisfaction	
	The proportion of the reference population included in the trial	
	Measures of health status or disease control	

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	Failures of the 'system' – e.g. how long are patients able to initiate clinic visits before the clinical team need to re- instigate regular follow-up clinics	
Setting	Secondary care	
Study design	Any comparative study design	
Date	No date restrictions	

1.2.2.2 Types of study to be excluded

- Animal models
- Pre-clinical and biological studies
- Narrative reviews, editorials, opinions, letters
- Reports published as meeting abstracts only, where insufficient methodological details are reported to allow critical appraisal of study quality

1.2.2.3 Study selection

The abstracts and titles of references retrieved by the electronic searches will be screened for relevance by one reviewer and independently checked by a second using the pre-specified inclusion/exclusion criteria. Full paper copies of potentially relevant studies will be obtained. Using the same methods, the retrieved articles will be assessed for inclusion. Discrepancies will be resolved by discussion, with involvement of a third reviewer, where necessary. All duplicate papers will be double checked and excluded.

1.3 Quality assessment strategy

The quality of individual studies will be assessed by one reviewer, and checked by a second. Any disagreement will be resolved by consensus and if necessary a third reviewer will arbitrate.

Appropriate quality assessment criteria will be used depending on the design of the included studies using the general principles published by the NHS Centre for Reviews and Dissemination.

1.4 Data extraction strategy

Data will be extracted from included studies by one reviewer into a piloted, standardised data extraction forms and checked by another reviewer. Discrepancies will be resolved by discussion, with the involvement of a third reviewer if necessary.

1.5 Data analysis and presentation

Data will be tabulated and discussed in a narrative review. Where appropriate, metaanalysis will be employed to estimate summary measures of effect on relevant outcomes, based on intention to treat analyses.

If meta-analysis is conducted it will be carried out using fixed and random effects models, using bespoke software and STATA. Heterogeneity will be explored through consideration of the study populations, methods and interventions, by visualisation of results and, in statistical terms, by the χ^2 test for homogeneity and I2 statistic and, where appropriate, using meta-regression. Small-study effects (including publication bias) will be visually assessed using funnel plots and quantified using Egger's statistic.

The effectiveness of patient initiated clinics in patients with chronic or recurrent conditions managed in the secondary care setting FINAL PROTOCOL 6th December 2010 **Appendix 1 - draft search strategy**

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1950 to Present>

Searched: 26-11-10

- 1 (open access adj5 (follow up* or followup*)).ti,ab. (15)
- 2 (open access adj5 (check up or checkup or check ups or checkups)).ti,ab. (0)
- 3 (open access adj5 appointment*).ti,ab. (18)
- 4 (open access adj5 (clinic or clinics)).ti,ab. (88)
- 5 (open access adj5 (out patient* or outpatient*)).ti,ab. (19)
- 6 (Patient* adj5 direct access).ti,ab. (106)
- 7 (Patient* adj3 initiate* adj5 (follow up* or followup*)).ti,ab. (44)
- 8 (Patient* adj3 initiate* adj5 (check up or checkup or check ups or checkups)).ti,ab.

(0)

- 9 (Patient* adj3 initiate* adj5 appointment*).ti,ab. (5)
- 10 (Patient* adj3 initiate* adj5 (clinic or clinics)).ti,ab. (10)
- 11 (Patient* adj3 initiate* adj5 (out patient* or outpatient*)).ti,ab. (18)
- 12 (Patient* adj3 led adj5 (follow up* or followup*)).ti,ab. (20)
- 13 (Patient* adj3 led adj5 (check up or checkup or check ups or checkups)).ti,ab. (0)
- 14 (Patient* adj3 led adj5 appointment*).ti,ab. (2)
- 15 (Patient* adj3 led adj5 (clinic or clinics)).ti,ab. (21)
- 16 (Patient* adj3 led adj5 (out patient* or outpatient*)).ti,ab. (8)
- 17 (Patient* adj3 request* adj5 (follow up* or followup*)).ti,ab. (58)
- 18 (Patient* adj3 request* adj5 (check up or checkup or check ups or checkups)).ti,ab.(2)
- 19 (Patient* adj3 request* adj5 appointment*).ti,ab. (28)
- 20 (Patient* adj3 request* adj5 (clinic or clinics)).ti,ab. (26)
- 21 (Patient* adj3 request* adj5 (out patient* or outpatient*)).ti,ab. (11)
- 22 (self* adj1 referr* adj5 (follow up* or followup*)).ti,ab. (13)
- 23 (self* adj1 referr* adj5 (check up or checkup or check ups or checkups)).ti,ab. (1)
- 24 (self* adj1 referr* adj5 appointment*).ti,ab. (1)
- 25 (self* adj1 referr* adj5 (clinic or clinics)).ti,ab. (47)
- 26 (self* adj1 referr* adj5 (out patient* or outpatient*)).ti,ab. (15)
- 27 (patient adj5 (led or request* or initiate*) adj5 review).ti,ab. (25)
- 28 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or

17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 (553)

- 29 "Delivery of Health Care"/ (53544)
- 30 "Referral and Consultation"/ (44989)
- 31 Health Services Accessibility/ (39281)
- 32 outpatient clinics, hospital/ (13274)
- 33 29 or 30 or 31 or 32 (143984)
- 34 28 and 33 (161)