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FINAL PROTOCOL

Title of the project: Computerised decision support systems in order communication for diagnostic, screening or monitoring test ordering: systematic reviews of the effects and cost-effectiveness of systems

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1. Plain English Summary

Order communication systems (OCS) [termed Computerised Physician Order Entry (CPOE) systems in the USA] are computer applications used to enter diagnostic and therapeutic patient care orders, for example laboratory test requests or prescriptions. These systems are used both in primary and secondary care settings and have the potential to automate the clinical test ordering process, to improve the quality and safety of patient care, and improve value for money. Some order communication systems incorporate a computerised decision support system (CDSS), which is intended to aid clinicians in the decision making process. These are systems that use two or more items of patient data to generate patient-specific assessments or recommendations that are then presented to clinicians for consideration. Such systems are currently being introduced within the NHS, but we do not know whether these systems are effective and offer good value for money when used for ordering tests (for diagnostic, screening or monitoring purposes). This project will describe which CDSS in test order communication systems are currently in use in the UK, and review the evidence for the impact of CDSS on clinical performance and patient outcomes compared to order communication systems without CDSS. The project will also examine which specific features of CDSS may be associated with clinician or patient acceptance of the system, and assess whether these systems are likely to be considered good value for money by the NHS.

2. Objectives of the Technology Assessment Report

This technology assessment report aims to address the following questions:

1. Which computerised decision support systems (CDSS) in order communication systems for test ordering are currently in use in the UK, and what are their main characteristics and their intended/actual scope of use?

2. What is the impact of CDSS in order communication systems for diagnostic, screening or monitoring test ordering compared to order communication systems without CDSS on process outcomes, patient outcomes and adverse events/safety?

3. What features of CDSS are associated with clinician or patient acceptance of CDSS in order communication systems?

4. What is known about the cost-effectiveness of CDSS in diagnostic, screening or monitoring test order communication systems compared to order communication systems without CDSS?

In order to address the above questions the assessment will comprise:
(i) a survey of NHS National Project for Information Technology (NPfIT), manufacturers and providers of order communication systems and General Practitioner systems which encompass CDSS facilities, and experts in the field to establish which systems are currently in use or are being implemented in the UK.

(ii) two linked systematic reviews to assess firstly, the impact of CDSS in order communication systems for diagnostic, screening or monitoring test ordering compared to order communication systems without CDSS on process and patient outcomes, and secondly, to examine what specific features of CDSS may be associated with clinician or patient acceptance of the system.

(iii) a systematic review of economic evaluations and cost comparison studies of CDSS in diagnostic, screening or monitoring test order communication systems compared to order communication systems without CDSS.

3. Background

Accurate and efficient diagnostic procedures are paramount in optimising patient management and use of health care resources. If a correct diagnosis is not made patients may receive inaccurate information regarding their prognosis, may undergo inappropriate medical treatment, or the correct treatment may be withheld. This can result in less than optimal outcomes, both in terms of the clinical management of patients and the use of health care resources. Furthermore, following the use of different tests to establish a diagnosis, further tests are often required to monitor disease progression, or to screen for the presence of other risk factors or concomitant disease.

To reach a diagnosis or manage a patient, a clinician may choose to order one or more medical tests. In this sense, "diagnostic test" refers to any procedure that tries to confirm or identify the presence or absence of a patients' symptoms or signs or alteration in a patient's condition. This includes laboratory measurements, e.g. biochemistry, haematology, bacteriology, imaging, and invasive procedures. There are a number of factors which may influence a clinician's decision to order a test including:

- A patient's medical history, signs and symptoms
- Therapeutic and prognostic factors, such as deciding on an appropriate course of treatment
- Patient-related factors such as demographics or patient preference

- Factors related to both the individual clinician and health care organisation.[1]

A recent systematic review of reasons and context for test ordering by clinicians highlighted that the majority of factors associated with test ordering were clinician related, including level of clinical experience, confidence in their clinical judgement, speciality, and working patterns. Availability of tests, type of health care organisation (salaried versus fee for service approach), and size of the primary care practice were also found to influence test requesting patterns.[1] This review therefore highlights the fact that clinician test ordering behaviour is influenced by a multitude of interactive factors, and therefore may be difficult to standardise as it will depend not only on the nature of clinical consultation, but also on the individual clinician working within a specific organisational environment.

Many potential benefits of order communication systems (OCS) (termed Computerised Physician Order Entry or CPOE systems in the USA) in hospitals have been identified. These include improvements in clinician ordering patterns, optimisation of clinical time, and aiding communication processes between clinicians and different departments.[2-5] These systems have the potential to automate the clinical test ordering process and to improve the quality and safety of patient care.[6-10] They often incorporate features such as decision support mechanisms, built-in alerts and rule-based prompts. However, order communication systems do not always improve clinical practice. In a recent systematic review of computer based systems, most (64%) significantly improved practice in some way, but 36% did not.[10] Furthermore, there is relatively little sound scientific evidence available to explain why some systems succeed and some systems fail.

Computerised decision support systems (CDSS) in health care are information systems designed to improve clinical decision making, and by and large are intended to support healthcare workers in the normal course of their duties, assisting in tasks that rely on the manipulation of data and knowledge. Although there is no consensus on the definition of a CDSS, they can broadly be defined as "active knowledge systems which use two or more items of patient data to generate case-specific advice".[11] Computerised clinical decision support systems match characteristics of an individual patient to a computerised knowledge base, with software algorithms used to generate patient-specific recommendations. Clinicians, health care staff or patients can manually enter patient characteristics into the computer system, or alternatively electronic medical records can be queried for retrieval of patient characteristics. Computer-generated recommendations are then delivered through the electronic medical record, by pager, e-mail, or through printouts placed in a patient's paper

chart. Additionally, CDSS can be used to check the potential duplication of services and highlight test orders that should be considered when one order is placed ("corollary" orders).

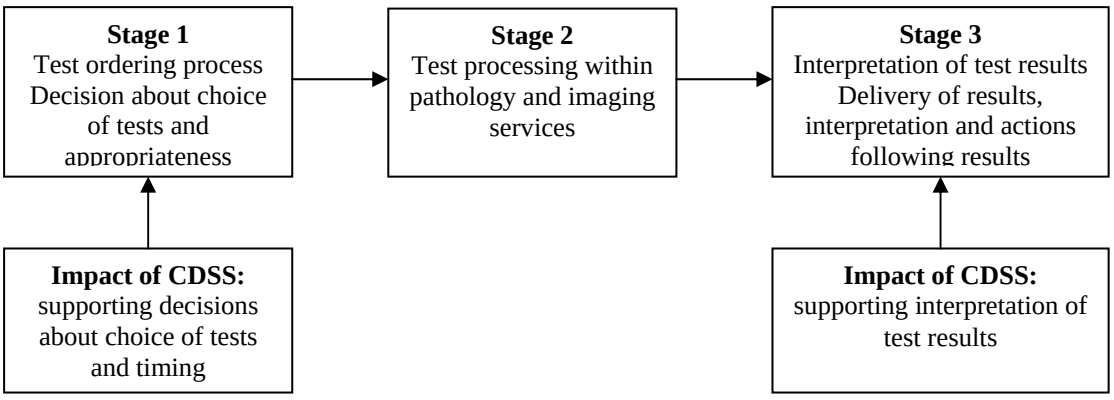
A large proportion of orders processed through order communication systems are for pathology and imaging services. The use of laboratory services for diagnostic testing has increased in many health care jurisdictions around the world.[12-14] The Healthcare Commission report 'Getting results: Pathology Services In Acute And Specialist Trusts', highlights the fact that in the UK pathology is the largest diagnostic service in the number of requests it meets annually (175 million), in expenditure (£1.8 billion in 2005/2006 and 5.1% of the total budget of NHS Trusts) and in the proportion of clinical decisions that it affects (reputedly over 70%).[15] Moreover the number of requests for biochemistry, haematology and microbiology tests continues to increase, and there is also an increase in the number of tests requested per sample. The report also highlights that in 2005 whilst tests were generally completed more quickly that in 2003, there was still considerable variation between laboratories in test turn around times. Additionally, many non-urgent tests were being completed more quickly than in 2003, raising the question of whether improved turnaround results in clinical benefits that may justify additional marginal costs.

In the test ordering process there are two distinct aspects to order communication systems:

1. Test requesting – the process of making a request to a diagnostic service.
2. Results reporting – the process of electronic reporting of results to the clinician.

Figure 1 outlines the flow of information in the test requesting and reporting process and the stages in which CDSS and order communication systems can have an impact.

Figure 1. Information flow in order communication



In the test requesting process the use of CDSS in order communication systems has the potential to impact on reducing the number of redundant tests that are ordered; ensure necessary tests are performed at the correct intervals by prompting clinicians; ensure tests appropriate to the specific clinical circumstances are ordered; ensure proper patient preparation (e.g. fasting) and correct sampling procedures for the tests that are ordered.

In the results reporting process the potential impact of CDSS in order communication systems with intelligent feedback lies in the provision of context-specific interpretative comments to help the clinician with the interpretation of test results (either alone or in addition to those provided by pathology or imaging services), and provide advice on the best course of action given a specific result, e.g. to undertake further investigations and the timing of such tests.

3.1 Types of order communication and CDSS

Order communication systems (OCS) vary in their level of sophistication with a distinction between systems which provide only knowledge support, those which provide audit feedback on aggregated data, and those which provide real-time decision support embedded in the clinical process. OCS can vary in at least four different ways, which have the potential to impact on any benefits and costs associated with the system:

1. Functions of the system. There are at least four important dimensions upon which systems can differ:
    a. only order tests versus order and display past / current results.
    b. ordering / result display alone versus system with knowledge support (e.g. an electronic lab handbook for browsing) versus system with decision support.
    c. with or without a regular audit report on the number and type of tests ordered by the user.
    d. location of the access points: fixed access points versus mobile computers.
    e. patient identification aids: none versus bar coding versus other identification such as Radio Frequency Identification (RFID) tags.

2. Scope of the orders covered:
    a. orders for tests from one single laboratory versus
    b. for all laboratories versus
    c. for laboratories plus imaging and ECG’s etc.
    d. versus for all tests and therapies and drugs versus
    e. all orders integrated into full electronic patient record.

3. Purpose of the tests ordered:
    a. test ordering for preventive care or screening versus
    b. diagnostic purposes versus
    c. monitoring of long-term conditions and drug dosing (e.g. insulin, warfarin.)

4. Aim of the advice offered by system:
    a. to increase appropriate use of tests versus
    b. to decrease over use of tests.

Additionally, as the systematic review by Kawamoto and colleagues (2005)[16] highlights other specific system features may be related to the success or failure of the CDSS in significantly improving clinical practice. In their review 15 decision support features whose importance had been repeatedly suggested in the literature were assessed alongside whether or not they had a significant impact on clinical practice. The absence or presence of each of the 15 features within a system were then used as predictors of system success or failure in terms of having a significant impact using multiple regression models. The 15 features assessed in the review are listed in table 1. Further explanatory variables to account for decision support subject matter (acute versus non-acute care) and two indicators for the study setting (academic versus non academic, and outpatient versus inpatient care) were also entered into the regression models. The authors found that four system features were independent predictors of improved clinical practice: automatic provision of decision support as part of clinician workflow, provision of recommendations rather than just assessments, provision of decision support at the time and location of decision making, and computer based decision support.[16]

Table 1: 15 features of clinical decision support systems assessed by Kawamoto and colleagues (2005)[16]

Features and sources*
General system features
Integration with charting or order entry system to support workflow integration.[17-21]
± Use of computer to generate the decision support. [a] [22-31]
Clinical-system interaction features
± Automatic provision of decision support as part of clinician workflow.[18 19 32-41]
No need for additional clinician data entry.[17 32 33 36 40 42-45]
Request documentation of the reason for not following CDSS recommendations.[40 42 45-47]
± Provision of decision support at time and location of decision making.[21 23 24 26 32 36 38-42 45 48-53]
Recommendations executed by noting agreement.[24 40 46 54]
Communication content features
± Provision of a recommendation, not just an assessment.[45 55 56]
Promotion of action rather than inaction.[36 39 51]
Justification of decision support via provision of reasoning.[17 46 51 57]
Justification of decision support via provision of research evidence.[34 51 57 58]
Auxiliary features
Local user involvement in development process.[18 35 45 48 49 51 53 57 59-62]
Provision of decision support results to patients as well as providers.[25 63-67]
CDSS accompanied by periodic performance feedback.[34 51 61 68-70]
CDSS accompanied by conventional education.[28 52 69 71 72]

* reviews or primary studies in which the authors suggested the feature was important for CDSS effectiveness; [a] feature not relevant to the scope of the current review; ± system feature found to be an independent predictor of system success

Additionally, as well as CDSS systems varying in their degree of sophistication, location of access points and timeliness and mode of feedback, and the information system in which they are located (Laboratory/Radiology Information Systems; Hospital Information Systems, or GP Practice Systems), CDSS also vary in the reasoning methods used to generate advice and the source of the information from which advice is generated. A typology of six types of reasoning methods for decision tools was described by Liu and colleagues.[73] This categorised the reasoning methods as either Bayesian methods, logistic regression extensions of Bayes theorem, based on discrimination rules, clinical algorithms, expert systems or machine learning methods. The current assessment will therefore use this suggested typology in the categorisation of reasoning methods used by different decision tools, as well as evaluating the information source from which advice is generated by the system.

3.2 Evaluation of CDSS

Wyatt and Spiegelhalter (1990) describe a systematic approach to laboratory and field testing of CDSS, suggesting that the final stages should include evaluation of effects on the health care process and on patient outcomes.[74] However, if a CDSS is to have an ultimate impact on health care processes or patient outcomes then acceptance of the system and usage rates must be high. User acceptance and satisfaction with a CDSS is therefore highly important; if users

are satisfied they are likely to modify their behaviour to use the system to their advantage, but if they are not then they will either not use the system or will use it in a sub-optimal manner.[75]

A literature review by Ohmann and colleagues (1997) which focused on user satisfaction with computer-based systems highlights the fact that satisfaction is a complex inter-play between both system-dependent and system-independent factors.[76] System-dependent factors include 'satisfaction with the content of the CDSS' and 'satisfaction with the interface of the system', whereas system-independent factors include personal factors, such as 'computer anxiety' and 'attitudes towards computers' as well as organisational factors, including the environment in which the system is used.

In terms of system-dependent factors acceptance of CDSS depends on a number of factors including:

- time taken to obtain the CDSS
- time taken to use the CDSS
- conceptual complexity of the CDSS (which affects ease of understanding and usage)
- number of data items to collect (if the data are not already available in electronic patient records)
- ease of data entry
- ease of interpreting the results (numbers, probabilities, graphs, advice etc.)
- perceived applicability of the CDSS knowledge base to the clinician's own patients.

Although it is recognised that system-independent factors are additionally likely to impact on user acceptance of CDSS, it is important to assess in an exploratory manner what features of CDSS are likely to make the system more or less acceptable to clinicians or patients, as ultimately acceptance of the system will impact on usage rates, and may influence both process and patient outcomes. Furthermore, it is acknowledged that few if any studies, are likely to have assessed more than one CDSS, so the context as well as the definition and measurement of 'acceptance' is likely to vary between studies and therefore limit comparisons between acceptance rates for different CDSS. On this basis, an exploratory review is therefore proposed of studies that have assessed acceptability of CDSS to examine what can be inferred about the association of different CDSS features and the acceptance of the systems to clinicians or patients.

Therefore in reference to the evaluation framework proposed by Wyatt and Spiegelhalter for CDSS[74] and the scope outlined by the Health Technology Assessment Programme this assessment will therefore be comprised of:

(i) a survey of NHS NpfIT, manufacturers and providers of order communication systems which encompass CDSS facilities, and experts in the field to establish which systems are currently in use or are being implemented in the UK.

(ii) a systematic review of the impact of CDSS in order communication systems for diagnostic, screening or monitoring test ordering compared to order communication systems without CDSS on process, patient outcomes, and adverse events.

(iii) a systematic review to examine what specific features of CDSS are likely to be associated with clinician or patient acceptance of the system.

(iv) a systematic review of economic evaluations and cost comparison studies which have assessed the cost-effectiveness of CDSS in diagnostic, screening or monitoring test order communication systems compared to order communication systems without CDSS.

4. Methods to address the questions

4.1 Study question 1: identification of CDSS in order communication systems for diagnostic, screening and monitoring test ordering currently in use in the UK

Computerised decision support systems in diagnostic, screening and monitoring test order communication systems currently in use or being implemented in the UK will be identified through contact with system manufacturers [e.g. Anglia Healthcare Systems Ltd, Pacific Knowledge Systems, Olympus Osyris, and suppliers involved in the GP Systems of Choice (GPSoC) scheme], NHS NpfIT, NHS Connecting for Health (NHS CFH), eHealth Strategy Board, "Informing Health Care", the Healthcare Commission,[15] NHS Purchasing Suppliers, the NHS Supply Chain and experts in the field, such as the Royal College of Pathologists and Radiologists. Additional systems previously evaluated in the UK will also be identified from studies included in the reviews to assess the impact and acceptability of CDSS (questions two and three). Where systems are identified from studies included in the reviews, study authors will be contacted to confirm whether the systems are now obsolete. The frequency of the use of each specific system will be tabulated (number of sites installed), and where possible results reported according to the clinical setting, (general practice versus out-patient versus routine in-patient versus intensive care), and academic versus non-academic setting. The frequency of the use of 'home grown' systems compared to 'off the shelf' systems will also

be tabulated, and where 'home grown' systems are identified their deployment in sites other than the system development site will be reported.

4.2 Generic methods for the conduct of reviews to assess the impact, acceptability and cost-effectiveness of CDSS systems in test order communication systems

Standard systematic review methods following the guidance on the conduct of systematic reviews published by the Centre for Reviews and Dissemination[77] will be used to undertake the reviews of the impact, acceptability, and cost-effectiveness of CDSS. The generic methods for the conduct of the reviews is outlined below with the specific inclusion criteria for each of the reviews, data to be extracted, and methods of synthesis for each outlined for the specific review questions in turn.

4.2.1 Identification of relevant studies

A generic search to identify potentially relevant studies for the three reviews will be conducted. A comprehensive search syntax using Medical Subject Headings (MeSH) and free text terms for CDSS and OCS along with terms for diagnosis, screening and monitoring will be developed. This will be used to identify relevant clinical, cost-effectiveness and cost comparison studies indexed on the following medical and social science databases between 1974 (the year of publication of the first article to evaluate the effect of a CDSS on clinician performance)[78] and 2008:

MEDLINE
EMBASE
Cochrane Controlled Trials Register (CCTR)
CINAHL (Cumulative Index of Nursing and Allied Health)
Database of Abstracts of Reviews of Effects (DARE)
Health Technology Assessment (HTA) database
HMIC (Health Management Information Consortium)
NHS EED
Econ Lit

In addition, conference proceedings from the American Medical Informatics Association (AMIA) Symposia and Proceedings of the Symposium on Computer Applications in Medical Care will be hand-searched for relevant abstracts, and bibliographies of all included studies will be checked. Where relevant conference abstracts are identified authors will be contacted for further details. All retrieved bibliographic references will be duplicated and managed in Reference Manager software. A preliminary draft search strategy for MEDLINE is displayed in Appendix 1.

4.2.2 Selection of primary studies for the reviews

The abstracts and titles of references retrieved by the electronic searches will be screened for relevance against the inclusion criteria for the three reviews. This will be conducted by one reviewer, with a random 20% of abstracts and titles then being checked by a second reviewer. Full paper copies of potentially relevant studies will be obtained. The retrieved articles will be assessed for inclusion by one reviewer and independently checked by a second, using the pre-specified inclusion/exclusion criteria. The extent of disagreements between reviewers for both decisions made on titles and abstracts alone, and for full text copies of studies against the inclusion/exclusion criteria will be quantified using Cohen's unweighted kappa statistic.[79] All duplicate papers will be double checked and excluded.

4.2.3 Publication language and status

Due to the time frame of the assessment, only studies published in English as a full journal article or report will be included in each of the reviews.

4.2.4 Conduct of the reviews

Two reviewers will be involved in all key stages of the review processes. Any discrepancies throughout the reviews will be resolved through examination of the relevant papers, and involvement of a third reviewer if necessary.

4.2.5 Data extraction and quality assessment processes

Data will be extracted from the included studies using a standardised data extraction form developed for each of the reviews. A draft data extraction form is displayed in Appendix 2. Where multiple publications of the same study exist, data will be extracted from all publications together, with priority given to data reported on the basis of 'intention to provide or communicate information'.[80] All data will be managed in Microsoft Access or Word as appropriate. The quality of the individual studies will be assessed according to study design. Randomised and non-randomised controlled trials, and pre-post studies will be assessed according to methodological criteria listed in CRD Report 4,[77] interrupted time series studies will be assessed according to criteria specified by the Cochrane Effective Practice and Organisation of Care (EPOC) Group, economic evaluations will be assessed using the CHEC list questions developed by Evers and colleagues,[81] and studies based on decision models will be assessed against the ISPOR guidelines for good practice in decision analytic modelling.[82] Where relevant surveys or qualitative studies that examine CDSS acceptability to clinicians or

patients are identified these will be assessed using criteria developed by Crombie and the Critical Appraisal Skills Programme tool respectively.[83 84]

4.3 Study question 2: What is the impact of CDSS in order communication systems for diagnostic, screening or monitoring test ordering compared to order communication systems without CDSS on process and patient outcomes?

Identification of studies eligible for inclusion to address review questions 2 and 3 will be undertaken in a staged approach. An initial 'mapping' exercise will be undertaken to assess the size of the relevant literature. All studies meeting the inclusion criteria specified below will be eligible for inclusion in this initial exercise.

4.3.1 Inclusion and exclusion criteria

Participants

Clinicians (e.g. physicians, nurses, dentists, psychiatrists) in practice or training, or patients undergoing testing for diagnostic, screening or monitoring purposes in a primary or secondary care setting will be included. Studies solely including medical students will be excluded.

Interventions

Studies which compare CDSS in order communication systems for diagnostic, screening or monitoring test ordering compared to order communication systems without CDSS evaluated in a clinical setting will be included. A CDSS will be defined as an active knowledge system which uses two or more items of patient data to generate patient-specific assessments or recommendations that are then presented to clinicians for consideration.[11] Studies in which the CDSS has not been evaluated in a clinical setting will be excluded. Studies in which the system (i) only provides summaries of patient information (i.e. no specific test ordering or test interpretative advice), (ii) provides feed-back on groups of patients without individual assessment, (iii) only provides computer-aided instruction (i.e. provides generic rather than patient specific advice) or (iv) is used in image analysis will also be excluded.

Outcomes

Studies which report an objective measure of process of care, e.g. test volume, time from test order to receipt of results, patient outcome, or adverse events will be included. Studies which only report the diagnostic accuracy of the CDSS compared to a gold standard (such as a diagnosis reached by the clinician without use of the CDSS) (i.e. sensitivity and specificity) will be excluded.

Study designs

Randomised and non-randomised trials with a contemporaneous control group, interrupted time series, and controlled and uncontrolled pre-post studies will be included.

The results from the 'mapping' exercise will be used to iteratively inform the development of final inclusion criteria for the review, if the size of the relevant literature is too large to be handled within the constraints of the assessment. The development of further inclusion criteria if necessary, will focus on both the internal and external validity of the identified studies in order to focus on studies that are most relevant to the use of CDSS in order communication systems for test ordering within the UK NHS. Study design will be used as a marker of each study's internal validity, with preference given to the inclusion of controlled trials, interrupted time series and controlled pre-post studies above uncontrolled pre-post studies. Assessment of external validity will be undertaken by considering the types of systems identified as currently in use in the UK (study question one), study year (with preference given to systems that are still likely to be in use), study setting (with preference given to studies conducted in healthcare settings where remuneration for activity and/or staff are block-funded, salaried or capitation-based, as opposed to fee for service/insurance based setting), and whether the system is 'home grown/in-house' or 'off the shelf/commercially developed'.

4.3.2 Data extraction strategy

Data will be extracted on the study setting, clinician and patient characteristics, study methods, intervention and comparator systems, area of impact, CDSS characteristics including the presence or absence of the 14 relevant features of CDSS identified as being potentially related to system success by Kawamoto and colleagues (2005),[16] and outcomes. Outcomes will be summarised using descriptive summary measures, including proportions (with 95% confidence intervals) for categorical variables and mean (standard deviation) for continuous variables.

4.3.3 Methods of data synthesis

It is anticipated that there will be considerable heterogeneity between the studies, in terms of the type of CDSS systems evaluated, their comparators, the study designs and settings, and outcomes measured. Studies will therefore firstly be grouped according to outcome measure, and further grouped according to the area of impact using the information flow process as a guiding framework (e.g. clinician decision to order, application of test results and efficiency of information flow). Studies will then be combined in a narrative synthesis with key features

of the CDSS system (reasoning methods, how rules are developed and what evidence they are based on) tabulated. Where feasible and appropriate, heterogeneity between the studies will be explored using univariate and multiple logistic regression analyses. Potential explanatory variables may include the presence or absence of the 14 relevant features of CDSS identified by Kawamoto and colleagues (2005),[16] decision support subject matter (acute care versus non-acute care), study setting (academic centre versus non-academic setting, and out-patient versus in-patient), presence of incentives for doctors to order tests (no incentive versus fee for service), and the status of the system evaluators (developers versus independent evaluators). All analyses will be conducted using Stata 9 or Comprehensive Meta-analysis software.

4.4 Study question 3: What features of CDSS are associated with clinician or patient acceptance of CDSS in order communication systems?

4.4.1 Inclusion and exclusion criteria

Inclusion criteria for eligible studies will the same as for the review of the impact of CDSS on process and patient outcomes in terms of the study participants. Inclusion criteria for the interventions will also be the same as for study question two, apart from a comparator system, ie. an OCS without CDSS is not required for inclusion. Outcomes that will be eligible for inclusion will be clinician or patient self reported rates of acceptability of the CDSS. Acceptability will be defined according to the definitions used in the primary studies. The study designs that will be eligible for inclusion will be: randomised and non-randomised trials with a contemporaneous control group, interrupted time series, controlled and uncontrolled pre-post studies, cross sectional and longitudinal surveys, and qualitative studies.

4.4.2 Data extraction strategy

Data will be extracted on the study setting, clinician and patient characteristics, study methods, intervention and comparator systems (where applicable), self-reported rates/scores of clinician or patient acceptability of the CDSS, and CDSS characteristics including where reported: time taken to obtain the CDSS; time taken to use the CDSS, methods of system reasoning; CDSS knowledge base, number of data items to collect (if the data are not already available in electronic patient records); ease of data entry and ease of interpreting results. All data on clinician or patient acceptance of the CDSS will be summarised using appropriate descriptive summary measures.

4.4.3 Methods of data synthesis

Studies will be grouped according to the type of CDSS system with key data on acceptability rates/scores and specific system features presented in tables. Findings will then be combined

using a narrative synthesis. Differences in rates/scores of acceptability between studies will be explored narratively by considering differences in the study setting, and CDSS characteristics.

4.5 Study question 4: What is the cost-effectiveness of CDSS in diagnostic, screening or monitoring test order communication systems compared to order communication systems without CDSS?

4.5.1 Inclusion and exclusion criteria

The inclusion and exclusion criteria for the systematic review of economic evaluations and cost comparison studies will be identical to those for the systematic review conducted to address question 2 apart from the study design criteria. For the review full cost-effectiveness analyses, cost-utility analyses, cost-benefit analyses, cost consequence analyses, and cost comparison studies will be included. Economic evaluations which only report average cost-effectiveness ratios will only be included if the incremental ratios can easily be calculated from the published data.

4.5.2 Data extraction strategy

Data on the design of each economic evaluation and the main results will be extracted into two tables. For the study design table; the study design (CEA, CUA or cost-analysis), model type or trial based study, service setting/country, study population, intervention, comparators, research question, perspective, time horizon and discounting, main costs included, main outcomes included, and sensitivity analyses conducted will be extracted.

For the results table, for each comparator the incremental cost, incremental effectiveness/utility and incremental cost-effectiveness ratio(s) will be presented. Comparators that are excluded on the basis of dominance or extended dominance will also be reported. Additionally the authors' conclusions will be noted, and also any issues they raise concerning the generalisability of their results documented.

4.5.3 Methods of data synthesis

All results will be presented in tables and narrative synthesis used to summarise the relevant studies.

5. Expertise in the Technology Assessment Group

5.1 Peninsula Technology Assessment Group

The Peninsula Technology Assessment Group (PenTAG) is part of the Institute of Health Care Research at the Peninsula College of Medicine and Dentistry. PenTAG was established in 2000 and carries out independent Health Technology Assessments for the UK HTA Programme and other local and national decision-makers. The group is multi-disciplinary and draws on individuals' backgrounds in public health, health services research, computing and decision analysis, systematic reviewing, information science, statistics and health economics. The Peninsula College of Medicine and Dentistry is a school within the Universities of Exeter and Plymouth.

Team members' contributions

The PenTAG team members undertaking the project have previously produced reports for NICE, the Health Technology Assessment Programme and the Department of Health. These projects have included Health Technology Assessment Reports, National Clinical Guidelines, and short reports. The members of the project team and their intended role in the project are listed below:

Ms Caroline Main; Research Fellow; Peninsula Technology Assessment Group (PenTAG); Peninsula College of Medicine and Dentistry; University of Exeter	Responsible for project coordination, drafting the protocol, conducting the survey, undertaking study selection, data extraction and quality assessment, data synthesis, and drafting the final report.
Mrs Mary Bond; Research Fellow; Peninsula Technology Assessment Group (PenTAG); Peninsula College of Medicine and Dentistry; University of Exeter	Responsible for undertaking study selection, data extraction and quality assessment, data synthesis, and final report preparation.
Ms Tiffany Moxham; Information Scientist; Peninsula Technology Assessment Group (PenTAG); Peninsula College of Medicine and Dentistry; University of Exeter	Responsible for devising the search strategy, conducting the literature searches, drafting the search methodology section, and commenting on the final report.
Professor Jeremy Wyatt; Director of Health Informatics Centre; Community Health Sciences Division; School of Medicine; University of Dundee	Responsible for providing informatics and clinical input at all project stages, commenting on the draft protocol and draft report.

Professor Jonathan Kay; Consultant Chemical Pathologist and Professor of Health Informatics; Oxford Radcliffe Hospitals Trust and City University; London	Responsible for providing informatics and clinical input at all project stages, commenting on the draft protocol and draft report.
Professor Ken Stein; Professor of Public Health; Peninsula Technology Assessment Group (PenTAG); Peninsula College of Medicine and Dentistry; University of Exeter	Responsible for providing clinical input at all project stages, commenting on the draft protocol and draft report.
Dr Rob Anderson; Senior Lecturer in Health Economics; Peninsula Technology Assessment Group (PenTAG); Peninsula College of Medicine and Dentistry; University of Exeter	Responsible for project direction, providing input and comments at all stages, drafting the review of economic evaluations and will have overall responsibility for the report.

6. Competing interests of authors

None.

7. Project timetable/milestones

The Health Technology Assessment Programme (HTA) has indicated that this project is allocated the equivalent of 1.0 TAR unit and should be submitted within the financial year 2008/09. The project will therefore be submitted by the end of March 2009.

8. References

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Appendix 1: draft search strategy for MEDLINE. Search strategy will be adapted as appropriate to run on other databases.

1. DIAGNOSIS-COMPUTER-ASSISTED.DE.
2. DECISION-MAKING-COMPUTER-ASSISTED#.DE.
3. CLINICAL-LABORATORY-INFORMATION-SYSTEMS.DE.
4. DECISION-SUPPORT-SYSTEMS-CLINICAL.DE.
5. HOSPITAL-INFORMATION-SYSTEMS.DE.
6. MEDICAL-RECORDS-SYSTEMS-COMPUTERIZED.DE.
7. POINT-OF-CARE-SYSTEMS.DE.
8. 1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7
9. (COMPUT$6 WITH (ORDER OR DIAGNOS$5)).TI,AB.
10. (COMPUTER$5 WITH DIAGNOS$3).TI,AB.
11. (COMPUTER$5 OR DECISION).TI,AB. AND (DIAGNOS$3 WITH ORDER$4).TI,AB.
12. (CPOE OR POE OR DDSS).TI,AB.
13. (ORDER$4 WITH (SYSTEM$2 OR COMMUNIC$6 OR COMPUTER$5 OR ENTRY$2)).TI,AB.
14. DECISION$2 SAME (TEST$3 OR ORDER$4).TI,AB.
15. 11 OR 12 OR 13 OR 14
16. 8 AND 15
17. Medical-Order-Entry-Systems#.DE.
18. iSoft.TI,AB.
19. (ripple ADJ down).TI,AB.
20. 17 OR 18 OR 19
21. 16
22. 20 OR 21
23. ANIMAL=YES NOT HUMAN=YES
24. 40 NOT 42

Appendix 2: draft data extraction form for study question 2

Study demographics		
Author; year; study ID Title: Country: Study objectives (indication): Health care setting: {ward; surgical department; other secondary care; A & E; primary care; other; unspecified} If secondary care, academic status of the hospital {University or teaching hospital; non-teaching nor university affiliated; some of both; not clear} Healthcare system: {fee for service; HMO; insurance; NHS model} Study design: {RCT; CCT; cluster randomised trial; non-randomised cluster trial; interrupted time series; controlled pre-post; uncontrolled pre-post} Number of sites: Funding source: {public sector; private sector; not reported} Was evaluator of tool also its developer? {yes; no; unclear}		
System users		
	Intervention group	**Control group**
CDSS user: {doctor; nurse; patient; researcher; other (state)}		
Practitioners (n)		
If the CDSS user is a doctor, complete n for the following: Consultant (Attending) Registrar (Chief Resident) SHO (Resident) HO (Intern)		
Practitioners (n) in analysis		
Inclusion criteria: **Exclusion criteria:**		
Patient baseline demographics		
Inclusion criteria: **Exclusion criteria:**		
Patients (n)		
Medical conditions (n)		
Age (mean; range)		
Gender (n male; n female):		
Ethnicity: (n and %)		
Patients (n) in analysis		
Interventions		
Intervention: **Comparator:** **Concomitant interventions:**		
CDSS tool		
Name of CDDS (if any)		
CDSS reasoning method	{Naïve Bayesian methods; logistic regression extensions of Bayes theorem; Discrimination rules; clinical algorithms; expert systems; machine learning}	
CDSS knowledge base	{e.g physician opinion; practice guidelines; RCTs}	
Did study use training set and test set data?	{training set; test set; unclear}	

For training set data complete the following:-		
Design	{consecutive; random; retrospective; unclear; other: (specify)}	
Target decision	State	
Sample characteristics:- Sample size (n) Age: (mean; range) Gender:(n male; n female)		
Setting	{ward; surgical department; other secondary care; A & E; primary care; other; unspecified}	
For test-set data complete the following:-		
Properties of test-set data	{split sample; jack-knife; new prospective data; unclear; other (describe)}	
Test centre	{same as for training set; new centre; unclear}	
Target decision	State	
Other CDSS information		
1. Information used in CDSS {number of items; signs; symptoms; history; biochemical tests (list)}		
2. Time to complete the CDSS (mins)		
CDSS output format: {score; probability graph; advice; etc}		
3. Is a description of pilot testing with users prior to implementation provided? {yes; no}		
4. Is user instructional training at the time of implementation described? {yes; no}		
5. Is the CDSS integrated with charting or CPOE to support workflow integration? {yes; no; unclear}		
6. Is automatic provision of CDSS output provided as part of clinician workflow? {yes; no; unclear}		
7. Is there a need for additional data entry by the clinician? {yes; no; unclear}		
8. Does the CDSS request documentation of the reason for not following CDSS recommendations? {yes; no; unclear}		
9. Does CDSS provide output at the time and location of decision making? {yes; no; unclear}		
10. Are the CDSS recommendations executed by the clinician noting agreement? {yes; no; unclear}		
11. Does the CDSS provide a recommendation rather than just an assessment? {yes; no; unclear}		
12. Does the CDSS promote action rather than inaction? {yes; no; unclear}		
13. Does the CDSS justify the output by provision of reasoning? {yes; no; unclear}		
14. Does the CDSS justify the output by provision of research evidence? {yes; no; unclear}		
15. Were local users involved in the CDSS development process? {yes; no; unclear}		
16. Is the CDSS output provided to patients as well as clinician? {yes; no; unclear}		
17. Does the CDSS provide periodic summaries of performance feedback? {yes; no; unclear}		
Is the CDSS used in conjunction with conventional education? {yes; no; unclear}		
Outcome measures		

Outcome 1:
Area of impact: {physician decision to order; test processing; application of test results; efficiency of information flow}
Outcome 2:
Area of impact: {physician decision to order; test processing; application of test results; efficiency of information flow}
Outcome 3:
Area of impact: {physician decision to order; test processing; application of test results; efficiency of information flow}
Outcome 4:
Area of impact: {physician decision to order; test processing; application of test results; efficiency of information flow}
Outcome 5:
Area of impact: {physician decision to order; test processing; application of test results; efficiency of information flow}
Outcome 6:
Area of impact: {physician decision to order; test processing; application of test results; efficiency of information flow}
Total length of follow-up:
Follow-up assessment times:
Rate of attrition at each follow-up time:
Methods of statistical analysis:

Results

Outcome 1

	Baseline period		Post-intervention period	
Group	No. events	Total observed	No. events	Total observed
CDSS + CPOE				
CPOE alone				

* If data for 2x2 table are not available but the following effect measures are reported, fill in:
RD:
RR:
OR:
Statistical significance: (reported by author or calculated by reviewer?)

Outcome 2

	Baseline period		Post-intervention period	
Group	No. events	Total observed	No. events	Total observed
CDSS + CPOE				
CPOE alone				

* If data for 2x2 table are not available but the following effect measures are reported, fill in:
RD:
RR:
OR:
Statistical significance: (reported by author or calculated by reviewer?)

Reviewers comments:

Authors conclusions: