## Care Pathways

**Version 1.0 (final)**

**8 August 2005**

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<td>NPfIT</td>
<td>Comms &amp; Messaging</td>
<td>Tim Jones</td>
<td>Margaret Baldock</td>
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**Version No**

1.0a
Care Pathways

Amendment History:

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<tr>
<td>1.0</td>
<td>8/8/05</td>
<td>Tim Benson</td>
<td>Revision</td>
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<tr>
<td>0.5</td>
<td>1.3.05</td>
<td>Tim Benson</td>
<td>Includes comments from CRUK</td>
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<tr>
<td>0.4</td>
<td>11/2/05</td>
<td>Tim Benson</td>
<td>Revised order and Discussion</td>
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<tr>
<td>0.3</td>
<td>4/2/05</td>
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Management Summary

Care pathways are one of the core elements of the NPfIT and are needed to support the vision of consistent and personalised care, by providing patient information and evidence-based knowledge wherever and whenever it is needed, giving benefits to patients, clinicians and managers. Electronic care pathways provide a means of supporting the practice of evidence-based medicine across all disciplines, but their introduction may involve significant changes to existing processes and needs to take account of local factors.

The terms used in discussing care pathways are defined. These terms include Guidance, Clinical Protocol and Care Pathway, as well as prefixes (uni-disciplinary, multi-disciplinary, cross-specialty and cross-sector) and suffixes (template, in use and ended).

A care pathway in use is logically part of an identified patient record, while a care pathway template is not linked to any individual patient - it is general clinical knowledge. Care pathways and their components may be located either inside or outside an individual patient record. This implies two logical repositories – patient care record and knowledge library. User interfaces provide views into these repositories.

This report reviews a number of tools, which have been proposed to facilitate the development of electronic care pathways. These are: PROforma, the Map of Medicine, BPMN and the HL7 Version 3 Clinical Statement Pattern.

PROforma is a guideline specification language, developed by Cancer Research UK (CRUK), which specifies each decision in terms of any number of candidate options and the arguments for and against each candidate. Each candidate is evaluated in terms of the available evidence for and against it. Decisions are contained within plans, which may also specify actions to be done and enquiries, which obtain evidence. PROforma is a declarative language, focussing on what is or is not known about the patient, as opposed to procedural languages that focus on the sequence in which tasks are carried out. In this way PROforma reflects clinical practice. PROforma has been developed over the past 12 years and an impressive body of published evidence has been accumulated, which demonstrates its practical value. PROforma is a platform-independent language, which at present has two platform-specific implementations (Infermed's Arezzo and CRUK's Tallis).

The Map of Medicine is an online clinical knowledge browser that provides desktop access to a wide range of specialist clinical information and evidence-based practice. The Map of Medicine is platform-independent and can be localised to meet local needs.

BPMN (Business Process Modelling Notation) is a new standard for business process modelling. It is now part of the OMG (Object Management Group). It provides facilities for documenting events, such as triggers, and for decomposing processes into sub-processes and tasks.

The HL7 Version 3 Clinical Statement Pattern is the model used for all clinical messages, including the exchange of patient records, in the NPfIT. Preliminary analysis suggests a fit between the needs of care pathways and the HL7 Clinical Statement Pattern, but this has not been demonstrated in practice and requires further work to identify issues and document recommendations.

The use of these tools is illustrated using two simple examples: GP referrals for possible colo-rectal cancer, and the triple assessment process for breast cancer diagnosis.
1 Why Care Pathways are Important

Care Pathways are one of the core elements of the NHS Care Record Service. This discussion is confined to electronic rather than paper-based care pathways. Electronic systems overcome the limitations of time and space, and the information may be rendered in the way best suited to the user’s needs. However, most practical experience in using care pathways is based on the limitations of paper documents, where any document can only be in one place at any time.

The NPfIT Output-based specification states:

*Care pathways are essential to support the service changes envisioned in the NHS Plan and GMS Contract. This functionality is needed to support the role of GP specialists and intermediate care teams in providing integrated care to patients.*

The same source lists the desired benefits and outcomes of care pathways:

**Benefits for Patients:**
- Improved organisation and continuity of care
- Avoidance of duplication of effort
- Involvement of the patient in the planning of care
- Use of evidence-based, locally-agreed best practice
- Provision of integrated services from more than one organisation
- Provision of a “manager” to monitor and record progress against a care pathway/plan
- Receipt of a printed or electronic copy of own care pathway/plan

**Benefits for Clinicians and social care professionals**
- Availability of patient’s record on-line for viewing
- Capture of clinical terminology and codes to improve quality and aid subsequent analysis
- Availability of the most up-to-date guidelines and best practice
- Ability to feed into the development process to provide continual improvement
- Ability to monitor progress along a care pathway
- Ability to measure deviance from a care pathway with reasons for that deviance
- Ability to integrate local and national standards
- Ability to document by exception

**Benefits for Managers**
- Improved ability to plan and measure the use of personnel and resources
- Ability to measure the difference between planned and actual care
- Delivery of more standardised care, linked to protocols and treatment plans
- Redesign of healthcare delivery made possible, thereby avoiding safety and quality risks posed by existing outmoded ways of working
- Ability to continually improve care pathways
- Ability to document by exception

Care pathways are a key enabling technology for the Care Record Development Board’s vision of “consistent and personal” care. Furthermore they provide a mechanism for the practical implementation of evidence-based medicine (EBM) throughout the NHS.

The intention of the NPfIT is that the National Library for Health (NLH) provides the evidence component with access through the Map of Medicine, which is an online clinical management tool that provides desktop access to specialist clinical knowledge and evidence-based practice. The Map of Medicine is discussed further in section 6 below.

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1 NPfIT Integrated Care Record Service, Part II LSP Services, Output Based Specification, Second Iteration, August 2003, section 105, page 72. [pdf]
2 [http://www.mapofmedicine.com](http://www.mapofmedicine.com)
2 Evidence-Based Medicine

Evidence-based medicine (EBM) has developed rapidly over the past 15 years. This section provides a short summary of EBM, which illustrates the central difficulty faced by clinicians in making decisions about the care of individual patients in matching the situation of individual patients with the great mass of medical knowledge. Care pathways provide a means of supporting the practice of EBM across all disciplines.

EBM is defined as:

The conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine requires the integration of individual clinical expertise with the best available external clinical evidence from systematic research and our patient’s unique values and circumstances. 3

A recent editorial in the BMJ summarised that:

Evidence based medicine’s biggest future challenge is one of knowledge translation, ensuring that clinicians base their day-to-day decision making on the right principles and on current best evidence. All too often clinicians are unaware of the available evidence or fail to apply it. Because clinicians’ values often differ from those of patients, even those who are aware of the evidence risk making the wrong recommendations if they do not involve patients in the decision making process. 4

Sackett and colleagues describe the practice of EBM in five steps 5:

1. Convert our need for information (about prevention, diagnosis, prognosis, therapy, causation etc.) into an answerable question
2. Track down the best evidence to answer the question
3. Critically appraise the evidence for validity and applicability
4. Integrate the critical appraisal with our clinical expertise and our patient’s unique biology, values and circumstances
5. Evaluate our performance.

The first step is to identify the answerable questions 6. There are two main types of question:

1. Background questions, when we have limited knowledge of the subject. These usually begin with a question root (who, what, where, when, how, why), followed by a verb and a disorder, e.g. “what causes babesiosis”? 7
2. Foreground questions asking for specific knowledge about managing patients with a disorder. These questions are usually specific to a patient’s problem, intervention (treatment, test, exposure, perception etc), comparison interventions (if relevant) and clinical outcomes of interest.

These questions can be grouped into ten central issues in clinical work 8:

1. Clinical findings – history and physical examination
2. Aetiology – causes of disease including iatrogenic forms
3. Clinical manifestations – how often and when a disease causes clinical manifestations
4. Differential diagnosis – possible causes (likely, serious and responsive to treatment)

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5 Sackett D et al. op cit, pages 3-4.
6 Sackett D et al. op cit, Chapter 1 pages 13-27
7 Babesiosis in humans is a rare, potentially fatal disease that is caused by the Babesia parasite and transmitted by the bite of an infected tick. Babesiosis occurs mainly in coastal areas in the northeastern United States.
8 Sackett D et al. op cit Table 1.2, page 19
5. *Diagnostic tests* – selection and interpretation of tests to confirm or exclude a diagnosis
6. *Prognosis* – likely clinical course and possible complications
7. *Therapy* – appropriate treatments
8. *Prevention* – risk factors and screening
9. *Patient experience and meaning* – empathy with the patient’s situation

This simple classification of types of clinical question could be used to classify access to answers in electronic knowledge tools, such as Map of Medicine, using appropriate icons or colour codes.

Detailed advice of a general in guidance needs to be tested for any “killer Bs” that make the instructions locally impractical. The killer Bs are:

- **Burden** – is the frequency too low to warrant action?
- **Beliefs** – do the risks outweigh the benefits?
- **Bargain** – are there better uses of our resources?
- **Barriers** – are there insurmountable barriers (geographic, organisational, traditional etc) to adoption?

The distinction between the evidence base for guidance and the obstacles to implementing them in any organisation (the killer B’s) is the same as the distinction between national guidance, such as that produced by NICE, and a local protocol. Problems and issues of integrating recommendations with the values and preferences of individual patients give rise to another important distinction between protocols and personalised care pathways (see section 3, below).

In her survey of implementing evidence-based findings, Greenhalgh notes that “standard issue” guidelines and protocols and didactic education are usually ineffective, while high quality, computerised decision support and interactive hands-on education are much more effective.\(^9\)

3 Definition of Terms

Three basic terms, Guidance, Clinical Protocol and Care Pathway have already been used above. These are defined in this section. Each of these may be qualified by prefixes and suffixes.

3.1 Guidance

Guidance is a systematically developed statement designed to assist practitioner and patient on decisions about appropriate health care for specific clinical circumstances. It is an evidence-based recommendation for the treatment of a particular problem focusing on what should be done and why. Guidance is not specific to any particular organisation (or patient). NICE (the National Institute for Clinical Excellence) produces guidance.

The term “guidance” is used, rather than “guideline”, in part because this is the term adopted by NICE, and in part because guideline is often used as an umbrella term for guidance, clinical protocol and care pathway.

3.2 Clinical Protocol

A Clinical Protocol is an agreed statement about a specific issue, with explicit steps based on guidance and/or organisational consensus. A protocol is not specific to a named patient but is usually specific to an organisation. It is locally owned.

3.3 Care Pathway

A Care Pathway maps out a pre-defined set of activities and/or choices within a specified scope, which may be applied to one or more issues or problems. It defines what should be recorded about the care delivered in such a way that variance between proposed and actual care can be audited and local practice refined accordingly. A care pathway may specify the goal and/or expected outcome, the data required, decisions and choices that may be appropriate (with supporting arguments) and actions to be carried out, when and by whom. A care pathway may reference guidance or protocols.

In this paper the term “care plan” is not used. This is because the term is used in different contexts to mean different things and also because the definition of care pathway is sufficiently broad to cover most uses of the term.

3.4 Prefixes and Suffixes

Prefixes and Suffixes are used as qualifiers of these basic terms to clarify just what is meant in different contexts.

Prefixes include:

- **Uni-disciplinary** limits to a single clinical discipline. Usually the name of the discipline will be substituted (nursing, physiotherapy, anaesthesia etc)
- **Multi-disciplinary** may cover more than one clinical discipline (e.g. nursing and physiotherapy)
- **Cross-specialty** covers more than one clinical (medical) specialty (e.g. cardiology and rehabilitation)
- **Cross-sector** covers may cover more than one care sector (primary, secondary, community or social services). It implicitly involves more than one organisation.

The prefix “integrated” (as in integrated care pathway or ICP) is not used here, because there is no consensus about what the integrated is meant to mean. It is better to use one of the more precise prefixes above.

Suffixes include:

- **Template** is not assigned to a specific patient; Templates are for multiple use (e.g. care pathway template). Templates are not part of the patient record.
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Note that the NCRS OBS uses the term "model care pathway" to mean the same as a care pathway template, but the term 'template' is preferred.

- **In Use** means active and assigned to a specific patient (e.g. care pathway in use). A care pathway in use is a snapshot of an active care pathway assigned to a specific patient and brings together information from the care record with that from the associated care pathway template. Care pathway in use may also show relevant patient preferences, allergies and comorbidities as well as variances and exceptions.

- **Ended** means closed and assigned to a specific patient (e.g. care pathway ended). The care pathway ended may be used for variance analysis and audit. Care Pathway Ended is the final stable point of a patient care pathway, when the care pathway has been completed, abandoned or discarded, or the patient has died. This provides a set of data for local and national audit, clinical governance and analysis.

Figure 1 shows that guidance informs both clinical protocols and care pathway templates. Care pathway templates are also informed by clinical protocols. In UML (Unified Modelling Language), a care pathway in use is a specialisation of a care pathway template, including (amongst other attributes) a patient identifier and the start time. The care pathway ended is a specialisation of care pathway in use, including the end time.

![Diagram of relationship between Guidance, Clinical Protocol and Care Pathways](image-url)
4 Architectural Aspects of Care Pathways

4.1 Integrating Patient Records and Knowledge

When discussing concepts, such as care pathways, we need a common framework or architecture to provide appropriate points of reference.

Writing in 1996, Richard Smith predicted that:

"The doctor's information tool of the future might be some sort of combination between the patient record and the Internet, with the doctor and the patient positioned together at the intersection but not having to pay attention to the technology."

A care pathway in use is logically part of an identified patient record, while a care pathway template is not linked to any individual patient - it is general clinical knowledge. This implies two logical repositories – patient care record and knowledge library (Smith’s Internet). The user interface provides views into these repositories.

The requirement about not having to pay attention to technology is reinforced by James:

"To be widely accepted by practicing clinicians, computerized support systems for decision-making must be integrated into the clinical work-flow. They must present the right information, in the right format, at the right time, without requiring special effort. In other words, they cannot reduce clinical productivity. They cannot require physicians to learn to use a series of disconnected computer systems and must not be at odds with physicians' concept of the medical record or sense of autonomy in decision-making."

The NHS Care Record Service can be considered in terms of (1) the patient care record, (2) the knowledge library and (3) views into both the care record and knowledge library. These three perspectives are supported by infrastructure that provides access control, messaging and communication tools, to present authorized users with the right information, in the right format, at the right time, without effort.

4.2 Patient Care Record

The patient care record documents the care process for a patient and includes information about past care events and future activities, which are planned or scheduled.

The patient care record is made up from care record elements, which are the fundamental building blocks of the patient care record, and relationships between care record elements within the record and with any external sources.

Care record elements are specific to an individual patient and include records of what is done and what is proposed for that patient, including data collection, assessment, procedures, goals, plans, review, outcomes and evaluation.

The relationships between care record elements include links between different care record elements within a patient care record as well as links from care record elements to components in the knowledge library or elsewhere.

4.3 Knowledge Library

The Knowledge Library is the repository of medical knowledge available. The Knowledge Library holds a wide range of information, which is not specific to an individual patient, including templates for care pathways, knowledge, decision-support and terminology services.

In this report, atomic (indivisible) artefacts in the knowledge library are referred to as components, while artefacts in the patient care record are referred to as elements.

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Care Pathways

4.4 Views
Clinical users work with seamless Views into both the patient care record and knowledge library, to enable the care of individual patients as well as aggregate reports for multiple patients. Access to patient information is through a view.

An individual patient view is specific to a particular patient (subject of care). Types of individual patient views include problem, care pathway, task list, medication, clinical chemistry, encounters and so on.

A population view is a report pertaining to a specific population of interest.

Each View is a snapshot for a particular purpose of the patient care record(s) and associated templates (from the Knowledge Library); it is specific to the time at which it is created and is only available to appropriately authorised individuals.

Any real EHR system supports a large number of standardised and configurable views. Every screen display and printed report is an instance of a view.

4.5 Care Pathways
A care pathway, as defined above (3.3) is a type of administrative procedure, which may be initiated by a Health Care Professional or triggered by computer software. Once assigned to a patient it becomes a care pathway in use, which is recorded in the patient record.

Each record of a care pathway in use includes the identity of its parent template as well as who initiates it, when, where and (optionally) why. At a finer level of granularity, each instance of a patient record element may be linked to one or more care pathway template components.

The components of the parent care pathway template, which are not specific to an individual patient, normally remain in the knowledge library and only patient-specific references, variances and data are entered as elements of the patient care record.

It is important to recognize that care record elements and template components both need to have the same logical structure in order to allow the same statement to be either in the knowledge library, if it is of general applicability, or in the patient care record, if it applies only to this patient. For example, a conditional statement, such as “if serum ferritin is less than 20, treat for iron deficiency anaemia”, could be found in a care pathway template or in a specific patient record.

The next part of this report provides a brief summary of four technologies which may prove to be valuable in the implementation and deployment of electronic care pathways throughout the NHS. These are:

- The PROforma guideline modeling language
- The Map of Medicine
- Business Process Modelling Notation (BPMN)
- HL7 Version 3 Clinical Statement Pattern.
5 The PROforma Language

PROforma is a specialised language, developed by Cancer Research UK (CRUK) over the past decade for representing the structure and content of guidance, protocols and care pathways in a form that can be interpreted by a computer.

The focus of the PROforma language is on clinical decisions; it specifies decisions in terms of candidate options and arguments for and against each candidate. Each candidate is evaluated in terms of the available evidence for and against it.

PROforma is a declarative language, processing what is or is not known about the patient at any one time. This is in contrast to procedural languages that specify the sequence in which tasks have to be done. In this way PROforma reflects clinical practice.

PROforma has both a strong theoretical base\(^ {12}\), which leads to reliability, and substantial field experience, which has produced an impressive evidence base, documenting how the method and technology have been used and evaluated in clinical applications:

5.1 Evaluation of PROforma

PROforma is essentially a platform-independent language, which, to date, has two platform-specific implementations (Arrezzo and Tallis). Each implementation has been used for a number of applications.

In general practice, evaluated applications include:

1. CAPSULE\(^ {13}\) - this early evaluation of PROforma describes evaluation of computer assisted prescribing using simulated cases. In this in vitro study of 42 general practitioners, the participants tended to pick drugs from the computer’s list of suggestions, resulting in a 30% improvement in the number of times that most cost-effective drug was used; furthermore the doctors prescribed more quickly with the decision support system.

2. RAGs\(^ {14}\) - this project evaluated the potential for using computer assistance for risk assessment of genetic factors in interpreting family histories of breast and ovarian cancer in primary care. As with CAPSULE, this was a comparative study using simulated cases. 36 GPs took part and it was found that RAGs led to significantly more appropriate management decisions and more accurate pedigrees although it took almost 50% longer (3 minutes rather than 2 minutes by hand). It was also greatly preferred (92% of GPs preferred using RAGs against 3% who preferred pen and paper.

3. ERA\(^ {15}\). Early referral application is an application of PROforma to assist GPs decisions in referring patients for suspected cancer. This was trialled by four groups of GPs and hospitals in Leicester, Southampton in parallel with two groups in Chichester and Aintree which used electronic referrals without decision support. The findings from the pilots support the view that electronic processing of referrals will speed the referral process and improve data quality. Favourable comments were made about the benefits of (PROforma) decision support, although the evaluation did not specifically address this issue.

In secondary/tertiary care, evaluated applications include:

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\(^{13}\) R T Walton, C Gierl, P Yudkin, H Mistry, M P Vessey, and J Fox. Evaluation of computer support for prescribing (CAPSULE) using simulated cases. *British Medical Journal*, Sep 1997; 315: 791 - 795. [html](http://www.bmj.com/content/315/7059/791)


\(^{15}\) NHSIA. Electronic Piloting of Referral of Patients with Suspected Cancer – Pilot Evaluation Report Version 1.0 Final, April 2002. [pdf](http://www.bmj.com/content/321/7262/28)

1. Retrogram (HAVANA Trial)\textsuperscript{16}, the Retrogram® system is a PROforma application developed by InferMed for Hoffman la Roche. Retrogram advises on the use of anti-retroviral therapy for HIV+ patients and is in use with more than 250 clinicians worldwide. The HAVANA multicentre trial (Tural, AIDS 2002) has shown that availability of genotype information significantly improves clinicians’ decision-making as measured by viral load, but with Retrogram providing genotype interpretation and decision support services one third more patients’ viral loads were reduced to the target level.

2. LISA\textsuperscript{17}, LISA is a PROforma system for advising on dose adjustment in treatment of children with acute lymphoblastic leukaemia. The first full trial (on retrospective cases) showed that without decision support clinicians deviated from the trial protocol on 37% of occasions but with support this dropped to zero. 35/36 of the clinicians said they would use LISA if it were routinely available.

3. REACT\textsuperscript{18} (Risks, Events, Actions and their Consequences over Time) is a decision support system, which is being tested in complex areas such as the management of patients with complex long-term problems, such as those with a high genetic risks of breast cancer or Type II Diabetes. It provides the clinician with immediate feedback about constraints, interactions and dependencies on and between treatment actions and possible outcomes of proposed plans.

4. CREDO\textsuperscript{19}, is concerned with developing a general model for cancer care pathways, and possibly other long-term and chronic conditions. The CREDO trial is modelling all the decisions in the journey(s), from initial presentation through workup, treatment and long term follow-up (about 65 decisions!). Triple assessment covers 4 decisions (detail of family history, type of imaging, type of biopsy and final diagnostic decision).

It is noteworthy that PROforma has been the subject of more evaluations, which have provided quantitative outcome data, than any other decision support technology; these evaluations have involved a wide range of participants (not just the original inventors); and that these evaluations are positive, without exception. This demonstrates that in an immature and rapidly developing field, PROforma is a relatively successful technology.

5.2 Tasks

The high-level structure of PROforma is simple. Everything is a task, and there are four specialised types of task: Plan, Decision, Enquiry and Action. \textsuperscript{20}

Plans are sets of tasks to be carried out to achieve a clinical goal. Plans are the basic building blocks of a guideline, protocol or care pathway and may contain any number of tasks of any type, including other plans, usually with an ordering imposed.

PROforma makes explicit and evaluates choices between different Decisions, based on evidence available and arguments supporting each one. Decisions are the choices made by clinicians to do one activity rather than another. Each decision involves the evaluation of one or more candidates, each of which may have arguments for and against, including the level of that support and any conditions. The overall recommendation may be based on the net support from all candidates or more complex methods (e.g. Bayesian methods) may be used. Decisions may execute automatically, without human intervention, or in response to a user command. The evaluation uses data derived from enquiries.

\textsuperscript{17} Bury et al a “A quantitative and qualitative evaluation of LISA, a decision support system for chemotherapy dosing in childhood Leukaemia” Proc. Medinfo 2004. pdf
\textsuperscript{18} Glasspool, DW, Fox J, Castillo FD, Monaghan V. Interactive decision support for medical planning. In: Proceedings of the 9th Conference on Artificial Intelligence in Medicine in Europe (AIME’03), 18th - 22nd October, Protaras, Cyprus. pdf
\textsuperscript{19} CREDO: a clinical trial of PROforma technology in improving consistency, quality and safety in the care of cancer patients. pdf
Care Pathways

Enquiries and Actions are the places where PROforma interacts with the outside world, either to get information (Enquiry) or to do something (Action). Each Enquiry may involve multiple sources and data definitions. Each Data Definition may be Boolean, Integer, Real, Text or an enumerated list of Text values (Range). Actions may be undertaken by people or by computer systems. The specification of links to and from other computer systems is one area where PROforma needs to be enhanced to reflect new standards in patient record architectures, SNOMED, HL7, ontologies and business process enactment.

5.3 Scheduling
PROforma has a rich set of mechanisms for scheduling tasks in sequence or in parallel, running automatically as background monitors or in response to event triggers, state triggers, user commands and preconditions.

Scheduling constraints are shown as arrows between tasks in a Plan and indicate that a task (or plan) cannot start until the previous task has completed.

Any Task may have the following attributes used for scheduling:

- Triggers – conditions which will initiate a task
- Pre-conditions – conditions necessary before a task may be started
- Wait conditions – conditions (in addition to pre-conditions) necessary for a task to execute
- Automatic, manual or repeating execution for a number of repeats or until a goal is reached
- Post-conditions – conditions true on task completion

The facilities that allow multiple decisions (and enquiries) to open and close automatically in the background is particularly important in providing useful clinical decision support without being obtrusive.

5.4 Tools
PROforma requires a set of supporting tools that support the whole lifecycle; these include a graphical editor (Composer), which supports the creation, editing and graphical visualisation of PROforma programs (guidelines); an execution engine, which enacts guidelines for testing purposes and for implementation, and a repository, which is a web-based repository of templates and PROforma components, allowing reuse.

There are two main implementations to date (Arezzo and Tallis). Infermed’s Arezzo is a Windows-based product. CRUK’s Tallis suite delivers web-based services enabling platform-independent applications, which can integrate with other components, including third party applications. Tallis Publisher, based on Java Servlets, allows guidelines to be published and enacted over the Internet. These are called “publets”.

The structure of this description of PROforma is summarised as a mind-map in Figure 2.
Care Pathways

Figure 2 PROforma mind map
5.5 A PROforma Example

The following example shows how PROforma can be used to handle a very simple example. Figure 3 shows a PROforma Composer screen for this example. The tree view of the guideline is on the left, and the main screen shows the tasks contained in the top-level plan. The detailed content of each task is not shown in this view. Note that the icons are not linked by scheduling constraint arrows, which means that the order in which the tasks are carried out is not constrained.

Figure 3 PROforma Composer Example

The same pathway is shown in Figure 4 enabled as a Publet (in plan view), running in a web browser. The left hand column displays the active tasks (in this case, just Introduction) and three triggerable tasks (In-depth history, Moderate history and Basic history), which can be made active by clicking on them.

Figure 4 PROforma Publet Enactment
5.6 PROforma Developments

PROforma is a powerful and proven system for clinical decision support, which takes account of the way that clinicians work. It is just one potential component of a suite of tools that need to work together seamlessly. Some of these components such as Business Process Modelling Notation, Map of Medicine and the HL7 Clinical Statement Pattern are described further in this paper. Others such as SNOMED CT and OWL also warrant mention.

The PROforma development team have proposals to enhance the present system to include:

1. Enhancement to the Enquiry and Action functionality to facilitate getting and putting information from and to patient care records using web services and similar technologies.

2. XML output in addition to the existing text specification of each guideline

3. Links within decisions (candidates and arguments) and actions to clinical knowledge using specialised browsers such as Map of Medicine (see section 6).

4. Links within the enquiry task to read data from electronic healthcare records (EHR); and in the action task to write to EHR. These links could use a standard virtual medical record structure, based on the HL7 V3 Clinical Statement (see section 8).

5. Scheduling constraints using standard workflow notation such as BPMN (see section 7).
6 Map of Medicine

The Map of Medicine® is an online clinical knowledge browser that provides desktop access to specialist clinical knowledge and evidence-based practice across primary and secondary care, working in partnership with the National Library for Health (NLH).

The product is web-based and can be accessed from any computer. The user interface, shown below in Figure 5, uses a simple consistent notation, so that people can use the Map with little or no training.

Figure 5 Map of Medicine user interface

The Map of Medicine provides a way for users to navigate to the appropriate National Library of Health (NLH) knowledge bases from within the National Care Record Service (NCRS).

Current uses for the Map include:

21 www.mapofmedicine.co.uk
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- Supporting appropriate choice of investigations and treatment and whether to refer to other professionals (the Map includes referral forms).
- Informing clinicians about local protocols within the context of national guidance.
- Enabling informed patient choice of treatments and access to services.
- Supporting continuing medical education.

The Map represents best practice that has been distilled from guidance (e.g. from NICE), clinical protocols and clinical evidence; it is organised into over 300 "patient pathways" spanning: A&E, medicine, obstetrics, gynaecology, oncology, palliative care, paediatrics, radiology, surgery and mental health.

Each page and node in the pathway may have supporting contextual information and is an access point to NLH and third party guidance, evidence, research, and patient resources, as shown in Figure 6. This supports the practice of evidence-based medicine (EBM).

![Figure 6 NLH while browsing the Map of Medicine](image)

**6.1 Structure**

Within the Map, a Pathway is a collection of Pages representing possible patient journeys from a specific starting point, which may be a clinical presentation, or a suspected or confirmed diagnosis.

Each Page is a collection of Nodes linked together by connectors in a tree-like structure that generally flows downwards. A Page represents a logical stage within a pathway.

A Node is a possible step in the care of a patient, represented by a coloured shape containing text. The type of activity represented by a Node (decision, action etc) should be clear from the text and the

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22 In the terminology used in this report, the Map of Medicine provides knowledge about Guidance and Clinical Protocols, but not Care Pathways because the information is generic and is not specific to a named patient.
Care Pathways

relationship of the Node to other Nodes on the Page. A Node may optionally be linked to contextual information, an action (e.g. referral), and/or another Page in the Map.

Connectors are lines that link a Node to one or more other Nodes. When a line connects two Nodes, the lower Node will typically follow the upper Node in the treatment of a patient. An arrow on a connector (directional connector) indicates any shortcuts or flows “up” the Page.

Contextual Information about a particular pathway or pathway component can be made up of backing text and knowledge links.

Any component can be associated with one or more SNOMED-CT codes, and this provides a basis for linking to and from third-party evidence and resources, and in the future, patient records.

Access the appropriate pathways and pages is via:

- Free-text searching,
- Browsing through a hierarchical classification by specialty,
- Selecting from an alphabetical index,
- In future, it is planned to provide “infobutton” and web services to deliver map content appropriate to specific clinical contexts from within clinical applications.

6.2 Localisation

The Map can be localised to reflect Local Health Community (LHC) practices using the Graffiti methodology. Map content is updated through an easy to use Content Editing tool. At present editing has to be done centrally, but there are firm plans to provide a suite of editing and version control management tools which will empower appropriate local users to localise the Map themselves. This suite has two components: one for content management, and another for page and node editing.

- The Content Management tool enables local users to manage the production, review and publication of local releases Figure 7.
- The Page and Node Editor enables local users to create, edit and review pages, nodes, links and backing text Figure 8.

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23 The Graffiti method brings together a group of clinicians (clinical reviewers) from the LHC, including primary and secondary care clinicians and from a multidisciplinary scope. As a group, they review and debate the clinical and administrative content of new or existing Map pathways, culminating in consensus on the content of localised pathways. A scribe captures comments during the session, and the agreed changes are then incorporated to the Local version of the Map by Medic-to-Medic staff. Experience in pilots has shown that, providing the right individuals are present and prepared, the process is well-organised, and reference material is provided where required, the process of review and agreement takes less than a day per specialty.
Figure 7 Prototype interface for Map of Medicine Content Management Tool
6.3 Development

The Map of Medicine is a user-friendly and content-rich clinical knowledge browser. Two main areas of technical development are:

1. Provision of an web service and info-button interfaces to enable direct human-readable access to clinical knowledge from clinical or decision support (and care pathways) systems using SNOMED CT terminology.

2. Tools to enable the localisation of guidelines (see above).

In addition there is an enormous and on-going development effort to maintain the quality and quantity of the clinical content, given the scope of its remit.
7 Business Process Modelling Notation (BPMN)

Business process modelling tools have been designed to describe the procedures used to deliver products or services on a repetitive basis, where it is appropriate to specify the “best” way to process each item in a common way. Some aspects of medical care fall into this category, but others, such as clinical decision making do not. Clinical processes are particularly difficult to model with existing tools, in part because they are inherently complex, but more importantly because each patient is different and each clinician may adopt a variety of different paths, depending on the specific clinical situation of the individual patient. This requires more business process specifications that take account of the full range of choices that clinicians have open at any one point in time.

BPMN (Business Process Modelling Notation) is a notation for documenting both simple and complex business processes. The BPMN notation is understandable by end users, but it is also capable of including the technical detail needed to specify messages involved in web services delivery and the generation of XML-based Business Process Execution Language (BPEL). BPMN is now part of the Object Management Group (OMG), which is also responsible for UML (Unified Modelling Language).

7.1 Why use BPMN?

BPMN is a standard for business process modelling with a notation that is similar to that used in UML Activity Diagrams. Some commentators regard the future of BPMN as a specialised “front end” to UML.

BPMN has several advantages over standard UML activity diagrams:

1. Shows explicitly who does what, where and in what sequence using the Pool and Swim-lane notation, distinguishing between messages which flow between actors from the flow of activities by a single actor or team.
2. Explicitly shows trigger events, delays and messages that precede or follow on from each activity
3. Allow drill down of sub-processes into greater detail of activities and tasks
4. Provide additional structured and/or free text documentation for any element.
5. Executable output, using Business Process Execution Language (BPEL), an XML-based language, which has industry support from Microsoft, IBM etc.

Most experience and documentation of the use of BPMN is to describe complex repetitive activities, such as web services orchestration for e-commerce applications. Initial assessment suggests that BPMN may be suitable for the sort of non-procedural processes used in clinical decision-making, but we found no published evidence or examples of this sort of use.

7.2 Activities

Activity is the generic term for Business Process, Process, Sub-Process and Task. These have a hierarchical relationship. To use an analogy: a business process is a group of one or more trees; a process is a single tree; a sub-process is a branch (and may have further sub-branches, sub-sub-branches and so on); task is a leaf, which is not subdivided further.

Business Process. Business Process is the top of the Activity hierarchy in BPMN. It is defined as a set of activities that are performed within an organisation or across organisations, shown on a Business Process Diagram (BPD).

Process. Process is limited to the activities undertaken by one Participant (organisation or role). Each Business Process may contain one or more Processes. A Process is an activity performed within an organisation, and is depicted as a set of activities (Sub-Processes and Tasks) contained within a single Pool (see below).

Care Pathways

**Sub-Process.** Each Sub-Process may be expanded as a separate, linked diagram, showing its component Sub-Processes or Tasks. The facility to expand or consolidate Sub-Processes is a useful feature of BPMN.

**Task.** A Task is an atomic activity, showing that the work is not broken down to a finer level of detail. Sub-Processes and Tasks are shown as rounded rectangles. Sub-Processes, which can be expanded, are shown with a "plus sign" at the bottom centre of the icon.

The relationships between these artefacts is shown in Figure 9 as a UML class diagram.

![Figure 9 BPMN Processes and Tasks](image)

### 7.3 Pools, Events and Connectors

Participants are each represented by a **Pool**, which may contain **Lanes**. Each Pool contains a single Process. A Pool may be subdivided into Lanes (like swim lanes in UML activity diagrams). Lanes may represent different roles within an organisation. If a diagram contains a single Pool, the Pool boundaries need not be shown. A Pool is a container separating each Process from others and showing the Sequence Flow between activities.

Shown as a small circular icon, an **Event** is something that happens during the course of a business process that affects the flow. Events may represent triggers for activities to begin or their outcomes. Start, Intermediate or End events are indicated by the thickness of the circle perimeter. An additional icon inside the circle shows the type of Trigger or Result (Message, Timer, Error, Cancel, Compensation, Rule, Link, Multiple or Terminate).

A **Gateway**, shown as a square diamond, is used to control branching, forking, merging and joining of paths. An icon inside the diamond shows the type of control (exclusive XOR, inclusive OR, parallel AND or complex).

**Connectors** link the flow objects (Activity, Event and Gateway). There are three types of Connector:

- **Sequence Flow** (a solid line with arrow head) shows the order that activities are performed within a Process.
- **Message Flow** (a dotted line with arrow head) shows connections between Processes (crossing the boundary of a Pool).
- **Association** (dotted line, no arrow head) is used to associate information (such as Data Objects) and Annotations with Flow Objects.
7.4 Business Process Example

A complete business process from start to finish is shown in Figure 10, which illustrates the traditional OP referral pattern (not using 14-day Appointment or Choose and Book) for a patient suffering from a bowel problem.

The Pools and Lanes show clearly who does what in what order. The dotted lines represent movement of information (messages) or of information sources (e.g. the patient).

Each of the tasks shown might better be represented as sub-processes and analysed further in subsequent diagrams. Clinical care is essentially fractal and can usually be decomposed into smaller and more detailed sub-processes and tasks.

Trigger events are shown as circles, with an icon indicating the type of trigger – an envelope indicates a message and a clock indicates a time trigger, such as an appointment slot.

Figure 10 Traditional OP Referral for Bowel Problem
8 HL7 Version 3 Clinical Statement

The NPfIT has adopted the HL7 Version 3 Clinical Statement\(^{25}\) as a common pattern for the development of all types of clinical messages, used for the exchange of information between different computer systems. The same pattern is used for complex messages, such as the exchange of complete electronic patient records between GPs using different systems, and also for simpler messages, such as prescriptions.

HL7 defines a Clinical Statement is defined as "an expression of a discrete item of clinical (or clinically related) information that is recorded because of its relevance to the care of a patient. Clinical information is fractal in nature and therefore the extent and detail conveyed in a single statement may vary"\(^{26}\).

Any clinical statement may have a number of participants, including subject, author, location, performer, participant and informer.

Each clinical statement is one of the following specialisations:

- Observation, which may refer to specimen(s) and reference ranges. Observations cover a very broad range of statements relating to history, examination, tests, diagnosis and prognosis
- Substance Administration or Supply, which may refer to products such as medication and are mainly used for prescribing, dispensing and administration of drugs
- Procedure, which may refer to a specimen(s) or images and is used for all invasive procedures including surgical procedures and imaging
- Encounter, which covers most administrative procedures including appointment scheduling and waiting list management
- Consent

Several types of associations between clinical statements are provided such as containment, cause and effect, problem linkage etc.

Two of the main differences (simplifications) between the NPfIT clinical statement and the generic HL7 clinical statement is that the NPfIT assumes the availability of a national care record system infrastructure and that SNOMED CT coding will be used.

In principle, both care record elements in the patient care record and the components of care pathway templates in the knowledge library can be treated as refinements of the Clinical Statement Pattern. However, this is only a hypothesis, which remains to be tested.

The HL7 Clinical Decision Support TC and Clinical Guidelines SIG are working on issues related to care pathways, but are not engaged actively in the development of the Clinical Statement Pattern.

The next part of this report shows how these technologies may be applied to two simple examples: Colorectal Cancer referrals, and Breast Cancer diagnosis.


\(^{26}\) HL7 V3 Ballot Pack, Patient Care, January 2005. (www.hl7.org)
9 Colorectal Cancer Referral

9.1 Scope

The first example is for a GP to refer a patient suffering from colorectal symptoms for urgent endoscopy to diagnose or exclude possible cancer. This example uses a two-stage process, based in part on the 2004 NICE Guidance27 and in part on the work of Selvachandran and colleagues at the Leighton Hospital, Crewe, applied to a GP surgery setting28.

The scope is limited to the business process and decision criteria used to make the “two-week possible colorectal cancer” referral decision by the GP in his or her surgery. All other aspects of the problem are out of scope. In particular, the processes used to book the GP and the endoscopy appointments, and consideration of problems other than possible colorectal cancer, are out of scope.

9.2 Background

Colo-rectal (CR) cancer is the second most common cancer, in terms of both incidence and mortality in England and Wales. With about 30,000 cases a year, each GP is likely to come across about one new case each year. Survival is strongly related to speed of diagnosis29 and the research literature shows evidence of delays, often lasting a year or more, between the onset of symptoms of colorectal cancer and diagnosis. This is due to patient delay in reporting symptoms, and to a lesser extent, delays by the GP and hospital. For example, a national survey of NHS patients in 1999/2000 found that 37% had to wait over three months for their first hospital appointment and 13% waited seven or more months.

The 2004 NICE Guidance concludes that streamlining referral systems and improving access to endoscopy are crucial to reducing colorectal cancer mortality, and should be given priority by all levels of the service – primary care, hospital Trusts and Cancer Networks. This example illustrates one way that this recommendation might be implemented.

9.3 Objectives

The primary objectives of the process described here are:

1. Reduce the delay between initial reporting of symptoms and final diagnosis.
2. Reduce the number of cancer cases missed (false negatives).
3. Reduce the number of urgent referrals for endoscopy that are subsequently shown to be free from cancer (false positives).
4. Minimise the work burden on GPs. Any process, introduced to facilitate the early diagnosis of CR cancer, must fit in with the day-to-day work of the GP and the surgery.
5. Reducing the work burden on hospital specialists by cutting out the need for the patient to be seen by a colorectal specialist before booking the endoscopy
6. Avoid extra hospital OP visits for patients.

9.4 Participants and Locations

Referral for possible CR cancer involves not only the direct participants, such as the patient, the GP and practice staff, but other stakeholders, notably the staff at the units to which the patient may be referred, including doctors, nurses, managers and clerks.

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29 Survival is strongly related to speed of diagnosis. Five-year survival is reported (op cit) as:
   - 83% for Dukes Stage A (localised within the bowel wall)
   - 64% for Stage B (penetrating the bowel wall)
   - 38% for Stage C (cancer in Lymph nodes)
   - 3% for Stage D (distant metastases, most often in the liver).
The Patient complains of symptoms and may have cancer. The Patient is the primary source of information about history and symptoms and must be present for physical and endoscopic examinations and diagnostic imaging as well as for providing samples of blood, faeces etc. for laboratory tests.

The second key participant is the GP, who takes the decision of whether or not to refer the patient for Endoscopy. Reception and secretarial staff in the practice may also undertake some tasks. Although CR Cancer is the second most common type of cancer, each GP sees about one new CR cancer patient a year. The incidence of symptoms that warrant detailed assessment is not an every day occurrence, so any tools used to facilitate this need to be unobtrusive. Perhaps a couple of patients a month present with symptoms that warrant further consideration and half a dozen patients a year need to be referred for urgent endoscopy.

Other actors, such as the e-Booking service and the Endoscopy unit, receive outputs from the interaction, but are not involved in the decision of whether or not the patient should be referred.

Although the main interaction takes place at the GP surgery, the patient may not know some of the information at the time and may need to consult relatives about details of family history or crosscheck the dates at which they first complained of symptoms. For these reasons, detailed history may be collected at the patient’s home using a web-based questionnaire. Much of the information used to make this decision is relevant to subsequent care and treatment and may be collected in a form suited for use in a referral letter.

9.5 Outcome

The outcome is a decision of whether or not to refer for urgent (possible cancer) endoscopy. The process can be thought of as two “yes/no” decisions.

1. Does this patient have any CR symptoms that might be indicative of CR cancer, sufficient to warrant more investigation – this “triage” decision is based on the NICE criteria, which include presenting symptoms, physical examination and the patient’s age. If this decision is positive, then take detailed history.

2. The second decision – whether to refer the patient for urgent hospital investigation – is based on a detailed structured history covering: symptoms and presenting history, family history and past medical history. If this is also positive, then refer urgently for endoscopy.

9.6 Storyboard

This section describes a single storyboard, providing a brief description of how the GP referral process might work in the future.

John Reeves is 64 years old. Over the past couple of months he has noticed that his bowel movements have become loose and more frequent. He makes an appointment to see his GP, Dr Ann Price.

Dr Price sees John, takes his history, examines his abdomen and suggests that he complete a detailed Colo-rectal History questionnaire, to be completed at home. John has access to the Internet at home, and the surgery emails John a set of details of the URL for his web-based questionnaire and his instructions.

John completes the form on his computer at home with some help from his wife who reminds him about some details of family history. Next morning, the surgery telephones him to say that the data is complete and asks him to come in and see Dr Price the next morning.

Next morning, he sees Dr Price, who now has the details of his history on her computer screen. The decision support algorithm (run by a PROforma publet) indicates that there is some cause for concern. Dr Price notices this and that the symptoms and history warrant urgent endoscopic investigation.

Patients who cannot use a web-browser can be given a paper questionnaire, which can be scanned or transcribed.
She explains the situation to John and makes a referral to the local Endoscopy Unit via Choose and Book (out of scope). The information collected by the OCR scanner is sufficient to produce a structured referral letter, which Dr Price checks, authorizes and sends.

John is naturally anxious and so Dr Price goes into the Map of Medicine, where it lists the main reasons for referral for possible CR cancer as well as other data. She prints out a copy of the relevant page and gives it to John.

The next day, John is contacted by the Endoscopy Unit and makes arrangements for the test to be done the next week.

Here only one storyboard has been provided, but in any real project a number of storyboards should be developed covering all of the main scenarios.

9.7 Business Process Diagram

The flow can also be shown as a business process diagram using the BPMN notation (Figure 11). This is similar to an activity diagram.

Figure 11 Colorectal Cancer Referral BPMN Diagram

The main locations (GP Surgery, patient’s home and specialist endoscopy unit) are shown as pools. The GP Surgery is subdivided into two lanes (reception and GP consulting room). The rounded rectangles represent separate tasks and the circular icons represent discrete events. The diamond shapes represent decision branches, and the “O” icon inside states that the branches are mutually exclusive (OR). The clock icon represents a time-specific event or delay, while the envelope icon represents a message.

The BPMN notation is a formal notation and the diagram can be exported in XML format.

The evidence and rules used to make these decisions are discussed below. We do not discuss what action to take if the answer to either question is “no”.

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9.8 Data and Rules

There are many possible causes of colo-rectal symptoms and it is important to take note of those combinations of symptoms that may indicate cancer and those which do not. Decision support tools may help in ensuring that the right patients are selected for urgent referral. However, the relatively low incidence of cancer means that any such tool should not be intrusive into normal day-to-day clinical activity.

NICE has listed criteria for urgent referral, based on combinations of symptoms and signs, from which a decision table has been derived (Table 1). Seven questions relate to presenting history, three to physical examination and one each for age and haemoglobin (iron deficiency anaemia).

The decision to refer urgently is based primarily on the patient’s report of his or her symptoms and medical history, the patient’s age, evidence (or lack of it) from physical examination and blood tests (haemoglobin). The eleven decision columns are split between eight high risk and three low risk combinations. Any column is “true” if every item with an “X” in that column are “true” and each item marked “O” is also false. Low risk items are shown as “(X)” to aid clarity.

This set of criteria is used for initial triage. Although about 85% of patients with colorectal cancer meet these criteria (sensitivity), the large proportion of all patients who have these complaints do not have cancer (specificity).

### Table 1 NICE Colorectal Cancer Referral Guidance as a Decision Table

<table>
<thead>
<tr>
<th>History and Symptoms</th>
<th>High Risk</th>
<th>Low Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rectal Bleeding</td>
<td>X X</td>
<td>X O O</td>
</tr>
<tr>
<td>Change in bowel habit to looser stools</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Change in bowel habit to increased frequency</td>
<td>X X</td>
<td></td>
</tr>
<tr>
<td>Change to decreased frequency</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change to decreased frequency and harder stools</td>
<td>(X)</td>
<td></td>
</tr>
<tr>
<td>Symptoms &gt; 6 weeks</td>
<td>X X</td>
<td>X X X</td>
</tr>
<tr>
<td>Anal symptoms (soreness, discomfort, itching, lumps, prolapse or pain)</td>
<td>O</td>
<td>(X)</td>
</tr>
<tr>
<td>Demographics</td>
<td></td>
<td>X X</td>
</tr>
<tr>
<td>Age &gt; 60 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Examination Findings</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Definite palpable right side abdominal mass</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Definite palpable rectal mass</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Abdominal pain without clear evidence of intestinal obstruction</td>
<td>(X)</td>
<td></td>
</tr>
<tr>
<td>Test Findings</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unexplained iron deficiency anaemia</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

An alternative way of showing this is as a mindmap (Figure 12):
A simple PROforma program running in background mode can process this decision table. The outline plan of such a program is shown below, Figure 13. The full text is provided as Annexe 1.

![Figure 13 PROforma Diagram showing Enquiries (diamond), Decision (circle) & Action (square)](image)

This program can be run on a web browser at: http://www.openclinical.org/newkpc/jumpstart.jsp?guideline=tb_public/CRtriage3

### 9.9 Patient Consultation Questionnaire

The final GP decision to refer for urgent endoscopy is based on a much more detailed history covering many more factors, developed by Selvachandran and colleagues. Table 2 shows the questions asked and the relative risk scores for colorectal cancer allocated to each of the major variables.
Table 2 Patient History Questionnaire and Relative Risks (based on Selvachandran)

<table>
<thead>
<tr>
<th>Item</th>
<th>relative risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Have you seen blood from the back passage?</td>
<td>2.71</td>
</tr>
<tr>
<td>If NO go to (2)</td>
<td></td>
</tr>
<tr>
<td>1B Is the blood:</td>
<td></td>
</tr>
<tr>
<td>Seen on Tissue only</td>
<td>0.77</td>
</tr>
<tr>
<td>Separate from stool</td>
<td>3.35</td>
</tr>
<tr>
<td>Mixed with Stool</td>
<td></td>
</tr>
<tr>
<td>Separate and Mixed in Stool</td>
<td>1.98</td>
</tr>
<tr>
<td>Uncertain Separate or Mixed</td>
<td>0.82</td>
</tr>
<tr>
<td>1A State whether the blood is:</td>
<td></td>
</tr>
<tr>
<td>Fresh or bright</td>
<td>1.08</td>
</tr>
<tr>
<td>Old or dark</td>
<td>2.65</td>
</tr>
<tr>
<td>Both Fresh and Old</td>
<td>3.53</td>
</tr>
<tr>
<td>1C When you see blood in stool is it:</td>
<td></td>
</tr>
<tr>
<td>Small amount</td>
<td></td>
</tr>
<tr>
<td>Large amount</td>
<td></td>
</tr>
<tr>
<td>1D How often have you seen blood when opening your bowels?</td>
<td></td>
</tr>
<tr>
<td>Every day, Every few days, Every week, Every few weeks, Every month, Every few months, Only once or twice in the past year</td>
<td></td>
</tr>
<tr>
<td>1E For how long have you seen blood when opening your bowels?</td>
<td></td>
</tr>
<tr>
<td>Less than four weeks, 1-3 months, 4-6 months, 6-12 months, 1-2 years, Over 2 years</td>
<td></td>
</tr>
<tr>
<td>1F Since you were referred to hospital has the bleeding:</td>
<td></td>
</tr>
<tr>
<td>Got worse, Improved, Remained the same, Completely settled</td>
<td></td>
</tr>
<tr>
<td>2 What has been your normal bowel habit? (your normal bowel habit prior to any recent change)</td>
<td></td>
</tr>
<tr>
<td>Normal motion or stools, Constipation (less frequent and harder stools), Loose Motion, Alternating loose motion and constipation</td>
<td></td>
</tr>
<tr>
<td>2A How often do you normally open your bowels? (your normal bowel habit prior to any recent change)</td>
<td></td>
</tr>
<tr>
<td>Once a day, Once in a few days, 2-3 times a day, Once a week, Varies few times a day to every few days</td>
<td></td>
</tr>
<tr>
<td>3 Do you have any change in your bowel habit?</td>
<td>2.34</td>
</tr>
<tr>
<td>3A If you have any change in your bowel habit.....</td>
<td></td>
</tr>
<tr>
<td>Loose motion or Diarrhoea</td>
<td>2.54</td>
</tr>
<tr>
<td>Constipation (less frequent and harder stool)</td>
<td>0.30</td>
</tr>
<tr>
<td>Alternating diarrhoea and constipation</td>
<td>0.97</td>
</tr>
<tr>
<td>3B Do you open your bowels more frequently than normal to you?</td>
<td>3.38</td>
</tr>
<tr>
<td>If YES: 2-4 times a day, 5-6 times a day, 7-10 times a day</td>
<td></td>
</tr>
<tr>
<td>3C Is the increase in opening bowels worse at any particular time of the day?</td>
<td>2.32</td>
</tr>
<tr>
<td>Morning</td>
<td></td>
</tr>
<tr>
<td>Night</td>
<td></td>
</tr>
<tr>
<td>3D Do you have to &quot;rush&quot; to have your bowels open?</td>
<td>2.00</td>
</tr>
<tr>
<td>3E How long have you had these symptoms?</td>
<td></td>
</tr>
<tr>
<td>Less than four weeks, 1-3 months, 4-6 months, 6-12 months, 1-2 years, Over 2 years</td>
<td></td>
</tr>
<tr>
<td>3F Since you were referred to hospital has the bleeding:</td>
<td></td>
</tr>
<tr>
<td>Got worse, Improved, Remained the same, Completely settled</td>
<td></td>
</tr>
<tr>
<td>4 Do you see?</td>
<td></td>
</tr>
<tr>
<td>Slime (jelly-like fluid) in your motion</td>
<td>0.86</td>
</tr>
<tr>
<td>Slime and blood in your motion</td>
<td>4.81</td>
</tr>
<tr>
<td>5 Do you feel that you have NOT emptied your bowels satisfactorily when your bowels are opened</td>
<td>1.56</td>
</tr>
<tr>
<td>6 Do you have pain in your tummy (abdomen)?</td>
<td>0.45</td>
</tr>
<tr>
<td>Lower tummy pain</td>
<td>0.98</td>
</tr>
<tr>
<td>Spasms of tummy pain</td>
<td>0.73</td>
</tr>
<tr>
<td>Left-sided tummy pain or discomfort</td>
<td></td>
</tr>
<tr>
<td>Right-sided tummy pain or discomfort</td>
<td></td>
</tr>
<tr>
<td>Pain all over tummy</td>
<td>0.44</td>
</tr>
<tr>
<td>7 Do you have symptoms around your back passage?</td>
<td></td>
</tr>
<tr>
<td>Pain on opening your bowels</td>
<td>0.82</td>
</tr>
<tr>
<td>Lump or swelling at back passage</td>
<td>0.53</td>
</tr>
<tr>
<td>Irritation and itching</td>
<td>0.30</td>
</tr>
<tr>
<td>Leakage and soiling at back passage</td>
<td>0.45</td>
</tr>
<tr>
<td>7A How long have you had these symptoms?</td>
<td></td>
</tr>
<tr>
<td>Less than four weeks, 1-3 months, 4-6 months, 6-12 months, 1-2 years, Over 2 years</td>
<td></td>
</tr>
<tr>
<td>8 Have you lost weight recently?</td>
<td></td>
</tr>
<tr>
<td>Over half a stone (3 Kg) in 3 months</td>
<td>2.53</td>
</tr>
</tbody>
</table>
Weight loss does not concern you
Due to dieting
9 Do you have loss of appetite? 1.05
10 Have you been excessively tired recently? 0.81
11 Do you take regular medication?
  Iron tablets
  Steroids / Prednisolone tablets
  Medication for diabetes
  Tablets for thinning blood / Warfarin
  Other medication ...
12 Have you had any of these illnesses in the past?
  Bowel polyps
  Colitis (inflammation of the bowel)
  Cancer
  If you have had cancer - in which part of the body?
13 Have any of your close relatives suffered cancer?
  Relation (when stating grand parents, aunts and uncles please indicate father's or mother's side)
  Age when cancer found
  Part of the body
14 Please give us any other information that you think may be relevant

This data set has also been programmed as a small PROforma publet and can be viewed at URL (tba).
The tree structure of this publet is shown in Figure 14.

This publet uses the relative risk scores to indicate the likelihood of cancer. This score is used together with clinical judgement to decide whether or not to refer the patient urgently for endoscopy.

![PROforma Publet Tree Structure for Colorectal History](image-url)
9.10 Map of Medicine

When referring a patient, the GP may well wish to reassure the patient and refer to supporting clinical knowledge reference material such as the Map of Medicine – see Figure 15 Map of Medicine - Suspected Colorectal Cancer.

Figure 15 Map of Medicine - Suspected Colorectal Cancer

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10 Breast Cancer Triple Assessment

10.1 Background and Scope
Breast cancer is the most common form of female cancer, accounting for nearly 30% of all cases of cancer in women. The lifetime risk is almost 11% (1 in 9).\(^{32}\)

Triple Assessment is used for the diagnosis of primary breast cancer, using (1) clinical examination, (2) imaging (mammography or ultrasound) and (3) histopathology (fine needle aspirate (FNA) or core biopsy). When all three tests give the same result, it is almost always correct. Here there is a single decision to be made – cancer or not cancer.

The scope in this short section is confined to the Triple Assessment process itself, after the patient has been referred to the breast clinic and before staging and the choice of treatment treatment.

10.2 Participants Stakeholders and Locations
The participants in the Triple Assessment are:

1. The patient is the subject of investigation and needs to be kept fully informed
2. Breast specialist who takes history and performs physical examination
3. Radiographer who performs mammography and takes fine needle aspiration (FNA) sample
4. Radiologist who reports on mammography
5. Pathologist who reports on FNA sample
6. The GP needs to be informed of the result
7. Specialist nurses for patient assessment and support
8. Audit and quality assurance staff who monitor quality of services and appropriateness of referrals.

Ideally, the three diagnostic services required for the triple assessment (clinical assessment, radiology and cytology) should be located conveniently in a single “one-stop” location, to avoid delays in transport and communication.

10.3 Outcome
The outcome of the Triple Assessment is a provisional diagnosis: normal, benign, suspicious or malignant, together with recommendations for: further clinic review, further investigations, admission, MDM (multi-disciplinary meeting) discussion, or discharge.

10.4 Storyboard

Jane Sharp attends the One Stop Breast Clinic, having been referred urgently by her GP after noticing a lump in her breast. She sees Dr Lee who takes her history (presenting symptoms, appropriate medical and family history) and performs a physical examination. Jane then proceeds to mammography, where a fine needle aspirate (FNA) is also collected. The mammograph is reported by a radiologist and the FNA by a pathologist. Jane is asked to return later to hear the result of these tests. On her return she is relieved to find out that the results are negative.

Figure 16 shows the triple assessment process as a BPMN diagram.

**Figure 16 Breast Cancer Triple Assessment as BPMN Diagram**


**10.5 Data and Rules**

The critical issue is not the sequence in which tasks are carried out, but rather that all the necessary information is available for the diagnostic decision. Figure 18 shows a fragment of a PROforma Triple Assessment publet enacted over the Internet. The URL is [http://www.openclinical.org/OCNET_Test/TA.start](http://www.openclinical.org/OCNET_Test/TA.start).

![Figure 18 Fragment of PROforma Triple Assessment Publet enacted on the World Wide Web](image_url)
The outline of the whole program can also be displayed as a tree structure.

- **Triple Assessment**
  - Patient examination
  - Provisional management decision at end of TA clinic
  - Patient demographics
  - Candidate placeholder enquiry
- **Radiology plan**
  - Which radiology?
  - Ultrasound result
  - Mammography result
- **Biopsy plan**
  - Which biopsy?
  - Post FNA enquiry
  - Post core biopsy action
  - Post skin biopsy action
- **Patient history plan**
  - Patient history
  - Get patient details
  - Get Further Data
  - Familial Genetic Risk Assessment Decision

**Figure 19 Tree Structure of PROforma Triple Assessment Publet**

**10.6 Map of Medicine**

The Map of Medicine can be used to show details of each aspect, such as Fine Needle Aspiration (Figure 20).
11 Conclusions

This report covers a broad scope. First, as a background, the scope and benefits of care pathways are described in relationship to the NPfIT and the practice of evidence-based medicine.

Definitions are proposed for the main artefacts, to reduce confusion created by the same terms being used in different ways (homonyms) and the same concept having multiple names (synonyms).

Care pathways lie at the intersection of the interaction of clinicians with the individual patient, their medical records and general clinical knowledge and best practice.

Four complementary technologies are described, which may contribute towards the successful development and deployment of care pathways through the NPfIT. These are: PROforma guidelines authoring language, The Map of Medicine, Business Process Modelling Notation (BPMN) and HL7 Clinical Statement pattern.

PROforma is a powerful and proven system for clinical decision support, which takes account of the way that clinicians work. The development team have proposals to enhance the present system to include XML output, SNOMED CT terminology services and standard workflow notation (BPMN).

The Map of Medicine is a user-friendly and content-rich clinical knowledge browser. It is being developed to enable access from clinical systems using SNOMED CT, and localisation of guidelines.

BPMN is designed for the detailed documentation of repetitive workflow procedures and provides a machine-processable XML output documentation.

The HL7 V3 Clinical Statement is a common pattern for clinical data, currently under development for all clinical messages in the NPfIT. These clinical messages use SNOMED CT codes and are implemented in XML. At present the Clinical statement has been developed for use with identified patient data, but the scope could be extended to cover both patient record elements and knowledge library components needed in care pathway templates.

At present, these are discrete developments, but it is relatively straightforward to see how they can be brought together for the benefit of the NPfIT, using XML, SNOMED CT and standard workflow notation as common factors.

12 Acknowledgements

John Fox, Tony Rose, Peter Skead, Ayelet Oettinger and Rory Steele of the Cancer Research UK’s Advanced Computation Laboratory in relationship to PROforma; Mike Stein, Enone Honeyman, Vanessa Wolfe-Coote, Nat Billington, John Ollier, Kit Lewis of Map of Medicine; Ruth Page of NHSIA; and S Selvachandran and David Cade of Leighton Hospital, Crewe.
Annexe 1  PROforma Example

/** PROforma (plain text) version 1.3.42 **/

plan  :: 'CRcaTriage' ;
  caption :: "CRcaTriage";
  description :: "This program uses the NICE colorectal cancer referral guidelines.";
  component :: 'Demographics' ;
    number_of_cycles :: 1;
    ltwh :: 123,24,42,36;
  component :: 'Symptoms' ;
    schedule_constraint :: completed('Demographics') ;
    number_of_cycles :: 1;
    ltwh :: 235,24,42,36;
  component :: 'Examination' ;
    schedule_constraint :: completed('Symptoms') ;
    number_of_cycles :: 1;
    ltwh :: 339,24,42,36;
  component :: 'Test_Findings' ;
    schedule_constraint :: completed('Examination') ;
    number_of_cycles :: 1;
    ltwh :: 443,24,42,36;
  component :: 'CRtriage' ;
    schedule_constraint :: completed('Test_Findings') ;
    number_of_cycles :: 1;
    ltwh :: 550,24,36,36;
  component :: 'Possible_CRca' ;
    schedule_constraint :: completed('CRtriage') ;
    number_of_cycles :: 1;
    ltwh :: 670,24,36,36;
  component :: 'CRcaUnlikely' ;
    schedule_constraint :: completed('CRtriage') ;
    number_of_cycles :: 1;
    ltwh :: 670,112,36,36;
end plan.

action  :: 'CRcaUnlikely' ;
  caption :: "CRcaUnlikely";
  precondition :: result_of (CRtriage) = CRcaImprobable;
  procedure : "It is unlikely that the patient has Colorectal cancer.";
end action.

enquiry  :: 'Demographics' ;
  caption :: "Demographics";
  source :: 'PatientAge' ;
  source :: 'Sex' ;
end enquiry.

enquiry  :: 'Examination' ;
  caption :: "Examination";
  source :: 'AbdominalPain' ;
  source :: 'RectalMass' ;
  source :: 'RightSideMass' ;
end enquiry.

decision  :: 'CRtriage' ;
  caption :: "CRtriage";
  context :: " ";
  candidate :: 'CRcaPossible' ;
    caption :: "Colorectal cancer is Possible";
    argument :: for,Haemoglobin = "less than 10"  attributes
        argument_name :: 'Haemoglobin = "less than 10" ' ;
end attributes
Care Pathways

; argument :: for, RectalMass = "YES" attributes
  argument_name :: 'RectalMass = "YES"';
end attributes
;
argument :: for, RectalBleeding = "YES" AND Symptoms6w = "YES" AND AnalSymptoms = "NO"
attributes
  argument_name :: 'RectalBleeding = "YES" AND Symptoms6w = "YES" AND AnalSymptoms = "NO"';
end attributes
;
argument :: for, RectalBleeding = "NO" AND ChangedBowelHabit includes "Looser Stools" and Duration6w = "YES" AND PatientAge > 60 attributes
  argument_name :: 'RectalBleeding = "NO" AND ChangedBowelHabit includes "Looser Stools" and Duration6w = "YES" AND PatientAge > 60';
end attributes
;
argument :: for, RightSideMass = "YES" attributes
  argument_name :: 'RightSideMass = "YES"';
end attributes
;
argument :: for, RectalBleeding = "YES" AND ChangedBowelHabit includes "Increased Frequency" AND Duration6w = "YES" attributes
  argument_name :: 'RectalBleeding = "YES" AND ChangedBowelHabit includes "Increased Frequency" AND Duration6w = "YES"';
end attributes
;
argument :: for, RectalBleeding = "YES" AND ChangedBowelHabit includes "Looser Stools" AND Duration6w = "YES" attributes
  argument_name :: 'RectalBleeding = "YES" AND ChangedBowelHabit includes "Looser Stools" AND Duration6w = "YES"';
end attributes
;
argument :: for, Haemoglobin = "10-11" AND Sex = "Female" attributes
  argument_name :: 'Haemoglobin = "10-11" AND Sex = "Female"';
end attributes
;
argument :: for, RectalBleeding = "NO" AND ChangedBowelHabit includes "Increased Frequency" AND Duration6w = "YES" AND PatientAge > 60 attributes
  argument_name :: 'RectalBleeding = "NO" AND ChangedBowelHabit includes "Increased Frequency" AND Duration6w = "YES" AND PatientAge > 60';
end attributes
;
recommendation :: netsupport(CRtriage, CRcaPossible) >= 1;
candidate :: 'CRcaImprobable';
caption :: "Colorectal Cancer is unlikely";
argument :: for, AbdominalPain = "Pain without clear evidence of obstruction" attributes
  argument_name :: 'AbdominalPain = "Pain without clear evidence of obstruction"';
end attributes
;
argument :: for, RectalBleeding = "YES" AND AnalSymptoms = "YES" attributes
  argument_name :: 'RectalBleeding = "YES" AND AnalSymptoms = "YES"';
end attributes
;
argument :: for, ChangedBowelHabit includes "Decreased Frequency and Harder Stools" attributes
  argument_name :: 'ChangedBowelHabit includes "Decreased Frequency and Harder Stools"';
end attributes
;
recommendation :: netsupport(CRtriage, CRcaImprobable) >= 1;
end decision.

enquiry :: 'Symptoms';
caption :: "Symptoms";
source :: 'AnalSymptoms';
Care Pathways

source :: 'ChangedBowelHabit' ;
source :: 'Duration6w' ;
source :: 'RectalBleeding' ;
end enquiry.

enquiry :: 'Test_Findings' ;
caption :: "Test Findings";
source :: 'Haemoglobin' ;
end enquiry.

action :: 'Possible_CRca' ;
caption :: "Possible CRca";
precondition :: result_of (CRtriage) = CRcaPossible;
procedure :: "Need to investigate possibility of CR Cancer further.";
end action.

data :: 'AbdominalPain' ;
type :: text ;
range :: "None","Pain with clear evidence of obstruction","Pain without clear evidence of obstruction";
end data.

data :: 'AnalSymptoms' ;
type :: boolean ;
caption :: "Anal symptoms (soreness, discomfort, itching, lumps, prolapse, pain)";
range :: YES,NO;
end data.

data :: 'ChangedBowelHabit' ;
type :: setof_text ;
caption :: "Change in bowel habit?";
range :: "No","Increased Frequency","Looser Stools","Decreased Frequency and Harder Stools";
end data.

data :: 'Duration6w' ;
type :: boolean ;
caption :: "Duration of symptoms 6 or more weeks?";
range :: YES,NO;
end data.

data :: 'Haemoglobin' ;
type :: text ;
caption :: "Haemoglobin (g/dl)";
range :: "Unknown","less than 10","10-11","more than 11";
end data.

data :: 'PatientAge' ;
type :: integer ;
caption :: "Age of Patient";
end data.

data :: 'RectalBleeding' ;
type :: boolean ;
caption :: "Rectal bleeding?";
range :: YES,NO;
end data.

data :: 'RectalMass' ;
type :: boolean ;
caption :: "Definite palpable rectal (not pelvic) mass";
range :: YES,NO;
end data.

data :: 'RightSideMass' ;
type :: boolean ;
caption :: "Definite palpable right-side abdominal mass?";
range :: YES, NO;
end data.

data :: 'Sex';
  type :: text;
  range :: 'Male', 'Female';
end data.