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An Evaluation Programme for the Hospital Information System Northern Province, South Africa

Proposal submitted to the Health Systems Trust – March 1999

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1. SUMMARY

The Northern Province is implementing a comprehensive integrated hospital information system (HIS) in 42 hospitals. This is the first attempt at a multi-site implementation of a HIS of this magnitude in the world. These include two mental health institutions, 8 regional hospitals (2 acting as a tertiary complex with teaching responsibilities) and 32 district hospitals. The overall goal of the HIS is to improve the efficiency and effectiveness of health (and welfare) services through the creation and use of information, for clinical, administrative and monitoring purposes. The project is being implemented at a cost of R 130 million (which represents 2.5% of the health and welfare budget on an annual basis). The implementation process commenced on 1 September 1998 with the introduction of the system into Mankweng Hospital as the pilot site and is to be completed in the year 2001. An evaluation programme has been designed to maximise the likelihood of success of the implementation phase (formative evaluation) as well as providing an overall assessment of its benefits and cost-effectiveness (summative evaluation).

The process undertaken to design the evaluation was innovative and complex and commenced in 1998. The evaluation process sought to involve as many stakeholders as possible at the same time as creating a methodologically rigorous study that lived within realistic resource limits as no provision was made for in the HIS budget for an evaluation of the project. The evaluation of the HIS project will thus have to rely on external funding.

The evaluation process was initiated with an interview study of 250 potential users, which generated 35 questions that should be addressed by an evaluation. These questions were presented to an initial workshop supported by the Health Systems Trust (HST) containing representatives of 10 stakeholder groups[1] and resulted in an expansion to 114 questions. Through a process of collation and distillation these were incorporated into 10 separate projects to create an evaluation framework.

A second workshop supported by HST was then convened to confirm the overall design of the evaluation programme, prioritise the projects, provide technical advice on the drafting of final protocol and proposal for submission to funding bodies and to discuss the organisational structures to support and implement the programme.

The result was the creation of a randomised controlled trial (RCT) in which 24 district hospitals included in the trial will receive the HIS either early or late.

This is the first attempt to do a summative evaluation of a multi-site implementation of a HIS in the world. Within this design the evaluation will utilise a range of qualitative and quantitative methodologies over varying time scales each addressing specific aims of the evaluation programme. In addition it will attempt to provide an overview of the general impact of introducing high technology solutions on people and organisations into a relatively unprepared environment. The study should help to stimulate an evaluation culture in the health and welfare services in the Northern Province as well as building the capacity to undertake such evaluations in the future.

This proposal is being submitted to the Health Systems Trust in order to secure funding to continue the formative evaluation and to undertake the summative evaluation linked to the RCT as the core of the evaluation programme.

[1] Hospital health care professionals, hospital support staff, hospital management, patients and tax-payers, scientific community, provincial health executive, national and provincial hospital Information systems representatives, HIS project management team and the HIS vendor.

2. INTRODUCTION AND BACKGROUND INFORMATION

South African Health (and Welfare) Services are currently undergoing a major restructuring. Changes include shifting resources from tertiary and secondary to primary care, creation and devolution of management structures down to district level and redistribution of resources in response to perceived geographical and sectoral need in consultation with the affected communities. For the successful implementation of these initiatives, managerial, administrative and clinical processes need to be efficient, effective and equitable. An essential pre-requisite to this happening is adequate information, not only to facilitate the original tasks, but also for short and long term monitoring. The generation of reliable, timely and useful information is expensive. In most developed and increasingly developing countries computerisation is perceived as the most cost-effective means of achieving this. However implementing such systems is difficult both technically and in human terms. Careful planning for a successful implementation is required as well as laying a solid foundation for sustaining the system after the initial phase is over. Success cannot be taken for granted based on experiences elsewhere in the world with information systems.

In the Northern Province (NP) this process commenced with the decision to implement a hospital based information system throughout all its hospitals. In late 1997, in addition to the HIS, a District Information System (DIS) development process was initiated and several key components of a DIS core package is currently being field tested at selected clinics in two districts. The DIS will eventually interface with the HIS to assist with providing the overall information requirements to manage the health and welfare services in the province as a whole.

To achieve this, a specific project was conceived in 1995 with the overall aim of computerising all 42 hospitals as part of the same project over a few years[2]. The design was such that each hospital will have its own application server managing local detailed data, but distributing some data at patient encounter level to other hospitals where the patient has been seen before and to a central server at the Welfare and Health Technology Operations Centre (WHITOC). Patient demographic information and a problem list based on ICD-10 is replicated from the originating hospital to the WHITOC and all other hospitals. The WHITOC therefor contains a master patient index and data to encounter level from all 42 hospitals. This information forms the basis for a data warehouse to serve management reporting and epidemiological needs. At hospital level the system provides the following functionality:

- Master patient index.
- Admission, discharges and transfers.
- Patient records.
- Appoinments.
- Order entry.
- Results reporting.
- Laboratory.
- Radiology.
- Operating theatre.
- Clinical services.
- Dietary services.
- Laundry.
- Financial management.
- Management information and hospital performance indicators.

The objectives of the hospital information system are shown in figure 1.

[2] Project Overview Report. Hospital Information System Project. Dr AJ Herbst. October 1997.

Figure 1. Objectives of the Hospital Information System

1. **Improved patient care:**

   i. By making information belonging to patients seen at other hospitals available at the hospital where the patient is currently being treated. This is particularly important in light of referral system for patients from district to regional and central hospitals in the province.
   ii. By improving the accessibility of patient related information to health care professionals during the treatment process, through improved medical records handling and shorter turnaround time for the release of diagnostic information such as laboratory and special investigation results.
   iii. By improving patient administration procedures resulting in shorter waiting times and better service to patients.

2. **To form an integral part of a larger quality improvement program in the department through:**

   i. The re-engineering and standardisation of patient administration and management procedures across hospitals.
   ii. Provision of information to do performance evaluation and health care audit

3. **To improve the management efficiency of hospitals through:**

   i. The facilitation of decentralised financial management capacity at hospital level
   ii. Improved revenue collection
   iii. Improved management decision-making through the availability of integrated management information
   iv. Cost savings through the identification of primary cost-drivers at hospital level and the monitoring of mechanisms introduced to lower costs.

The HIS Project is managed by a project team consisting of members from the Department of Health and Welfare (DHW) and IBM and its subcontractors: Intersolve Health Informatics (IHI), Faritec, and 6 local business partners (LBPs)[3]. Dr Kobus Herbst (Department of Community Health, MEDUNSA Polokwane Campus) is the project leader on behalf of the DHW and the project manager is Mr Andre van der Laar (IBM). The HIS Project is steered by a policy formulation and decision-making body, the HIS Steering Committee where all stakeholders are represented. Dr V Buthelezi, Chief Director: Hospital and Support Services Directorate, DHW chairs the committee as system owner.

[3] Norprobs, Mvelaphanda, Northern Training Trust (NTT), Mameriri, Great North and STEP Ahead.

3. LITERATURE REVIEW

A vast amount of money has been spent world wide on information technology e.g. in the UK alone a billion pounds has been spent on computer systems for the NHS in this first half of this decade (1) but the evaluation of systems has not kept pace with investment. This review assesses the literature on the evaluation of hospital information systems, with particular regard to any multi-site installations that are similar to those being established in the Northern Province.

A search of the MedLine database was conducted to find papers published within the last five years. It was considered that any literature from before 1993 would be irrelevant to today's sophisticated systems. This search yielded a total of 1063 references on evaluation of information technology in healthcare. A brief scan of reference lists from some key papers was also undertaken.

The vast majority (>90%) of these papers were evaluations of the computer systems integrated into the operation of complex items of diagnostic or therapeutic equipment such as pathology analysers, or imaging equipment (2-4). Others related to single departmental information systems, such as in diabetic clinics, or imaging departments (5,6) but these tended to be more than 5 years old. In the last two or three years the use of teaching packages available on the Internet (7,8) has also been evaluated. There was nothing in this literature on the evaluation of whole-hospital clinical management systems, let alone any multi-site installations.

In the early 1990s four UK hospitals were selected for the installation of Hospital Information and Support Systems (HISS), including Greenwich. No formal evaluation has ever been published in a peer-reviewed journal, although there are publications by the computer industry and the NHS Executive (9,10). These appeared relatively early in the implementation of the system, rather than after a few years of operation.

There is apparently an annual conference of healthcare computing, which publishes its proceedings in the British Journal of Healthcare Computing, but access to this journal has not been possible.

In an article in the BMJ in 1996 (11), Lock highlighted the problem and the lack of evidence to support the benefit of all this investment. This is particularly ironic as the systems, once installed but unevaluated, are then used to monitor the cost effectiveness and performance of the 'evidence-based' medical care in those hospitals (12). It is difficult to identify clear outcomes and benefits from such information systems. There are difficulties in quantifying improvements and identifying them directly with the use of the computer systems.

For instance the Greenwich HISS system cost over £12 million in capital and revenue during development, but the only quantified savings are £86,000 per annum in Radiology and £40,000 in Pharmacy. Nevertheless there needs to be some attempt to evaluate systems, probably using a combination of economic and clinical evaluative techniques.

Lock cites 65 references in his paper, but 40 of them are proceedings of the healthcare computing conferences. Unfortunately even he is not an impartial researcher, as Siemens Nixdorf seconded him to University College London. There has been one systematic review of the effect of computerisation in primary care (13). This found that of 30 studies (published world-wide between 1984 and 1994), only 3 measured the impact on patient outcome. Consultation took longer, with the doctor/medical component increasing at the expense of the patient/social component. The authors decided that the effect on patient outcomes was inconclusive. There have also been some evaluations of nursing systems (14,15). A review

of European literature also found few studies, with only 13 of the 108 identified including any economic analysis (16)

Evaluation is a rather misused word in this context. In the literature it rarely seems to mean the systematic appraisal of the effectiveness of an information system which has already been installed, in order to determine whether it represents value for money, or has been instrumental in improving patient care. Rather 'evaluation' is used of the assessment process which potential system purchasers should undertake, in theory, prior to or as part of the procurement or tendering process. Thus there are papers on what to consider (17), but not on whether any implementation really works in practice. An American consortium of organisations has even developed a guideline for responsible monitoring and regulation (18) but recognises that the Food and Drug Administration cannot begin to regulate computer systems in healthcare.

Heathfield et al (19) have recommended that the problem of methodology can be addressed by using a framework for evaluation, especially in complex multidisciplinary healthcare situations. Methodology is a problem, and randomised controlled trials do not seem to be appropriate (20). These tend to produce negative results, which then remain unpublished, and do not provide constructive criticisms and directions for improvements. Heathfield et al suggest that to look for evidence of cost effectiveness is actually to ask the wrong question, but not all those involved in paying for or using such systems would necessarily agree. Clinical Informatics needs to develop multi-perspective evaluations integrating qualitative and quantitative methods (20).

To date no one has actually achieved this, and the situation remains very much as it was 2 years ago when Lock wrote his article for the BMJ.

4. Aims of the Evaluation Programme

In view of the considerable expenditure and the importance of this system for national as well as provincial health care (and welfare) services, it was decided to undertake a formal evaluation after the HIS Project had been initiated.

The one aim of the evaluation programme are to increase the likelihood of success of the HIS through formative evaluation. The other aims are to assess its overall impact (benefits and cost-effectiveness) through a summative evaluation and to disseminate lessons learnt widely, nationally to other provinces embarking on similar ventures and internationally.

Evaluating information systems is notoriously difficult for many reasons, but perhaps the most important challenge is satisfying the varying expectations of the many stakeholders involved. Evaluating a multi-site HIS adds a further dimension to the complexities inherent in evaluating information systems. Indeed, our literature review revealed that there are no multi-site evaluations in peer reviewed journals. We thus had to 'invent the wheel' i.e. develop an evaluation programme for a multi-site HIS.

4.1 Development of an Evaluation Programme

The approach and the process of developing the evaluation programme is outlined below.

The process consisted of four separate, but inter-linked activities:
(i) An Orientation Study.

This was the first formal study conducted as part of the evaluation process. The aims were to obtain the views of what users thought the evaluation should address, identify potential problems where some preventative measure taken by the project might improve the outcome of the project, and undertake a knowledge, attitude and perception analysis. 250 potential users were interviewed which generated 35 questions that should be addressed by the evaluation.

(ii) The Creation of an Evaluation Framework.

The 35 questions were presented to a workshop supported by the Health Systems Trust containing representatives of 10 stakeholder groups and resulted in an expansion to 114 questions. Through a process of collation and distillation these were incorporated into 10 separate projects to create an evaluation framework.

(iii) Designing the overall Evaluation Programme.

A second workshop supported by HST was then convened to confirm the overall design of the evaluation, prioritise the projects in the evaluation framework, provide technical advice on the drafting of the final protocol and proposal for submission to funding bodies and to discuss the required organisational structures to support and implement the programme.

The conclusion of the second workshop was that a randomised controlled trial (RCT) would be the most robust method for undertaking the summative component of the evaluation. The RCT will form the core of the summative evaluation and it is hoped to expand this component if and when additional resources (human and financial) become available. Other individuals and institutions will be encouraged to built and expand on the core

(iv) Undertaking the Evaluation.

The formative evaluation component of the overall evaluation has been an ongoing process. Aspects of the summative evaluation (RCT) are currently in a pilot phase to select the final outcome variables, refine the measurement of these and the arrangements for the required steering, management, employment and funding structures are being finalised.

The results of the first three activities have already been written up and are summarised in workshop reports (Collinson 1998 and Rawlinson 1999). **This protocol presents the details of the trial design and the estimated resources required to undertake the RCT.**

4.2 Aim of the Randomised Controlled Trial

The RCT is derived from the aim of the project that was given top priority in the second workshop: Assessing the quality of decision-making information for clinicians, hospital management, provincial health executive and the public; and the accessibility and utilisation of this information.

The aim of the RCT will be to test the hypothesis that the implementation of the Hospital Information System improves the quality of decision-making information available to clinicians, hospital management, provincial health executive and the public and is accessible and used to improve the efficiency and cost-effectiveness of the health (and welfare) services. The outcome variables measured to test the hypothesis will also indirectly evaluate some aspects of the other projects in the evaluation framework.

5. Methods

5.1 Study Design

To ensure reliable conclusions can be drawn linking the introduction and use of the HIS in each hospital to observed changes, we plan to carry out a randomised controlled trial (RCT). It is not practical to randomly allocate patients or staff to use the HIS, as such an information system is too pervasive, with implications for all staff and patients in a hospital. Thus, contamination would reduce any differences between control and HIS patients or staff. However, since training and technical resources are both limited, it is both feasible and necessary to implement the HIS in phases throughout Northern Province. Thus, we have obtained agreement from the HIS Steering Committee, DHW (see attached letter) and the HIS Project Management Team to randomly allocate the hospitals selected (to be included in the RCT) to either early or late implementation. 24 district hospitals were selected and half (12) was randomised to early and the other half to late implementation.

This random allocation of the 24 district hospitals (to early or late implementation) was then used by the project management team to determine the final HIS implementation schedule. This not only allows for the most rigorous kind of design possible, but also protects the DHW and HIS project management team from any accusation of favouritism. The overall design of the RCT is shown in figure 2.

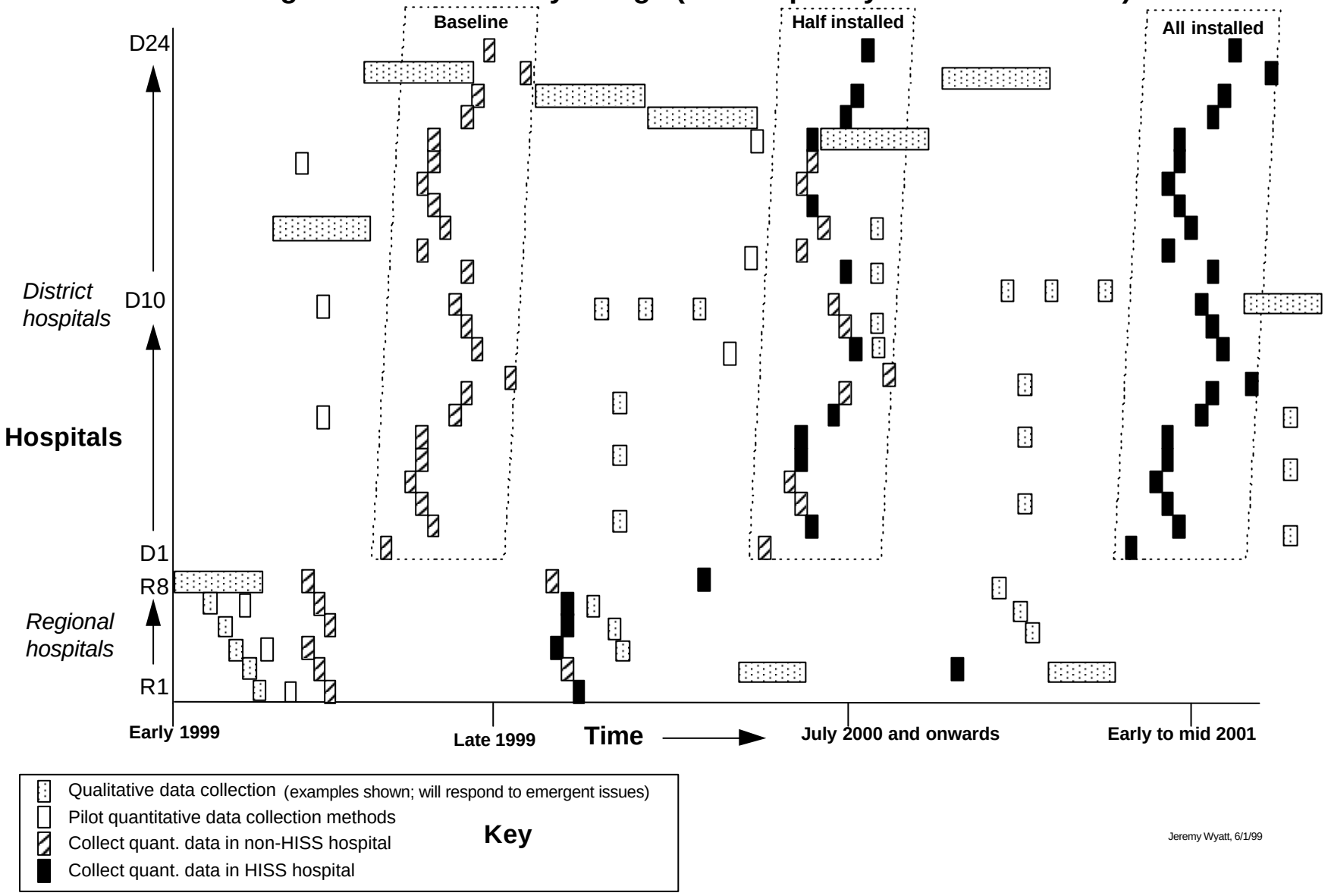
5.2 Participant Selection and Stratification

There are currently 45 hospitals in the Northern Province some of which are being transformed, relocated or phased out. A total of 42 sites are included in the HIS Project. Two of these are purely mental health institutions, 8 of these are larger regional hospitals, 2 of which are both regional and tertiary hospitals with teaching responsibility. These 8 represent a different level of technology, investment, patient case mix and scale from the 32 district hospitals. One of the regional/tertiary hospitals, Mankweng, is already serving as a pilot HIS site. Together, Mankweng and Pietersburg hospitals form the tertiary complex for the province. They also form the nucleus of the evolving academic complex in the province that will extend over several other facilities and provide teaching and research at all levels in the health care hierarchy.

A meeting between the evaluation core team and the project management team took place in late November (after the Evaluation Programme Design Workshop) to identify variables that could be used to pair or match hospitals before randomisation and related practical issues. Confounding factors that may necessitate stratification of the hospitals were also explored at the meeting. Hospital profile documents were then compiled to facilitate the process to pair/match hospitals before randomisation. This approach was eventually abandoned[4] and it was decided to only stratify the selected hospitals before randomisation.

[4] After reading around cluster trials recently, I'm moving away from pairing hospitals up to simply defining 2-3 significant strata, e.g. size and then randomise hospitals within each stratum. This is c. 10% more powerful than pairing. (Personal communication – Jeremy Wyatt)

Figure 2: Overall Study Design (and frequency of measurements).



5.2.1 Participant Selection

In view of the small numbers of remaining regional hospitals, their imminent stage of implementation and their differences from the district hospitals, they were excluded them from the RCT. The 2 psychiatric institutions were also excluded because of their differences from the district hospitals. 8 of the remaining 32 hospitals were excluded on the following grounds (see Appendix 1):

- Not Y2K compliant (3)
- Pilot district hospital (1)
- Uncertainty whether hospital infrastructure will be sufficiently established to function as a district hospital i.e. ready to 'receive' the HIS – some are being transformed or relocated and some are still functioning as Community Health Centres at this stage.

This left is with 24 district hospitals to include in the RCT (n=24).

5.2.2 Stratification

The total sample size of the trial is therefore 24 and in the end we decided to stratify the district hospitals into three groups based on number of beds only:

1. <100 beds (n=6)
2. 101 to 200 (n=8)
3. >200 beds (n=10)

Originally it was thought necessary to stratify hospitals by their local HIS training centre as well (12 in all), roughly corresponding to the region in which the hospital is located. This additional factor was thought necessary in order not to overload the training capacity. 20 PCs X 20 days means there is a limit of 400 person training days per month at each training centre. However subsequent calculations suggested that this would not be necessary.

5.3 Randomisation Method

This was undertaken by Jeremy Wyatt on the 22nd January 199 by the double randomisation method (see Appendix 2). Because of the need for the implementation team to plan the roll out of the 24 district hospitals from the year 2000 onwards, randomisation had to occur before the baseline data could be collected. To minimise any risk of bias, the principal researcher and co-ordinator were blinded to the process and not provided with the results of the randomisation.

5.4 Sample Size Calculation

This is difficult, as there are a range of outcome variables with little prior knowledge of their values. However, for binary variables, a chi-squared test will be used for analysis. This is a cluster randomised trial, so the key issues determining power (with their estimated values for this trial) are:

- The baseline value of the primary outcome measure (say 30%)
- The minimum worthwhile improvement which would justify installing a HIS (absolute increase of 20% to 50%)
- The number of clusters (this is fixed at 24 hospitals)
- The intra-cluster correlation coefficient (estimated as 0.1)
- The values of alpha (5%) and beta (80%)

The parameter, which we wish to determine, is the number of cases that need to be studied per cluster, to obtain the required precision in the estimated value of the measure [Cornfield '67, Bland

'98]. An initial sample size calculation using the "Cluster" sample size calculator *(Marion Campbell, Aberdeen Univ.)* gives an estimate of 75 patient records that need to be studied per hospital.

Stratification can improve the power of a trial by limiting the imbalance in baseline factors and so also can calculation of the amount of improvement per hospital using baseline data for each hospital. However, given the other uncertainties surrounding any multi-centre study, especially of complex interventions such as a HIS, no allowance has been made for these two potential benefits in the sample size estimate above.

In addition for the other measures results will be quoted using confidence intervals to allow readers to interpret the possible range of true results, even if conventionally insignificant, for themselves.

5.5 Outcome Variables

Most evaluations of information systems have limited their data collection to qualitative assessments of users' perceptions of usefulness. If quantitative data has been collected, it has usually been limited to structural and process features. There has been a dearth of outcome data, particularly addressing cost-effectiveness. The RCT makes outcome data collection feasible. Little research has been undertaken in this field.

The second workshop identified the priority project where outcome assessment was considered to be most informative and also generated a number of key outcome questions. After the workshop, these were cross-referenced to create a series of 9 outcome variables that would cover as broad a perspective as possible. The criteria for deciding on the variables were that they were:

(i) Likely to be effected by the HIS.
(ii) Feasible to measure without the HIS in place (for baseline measures in all hospitals and follow up measurements in late implementation sites).
(iii) Reflect a key hospital or health care process.
(iv) Associated with improved or worsened patient experience (total time in the hospital) or outcome (e.g. unintended re-admission rate)
(v) Associated with availability of improved administrative, managerial or policy information.
(vi) Can be made repeatedly without exerting a strong Hawthorne effect.
(vii) Can be made repeatedly using routine data to allow time course of changes to be studied.

The chosen variables will be piloted in a number of hospitals to assess their ease of collection. This will also be a process of refinement of the outcome variables measured. This process does not exclude the inclusion of other outcome variables or the exclusion from the current set of measures. The required number of cases to be collected per a hospital will be finalised after the pilot.

Median Time Outpatients spend in hospital.

This is an overall indicator of the efficiency of outpatients, as well assessing some aspects of effectiveness, being a function of appropriate transfer between clinics within the hospital (criteria i, ii, iii, iv, v, vi).

A brightly coloured form will be issued to each outpatient on entry in hospital. Time will be stamped on entry and on leaving. We have data on the number of outpatients usually seen in each hospital and power calculation will be used to decide on how many days data will be collected. Average times will be predicted after the pilot phase. Data will be collected in the same way for the baseline and post computerisation.

Length of Stay.

This is an Indicator of administrative efficiency and clinical effectiveness (criteria i, ii, iii, iv, v).
Measured from routine monthly statistics complied from ward books and collated by each hospital. This method will be used both pre- and post-implementation. In future these statistics will be generated routinely by computer. Collection over time will also allow time trend analysis. The validity of these statistics will be verified during the pilot phase.

Throughput per Bed.

Same as for 2.

Rate of unintended repeat orders for X-rays.

This is a measure of clinical effectiveness and efficiency (i, ii, iii, iv, v, vi).

Analysis of departmental records, backed up by case notes if necessary. During the pilot phase we will identify how common this is in order to identify the time period for collecting data.

Number of drug prescriptions per patient.

This is a measure of clinical effectiveness and efficiency (i, ii, iii, iv, v, vi).

Analysis of pharmaceutical records, backed up by case notes if necessary.

Improved Revenue Collection.

Indicator of hospital efficiency (I, ii, iii, v, vi).

Information on revenue collection is collated monthly in each hospital. During the study period this will be collected and compared to predicted amounts created from financial models developed by the Department of Community Health.

Closer link between Budget allocated and requested.

Measure of use of information for accurate costing and planning (i, ii, iii, v, vi).

During the pilot phase the previous year's allocations will be compared with requests using data held by Provincial Department of Health and Welfare records.

Cost per Case.

Measure of hospital efficiency and clinical effectiveness (i, ii, iii, iv, v, vi, vii).

This data is generated routinely and will be able to be assessed over a continuous time period.

Use of information by managers.

This is a measure of whether it is used at all and secondly whether it is use effectively (i, ii, iii, iv, v, vi, vii).

Quantitative assessment will be through analysis of managerial minutes and how often information is requested and acted upon. After computerisation, requests for information will be automatically collected. During the pilot phase, the number of meetings and the frequency of information requests will be assessed.

Note:

The format of the data extraction forms (questionnaires), the most reliable source of data, the number of forms and time to complete each will also be determined during the pilot phase. The pilot will thus allow an estimate of how many days of data collection will be required per hospital and therefore the number of fieldworkers (currently estimated at 6) that will be required over which period of time.

5.6 Baseline Data Collection

This will occur in the latter half of 1999 over an estimated 2 month period. The PI, coordinator, the research assistant and fieldworkers will share the data collection across the 24 hospitals. A database will be established and preliminary analysis will be undertaken.

5.7 Follow-up Data Collection

The second round of data collection will occur around the middle of 2000 for an estimated two month period (or longer) and the final data collection will occur in the early to latter half of 2001. This will be supervised by the PI or coordinator and undertaken by the research assistant and fieldworkers (see Trial Design – Figure 2). The exact time frames and phasing of data collection still has to be finalised.

5.8 Other measures – Formative Evaluation

In addition to the quantitative measures within the summative assessment, a programme of qualitative studies will continue, focussing particularly on the non-randomised hospitals to reduce the Hawthorne effects, but including a sample of the district hospitals to check findings elsewhere. These studies will consist of:

(i) Interviews with opinion leaders, clinicians, managers, clerks, records staff and others influenced by the HIS during and after implementation to describe their expectations, experiences and difficulties.

(ii) Analyses of documents, help desk logs, training session observations, free text surveys on surveys and interviews to identify recurrent and important themes as they emerge.

(iii) Analysis of activity logs to reveal times of system use, numbers of users, which modules are used and how long users spend in each.

(iv) Log of possible and actual security breaches to determine threats posed by the HIS to patient or provider confidentiality.

Findings from these data gathering exercises will be fed back to the project management team and HIS Steering Committee as part of the formative evaluation process.

5.9 SWOT Analysis, Potential Biases and measures adopted to reduce them.

This is an ambitious evaluation with considerable pit-falls. These have been summarised in the appended SWOT analysis (Appendix 3). The risk presented by a number of biases as outlined under threats in the SWOT analysis has already been reduced.

5.10 Statistical Analysis

Analysis of data from cluster randomised before-after trials is a matter of statistical research at present [Thompson '97]. However, consensus is emerging that a statistically conservative analysis method is to treat each cluster like a trial in a meta-analysis, applying standard Mantel-Haensel test of heterogeneity and using appropriate techniques to calculate confidence intervals. This technique can be applied to both continuous and binary data and results in a single measure of the effect size with 95% CIs, which can be expressed as the risk ratio for failure to improve [eg. see Wyatt '98].

We are lucky to collaborate with the Oxford Centre for Statistics in Medicine and provided the raw data from a previous cluster trial to support the work carried out by Thompson et al, so will ensure that we are in close touch with any relevant developments during the trial. Such developments would if anything increase the power of the trial to detect a difference.

The University of the North will provide local statistical support. In addition our database could provide scope for higher degree students to undertake statistical projects.

Ethical Considerations

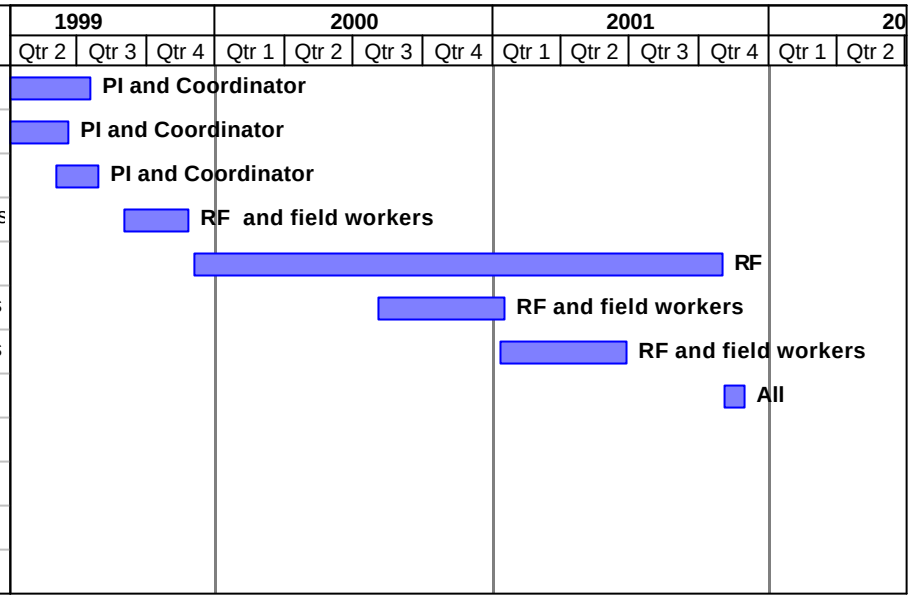
The HIS project existed and was fully funded before the evaluation project was conceived, so no ethical approval seems necessary for implementing the HIS. The rollout process would have been staged over a similar time frame whether the choice of hospitals for early or late implementation was based on alphabetical order, random order or some other method. Thus, the evaluation activities require ethical consideration only as far as access to patient data is concerned. Since much of the data collected will be used to improve the hospital service in Northern Province, we anticipate that this evaluation project will be accepted as an extension of a routine clinical audit activity and should not pose ethical difficulties.

The proposal has been submitted to the Provincial Research Committee for permission to conduct the research and to the MEDUNSA Ethics Committee for ethical approval.

Work Plan

The time frame of the trial is outlined in figure 1. In addition the time frames for piloting, recruiting, training staff, capturing data, analysis and report writing are presented in figure 3.

ID	Task Name	Duration	Start	Finish	Resource Names
1	Pilot study	24w	Mon 99/02/01	Fri 99/07/16	PI and Coordinator
2	Employ and train Research As	16w	Mon 99/03/01	Fri 99/06/18	PI and Coordinator
3	Employ and train field workers	8w	Tue 99/06/01	Mon 99/07/26	PI and Coordinator
4	Baseline data collection	12w	Wed 99/09/01	Tue 99/11/23	RF and field workers
5	inout data and undertake prelir	100w	Wed 99/12/01	Tue 01/10/30	RF
6	First data collection	24w	Tue 00/08/01	Mon 01/01/15	RF and field workers
7	Second data colection	24w	Tue 01/01/09	Mon 01/06/25	RF and field workers
8	Report and dissemination	4w	Thu 01/11/01	Wed 01/11/28	All
9					
10					
11					
12					



Organisational Structures to support and implement the Evaluation Programme

At the second workshop the human and financial resources required to undertake the evaluation programme was discussed. It was concluded that there should be a Principal Investigator, an evaluation coordinator, a research assistant and fieldworkers to assist with the data collection and capturing process. In addition, support will be required in health economics and statistical analysis. An advisory group, consisting of some of the original SAGE members, new members as well as co-opted members (as required), will provide ongoing support on a voluntary basis. When the particular expertise required is not available in the 'knowledge pool' of the SAGE members, it might also be necessary to commission consultants to provide the technical support.

Subsequent to the Evaluation Programme Design Workshop, a lot of discussion went into exploring the organisational structures required to support and implement an ambitious evaluation programme such as this. The following are the structures decided upon, some have been established and the arrangements for the establishment of others are almost complete.

8.1 Evaluation Programme Steering Committee

This structure will function as the policy formulation, advisory and decision-making body for the evaluation process as a whole (similar to the HIS Steering Committee) i.e. 'steer' the evaluation.

The following evaluation team members and organisations will serve on the committee:

- Principal Investigator: Prof Peter Littlejohns.
- Evaluation Coordinator: Dr Jakes Rawlinson (acting).
- WHEC Board member: Prof T Mariba or Prof Molehe.
- Department of Health and Welfare, NP: Dr W Shilumani.
- Funders: HST.
- MEDUNSA representative: To be nominated.
- SAGE representative: To be nominated.
- NHIS/SA representative: To be nominated.

8.2 Evaluation Team

As a result of the uncertainty about funding, only the absolute minimum full time members required were decided upon to undertake the core evaluation. If and when more funds become available, it is hoped to employ additional members to expand the scope of the evaluation.

<u>Full Time:</u>

- Principal Investigator:

Professor Peter Littlejohns has been appointed as the principal investigator. He is on one year sabbatical from the Health Care Evaluation Unit, St. George's Hospital Medical School, London, UK and now holds an honorary Professorship in the Department of Community Health, Medical University of Southern Africa.

- Evaluation Coordinator:

The initial coordinator was Mark Collinson who undertook the preliminary qualitative work culminating in the first workshop and the development of the evaluation framework. Mark will continue as a member of the advisory group. Dr Jakes Rawlinson took over as the acting evaluation coordinator in August 1998 to organise the second workshop and prepare the ground for the randomisation of the

hospitals. He also assisted with the writing of the final proposal and getting the organisational structures in place. He is still currently responsible for the overall coordination of the evaluation.

- Research Assistant/ Programme Administrator:

The post will be advertised and suitable candidates will be interviewed. The successful candidate will be employed on through MEDUNSA (Main Campus). It is hoped to employ the research assistant from July 1999 onwards for at least two years. She/he will assist with the overall formative evaluation and assist with the data collection and supervision of the fieldworkers during the RCT. The research hassistant will also oversee and assist with the data capture process and be responsible for the day to day administration of the programme with the other members.

Part Time:

- Fieldworkers:

An estimated 6 fieldworkers (number still to be finalised after the pilot phase) will be employed at the time of data collection and to assist with the data capture process. There will be three periods of data collection - baseline, 1st and 2nd data collection points (see Trail Design – Figure 2). The time frame for the baseline data collection will probably be about 2 months. The time frames for the 1st and 2nd data collection points still needs to be verified and finalised depending on the phasing of the data collection. The time required to capture the data will also assist to help the time frame of employment and the number of fieldworkers required.

To limit the time and resources required for training the fieldworkers, it is proposed to employ fieldworkers that assisted with the SA Demographic and Health Survey and are thus familiar with data collection. Additional training will be provided as dictated by the requirements for the data collection.

8.3 Scientific Advisory Group of Experts (SAGE) and Consultants

The evaluation team will be supported by the SAGE to provide expert advise on a voluntary basis as and when required to conduct the evaluation. Two additional workshops are planned to which some members will be invited to participate at different phases of the evaluation.

- Jeremy Wyatt (Medical Informatics Evaluation)
- Michael Power (Medical Informatics)
- Kobus Herbst (HIS Project/Data sources)
- Jorn Braa (System Analyst/Humanware)
- Jeff Muschell (Health Economist)
- Mbulaheni Nthangeni (Statistical Support)
- Mark Collinson (Qualitative Evaluation)
- Biagio Longano (HIS Vendor)

It is hoped that Merrick Zwarrenstein (Methodolgy/Trial Design) will be able to assist on a voluntary basis. When indicated, it might also be necessary to commission consultants to look at specific areas when the particular expertise required is not available in the 'knowledge pool' of the SAGE members.

8.4 Funding Structure/Mechanisms

Once funding has been approved, the money will be paid into the Welfare and Health Education Consortium (WHEC) Trust Fund. They will be the overall administrators of the funding and

accountable to the funders for the authorised expenditure. Signatories will be 2 WHEC Board members and a senior member of the evaluation team.

As it is a long process to access funds by this mechanism, it is proposed that small amounts (R 10 000 or less at a time) will be transferrred to the Department of Community Health's Development Fund (MEDUNSA) for incidental expenditure and day to day running of the evaluation programme. This additional mechanism will be to facilitate easy access to small amounts as the need arise. Signatories will be the head of the DCH and a senior member of the evaluation team. The DCH's Development Fund will be accountable for the authorised expenditure to the WHEC Board.

8.5 Employment Structure

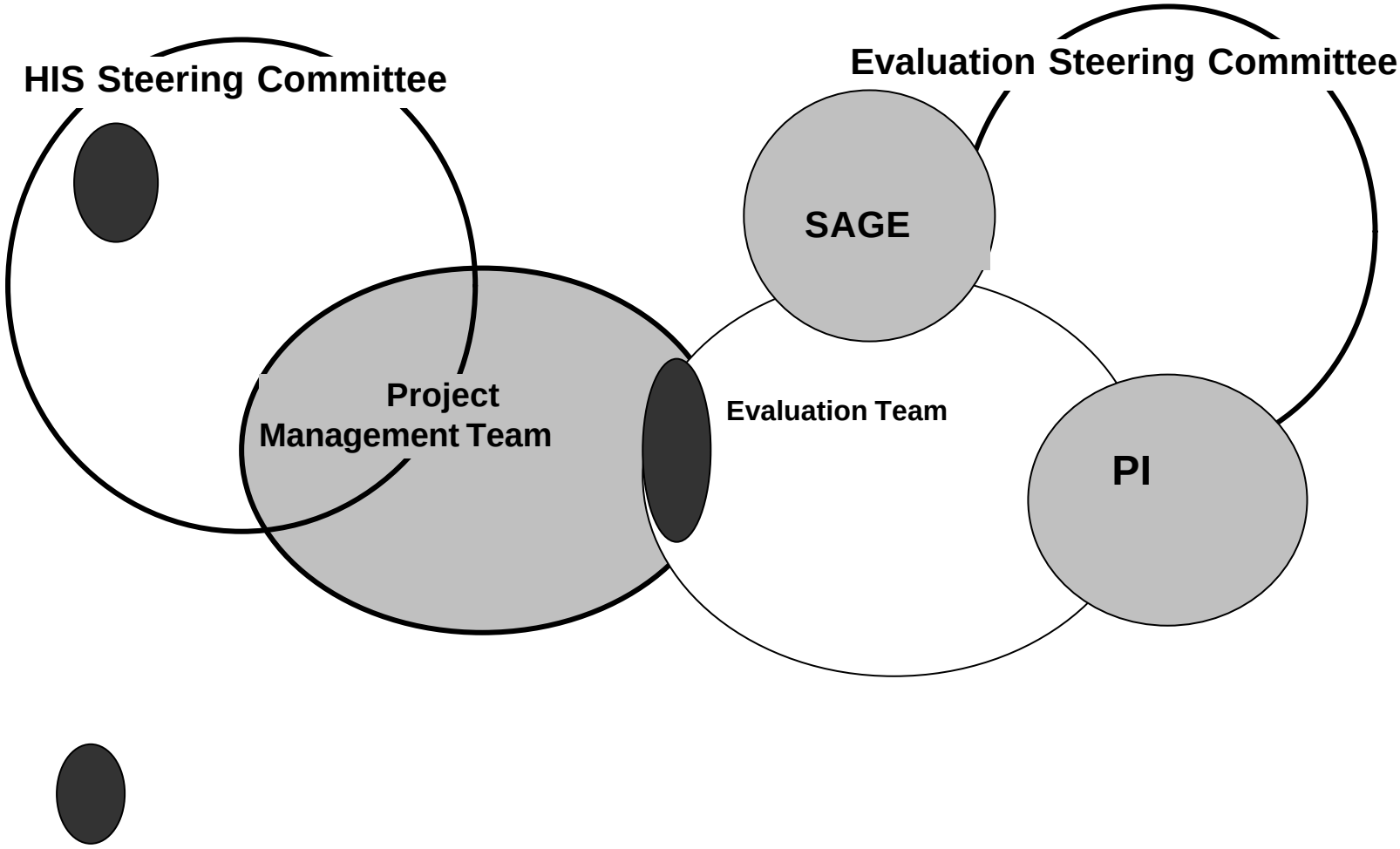
The research assistant and fieldworkers will be employed through MEDUNSA (contract basis) and will be subject to their terms and conditions of employment.

8.6 Interface between the HIS Project and Evaluation Teams

It became necessary to define this interface when ‘blinding’ of the evaluation team to the randomisation process was introduced to reduce bias during the baseline data collection. It was also argued that ‘blinding’ the project team to the outcome variables, will prevent ameliorative actions that could bias the measurements. The overall organisational structure and interface is illustrated in figure 4.

FIGURE 4

Organisational Structure and Interface between the Project Management and Evaluation Teams



Till after the baseline data collection, the following interface have been agreed upon to reduce the introduction of potential bias:

Liaison between the two teams will be through the Quality Assurance Manager for the HIS Project (Johan van der Walt).

Apart from the attending the monthly HIS Steering Committee meetings and Implementation Committee meetings at all HIS implementation sites, the evaluation team has to get permission from the project team to attend project management and other HIS related meetings. The HIS Steering Committee meetings will be the forum for feedback to the project team, discussion of reports and publications and feedback to the evaluation team.

The interface will be redefined after the baseline data collection phase.

Resource Requirements and Budget

9.1 Motivation

The literature review by and large illustrated that the word 'evaluation' is rather a misused word in the context of 'evaluation' of (hospital) information systems. In the literature it rarely seems to mean the systematic appraisal of the effectiveness of an information system, which has already been installed, in order to determine whether it represents value for money, or has been instrumental in improving patient care. Rather 'evaluation' is used of the assessment process which potential system purchasers should undertake, in theory, prior to or as part of the procurement or tendering process. Thus there are papers on what to consider, but not on whether any implementation really works in practice. This is still the situation as to how far our knowledge has developed of the real benefits of implementing hospital information systems.

This summative evaluation (RCT) is a sincere attempt to determine whether the implementation of hospital information systems really represents value for money and is instrumental in improving patient care.

In addition to the quantitative measures within the summative evaluation, a programme of qualitative studies (formative evaluation) will continue as outlined in 5.8. It is our belief that without the core of the summative evaluation (RCT) being funded, the formative evaluation process and overall evaluation process will not be sustainable.

9.2 Outline of resources required

Furnished office space has been provided by the DHW at Mankweng Hospital for the evaluation team as a base to operate from. The computer hardware and software required initially, will be provided from the HIS Project budget. Transport has been allocated to the HIS evaluation team by the DHW to conduct the evaluation.

Section 8 (Organisational Structures) outlines the human resources required to conduct the evaluation and their respective proposed functions.

Resources are therefore required for:

PI: Funding will not be required for 1999. The PI is spending a 1 year sabbatical period the Northern Province and these costs will be recovered from the Redistributive Conditional Grant.

Evaluation Coordinator: Funding of a salary will not be required for the coordinator at this stage as he is employed in the DCH at the Pietersburg-Mankweng Hospital Complex and has been seconded to the evaluation team.

9.3 Budget

The details of the budget are outlined in figure 3. The grand total of R842 050 is an estimate of the cost of conducting this complex and ambitious evaluation programme successfully and make the core of the evaluation sustainable for at least 3 years. It is estimated that it will take about 3 years to complete the RCT and evaluate the implementation process to near or full completion. It may be a large sum of money, but the nature and importance of the evaluation process to run successfully to a logical conclusion warrants the investment especially in the light of the amount (R130 million minimum) being invested in the HIS. Without that, the lessons that could be learned during the implementation process with this unique window of opportunity, can not be disseminated nationally (to other provinces embarking on similar ventures) and internationally. It would also be a lost opportunity to determine whether the implementation of hospital information systems really represents value for money and is instrumental in improving patient care.

If funding for the total amount is not feasible, consideration should be given to fund at least the first two years (1999 and 2000) which amounts to R 560 700. This will keep the evaluation process going at this critical phase and give the evaluation programme enough time to seek additional sources of funding based on the merits of the output and constructive role of the evaluation process.

Figure 3. Budget Details

		1999	2000	2001	Total
1. Principal Investigator	Travel and Accommodation	-	20 000	22 000	42 000
2. Evaluation Coordinator	Salary: July 1999 to July 2000	40 000	44 000	-	84 000
3. Research Assistant	Salary: July 1999 to December 2001	40 000	84 000	88 000	212 000
4. Fieldworkers	Salary: 6 X 2 months (Baseline) 6 X 2 months (1st Data) 1 X full time (August 2000 >	40 000	 44 000 18 000	 42 000	 40 000 44 000 60 000

5. Consultants	Data analysis and other.	10 000	22 000	24 000	56 000
6. Training	As outlined	20 000	10 000	-	30 000
7. Workshops	Early 2000: Workshop costs Airfare (Jeremy Wyatt) Early to mid 2001: Workshop costs Airfare (Jeremy Wyatt)	-	15 000 5 000	20 000 5 500	15 000 5 000 20 000 5 500
8. Consumables and software	As outlined	10 000	10 000	10 000	30 000
9. Accommodation and Transport	As outlined	18 000	20 000	22 000	40 000
10. Reports and dissemination of results	As outlined	5 000	5 000	15 000	25 000
Annual Subtotal		**183 000**	**297 000**	**238 500**	**698 500**
WHEC Administration	10% of Subtotal	18 300	29 700	23 850	69 8500
MEDUNSA Overheads	15% of salary costs	12 000	22 000	20 000	54 000
Total		**213 000**	**347 700**	**281 350**	**842 050**

10. Expected Outcomes and Deliverables

Quarterly progress reports will be compiled and distributed widely to all stakeholders.

The results/reports generated by the ongoing formative evaluation process will be presented at the HIS Steering Committee meetings on a monthly basis and distributed to all other stakeholders.

The final report will be written during the end of 2001 and presented nationally and hopefully internationally at seminars and conferences.

Comprehensive understanding of HIS function, usage, impact in hospitals is still not available, despite multiple weak studies. This evaluation should provide some of the answers to improve our understanding of information systems and their impact.

The project results and lessons learnt will be presented through a series of local and national seminars on an ongoing basis as they emerge. These will be in a number of locations to allow all other provinces to attend.

A newsletter will be created - in hard copy and also on the WWW

Various aspects of the project will be submitted to conferences and peer review journals.

The project will help build an 'evaluation' culture in all the involved hospitals i.e. most of the hospitals in the Northern Province. In addition, there will be a number of trained research staff in the

province who will also disseminate the generic lessons learnt. In that way, we will be building capacity for health systems research / health technology assessment in the Northern Province.

It is expected that additional projects will be added on to this core programme and separate additional resources will be sought.

In addition our database could provide scope for higher degree students to undertake statistical projects.

Development of novel evaluation methods or novel combinations/applications of existing methods.

The evaluation could facilitate multiple satellite projects.

Close collaboration between the evaluation team and the District Information System (DIS) development process will aim to facilitate an interface between the HIS and the DIS at district level to facilitate the establishment of an integrated information system required to manage the district health and welfare system.

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Apendix 1

Northern Province District Hospitals Profile Document						
Number	**Name**	**Region**	**Type**	**Current Bed Size (Future Bed Size)**	**CURRENT STATUS of HOSPITAL**	**'Safe' Early and Late**
1	Ellisras	Bushveld	District	65	Functional, HIS can be implemented if dataline in place. Note: Running on Unimed-P System - not Y2K compliant.	Early
2	FH Odendaal	Bushveld	District	181	Functional, HIS can be implemented if dataline in place.	Early
3	Thabazimbi	Bushveld	District	73	Functional. Uncertainty about public/private mix situation. Wait at least 6 months for situation to reslove.	Late
4	Witpoort	Bushveld	District	55 (108)	Functional, HIS can be implemented if dataline in place.	Early
5	George Masebe	Western	District	251	Functional, HIS can be implemented if dataline in place. Upgrading complete in 3 months.	Early
6	Voortrekker	Western	District	107	Functional, HIS can be implemented if dataline in place. Note: Running on Unimed-P System - not Y2K compliant.	Early
7	Donald Fraser	Central	District	355	Functional, HIS can be implemented if dataline in place.	Early
8	WF Knobel	Central	District	258	Functional, HIS can be implemented if dataline in place.	Early
9	Botlokwa	Central	District	40 (108)	Functional, HIS can be implemented if dataline in place. Construction will start soon to enlarge to 108 beds.	Early 40 - Late 108
10	Seshego	Central	District	45 (153)	Functional, HIS can be implemented if dataline in place. Construction will start soon to enlarge to 153 beds.	Early 45 - Late 153
11	Helene Franz	Central	District	121	Functional, HIS can be implemented if dataline in place.	Early
12	Elim	Northern	District	511	New sections (Admin,OPD and Casualty) under construction & as activated, older sections will be phased out. Final size: 400 beds. >1 year	Late
13	Louis Trichardt	Northen	District	40	Functional, HIS can be implemented if dataline in place.	Early
14	Malamulele	Northern	District	182	New sections (Casualty, laboratory) under consruction. 6months to 1 year.	Late
15	Messina	Northern	District	80	Functional, HIS can be implemented if dataline in place.	Early
16	Sekororo	Northern	District	273	Ward upgrading under way.	Late
17	Siloam	Northern	District	458	Functional, HIS can be implemented if dataline in place.	Early
18	CN Phatudi	Lowveld	District	148	Functional, HIS can be implemented if dataline in place.	Early
19	Kgapane	Lowveld	District	262	Functional, HIS can be implemented if dataline in place.	Early
20	Maphutha L Malatji	Lowveld	District	196	Functional, HIS can be implemented if dataline in place.	Early
21	Nkhensani	Lowveld	District	295	HIS should not be installed in old Nkensani. First phase of new hospital complete - OPD + 36 beds	Late
22	Phalaborwa	Lowveld	District	48	Functional, HIS can be implemented if dataline in place. Note: Running on Unimed-P System - not Y2K compliant.	Early
23	Van Velden	Lowveld	District	50	Functional, HIS can be implemented if dataline in place. Capacity will be increased in future.	Early
24	Matikwana	Bushbuck	District	176	Functional, HIS can be implemented if dataline in place.	Early
25	Tintswalo	Bushbuck	District	276	Functional. Phased development - Admin.	Late
26	Matlala	Southern	District	270	Functional, HIS can be implemented if dataline in place.	Early
27	HC Boshoff	Southern	District	288	New HC Boshoff (Dilakong) being built. HIS should not be installed in old HC Boshoff. Look at >3 years timeframe.	Late
28	Jane Furse	Southern	District	423	New Jane Furse being buillt. Currently can function as a Health Centre. HIS not to be installed in old. Look at >3 years timeframe.	Late
29	Lebowakgomo	Southern	District	0 (36) (108)	Currently operating as Health Centre. In process of modular expansion - 36 to 108 to 400 bed hospital. Projected - April/May 2000.	Late
30	Zebediela/Magatle	Southern	District	0 (36) (108)	Currently operating as Health Centre. In process of modular expansion - 36 to 108 bed hospital. Projected - April/May 2000.	Late
31	Mecklenburg	Southern	District	108	Functional. Phased upgrading of OPD, Casualty. Projected - April/May 2000.	Late
32	Penge	Southern	District	80	Replaced Evuxakeni in HIS Project. Construction complete. Needs to be activated. Involves redeployment of staff. Projected-March '99.	Early
				5696 (6340)		

Appendix 2

Randomisation Method

1. 24 eligible hospitals were selected using criteria stated as stated in participant selection (see Appendix 1).

2. Hospitals grouped into 3 categories by stated bed size: < 100 beds, 100-199, 200 or more. Fortuitously, there was an even number in each category: 6 small, 8 medium and 10 large.

3. For each group, two lines of random number pairs from the table of computer-generated random numbers on p 540 of Doug Altman's "Practical Statistics for medical Research" (Chapman & Hall 1991) were used.

4. Hospitals were arranged in numeric order by size - numbers from the table (see Appendix1).

5. For each of the 3 strata, the rank order of the first hospital to assign was chosen by the 1st digit of the 2-digit pairs in the relevant line of the table. (0 was taken as 10 for this purpose). The assignment of that hospital was recorded as "early" if the 2nd digit of the pair was 0-4, "late" if it was 5-9.

6. The rank order of the next hospital to assign within the stratum was chosen by the 1st digit of the next pair, unless it had already been assigned or the digit was out of range (e.g. "8" when assigning small hospitals - only 6 of these). The 2nd digit of that pair was used to give the actual assignment in the same way.

7. This process was repeated using the next applicable digit pair in the relevant line of the random number table until exactly half of the hospitals in that stratum had been assigned to either "early" or "late". Any remaining hospitals were then assigned to early or late by default.

8. The next stratum was then assigned using the next pair of lines of random numbers in the table, until all strata were assigned.

Appendix 3

Original SWOT Analysis of the HIS Evaluation Programme (RCT)

	Details	*Impact*	Comments
Strengths (at present)	HIS product, training, technical support and implementation plan	1	Of international quality and interest
	Enthusiasm for randomised roll out to 21 District hospitals	1	Unlocks scientific rigour; insulates from all bias; allows wide range of accompanying evaluations; only fair way to allocate priority
	Wide engagement of stake holders in evaluation questions and methods	1	Thanks to activities and co-ordinators to date
	Good range of skills in evaluation team	1	Ditto
Weaknesses (at present)	Baseline data collection must start before first phase roll out ? March '99	2	Omitting baseline data in some hospitals may be permissible if measures not too variable
	No funding at present	1	HST seem convinced
	No full time PI at present	1	Under discussion
	Hospitals widely spread in province with variable infrastructure	1	Filed worker training programmes may provide suitable source of locally based researchers
	No precedent for such a wide-ranging multi-centre evaluation of HIS	2	Apply standard clinical epidemiology / health technology assessment principles; look for analogues e.g. COMMIT trial
Opportunities (in future)	Building capacity for health services research / health technology assessment in NP	1	Major criterion for HST funding?
	Comprehensive understanding of HIS function, usage, impact in 42 NP hospitals	1	Still not available, despite multiple weak studies, (first was carried out at Embarcadero Hospital, Ca, 1978)
	Development of novel evaluation methods	2	Or novel combinations / applications of existing methods
	Facilitates multiple satellite projects	2	e.g. Single site before-after study in one dept.; questionnaire validation; cost studies
	Clear messages to HIS / health informatics communities about evaluation methods, feasibility	2	
Threats (in future)	Postponement or cancellation of a fraction of HIS implementations	1	Adjust 1st follow-up data collection to coincide with introduction of HIS in about 50% of District hospitals.

	Details	*Impact*	Comments
	Incomplete or poor quality data collection	1	Careful recruitment & training; good communication with hospitals; supervision and QA activities; monthly data reports to SAGE
	Hospitals in early / late HIS roll out not well matched at baseline	1	1. Assign an individual to collate & check data about the main factors, which may / do predict baseline performance, e.g. region, size, staff-patient ratio, DHW performance Indicators, informed opinion… 2. Prioritise above factors; factor in other issues such as feasibility (below) 3. Develop a simple algorithm to match hospitals in pairs using the factors in approximate priority order
Threats (continued)	Failure to adhere to accepted random schedule for HIS roll out, e.g. roll out to a late implementation site before an early site because of technical, staffing, political or economic pressures	1	1. Capture and use practical constraints in pairing process, e.g. avoid saturating local training centres 2. Publicise randomisation process at high level (e.g. NP Chief Exec does randomisation Lottery style at public meeting, with Press coverage 3. Seek local approval / acceptance; monitor roll out sites and pressures 4. Analyse study by intention to install a HIS, not actual HIS installation
	Other kinds of interference in major study aspects	2	Ensure study is overseen by local person with good communication / diplomatic links to all regions; work hard to communicate goals, methods and head off potential difficulties; use satellite projects, international profile, funding contracts to clarify project importance
	Loss of significant study resource / asset during study	2	1. Team member: identify deputies 2. Data from hospitals: obsessional backup; use generic tools or store copy of any study-specific software source code in escrow 3. Study hospital withdrawn: study sponsor + local knowledge to bring back

	Details	***Impact***	**Comments**
	Hawthorne Effect (human performance improves when it is studied)	2	1. Limit evaluator contact with study hospitals to bare minimum by carrying out piloting of data forms, ethnographic studies in Regional hospital + pilot district sites 2. Measure data pertaining to month before data collection visit 3. For routine data, check weekly, look for effects that persist after data collection visit 4. Don't feed back performance data to hospitals until months later
	Checklist Effect (clinical performance improves when well structured form used to capture data)	2	Give clinicians in control hospitals pre-printed encounter forms with same headings
	Data Completeness Effect (HIS may lead to more complete capture of data used for evaluation purposes than in control hospitals)	2	1. Select measures which are feasible / trivial to collect in non-HIS hospitals 2. Compare duplicate manual & computer data collected in 1-3 HIS sites
	Placebo Effect (presence of IT may impress patients & others so much as to improve some measures of benefit)	3	Select measures which are objective [Providing placebo computers in control sites is infeasible!]
	Data collection bias (data collectors or interpreters may massage results based on prior belief in / suspicion of HIS)	3	For measures requiring a subjective quality assessment (quality of prescribing, test ordering, etc.), capture raw data & ask external judge to assess quality, blind to whether it came from a HIS or control site
	Tailored intervention bias (intervention developers / trainers / support staff tailor their efforts to improving the measures being evaluated)	3	Blind HIS development team, trainers, help desk etc. to key measures, items used, measurement time scales, etc.
	Other methodological errors or omissions	3	Circulate protocol widely; pre-publish e.g. In Lancet?