

## What constitutes clinical data?

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*“The medical profession is unlikely ever to start using the stethoscope because its beneficial application requires much time and gives a good bit of trouble”*

- The Times, 1834.

### Abstract

*The following article outlines the development of a computerised Clinically Integrated System (CIS) Model as a method of collecting and utilising clinical data at the point of patient care delivery. During this process multiple complexities emerged in relation to the collection, analysis and presentation of clinical data. However, the ultimate challenge was recognising the need for an interdisciplinary philosophy of patient care management that provided the foundation for determining what constituted clinical data. As a consequence, the initial perception of clinical data in purely statistical terms was widened to include evidence-based practice, clinical redesign, and outcome management.*

*As the CIS Model concurrently tracked and analysed individual and patient group progress the clinical data collected not only resulted in improving patient care but helped to understand the discrepancies between total patient costs and loss of revenue.*

### 1. Introduction

*“There is only one rule of clinical practice put yourself in the patient’s position”*

– Joseph Lister

With the rapid growth of information technology (IT) systems during the 1990s it had been assumed that, since they operated in a knowledge intensive industry, health care organisations would quickly adopt these technical tools as a means of spreading innovation into health care solutions. The hope was that IT would substantially improve care by bringing clinical decision support systems to the point of care delivery, thereby reducing inefficiencies and errors, containing costs and allowing patients to actively participate in their care.[1,2]

However, the health care industry has unique characteristics compared to others. For example, because of the unpredictability and complexity of patient presentation combined with an ethical obligation to “first do no harm”, clinicians are very reluctant to support innovations that do not resonate with their individual clinical experience.[3,4]

As information vendors have entered the health care arena, many compromises have been made in the race to produce commercial products resulting in the current situation of non-integrated systems.[5,6] Problems have also arisen as vendors have attempted to simplify and merge clinical practice activities with administrative tasks through standardised templates. Consequently, while clinicians will use administrative databases, research consistently shows that attempting to force them to adhere to uniform computerised CIS (CCIS) fails. The most commonly cited reason for this resistance is a lack of organisational change programmes to support new IT initiatives, and an inability to actively engage clinicians in this process.[7–10] However, a more subtle barrier, the perceived threat of losing professional autonomy, is emerging as a major constraint.[9,12,13]

Despite opposition from clinicians, there is a growing imperative for the use of CCIS in clinical practice. The paternalistic relationship which has traditionally existed between patients and physicians, with the patient following orders while the physician retained information and decision rights [14] is now being superseded by

specialised health care teams which require effective and efficient sharing of information and knowledge not only between these teams,[3] but also with the patient. Indeed, the control and demand for innovative health care delivery is being driven by consumers of health care as they are exposed to new possibilities via information systems, such as the Internet.[15] Consequently, a new model of collaborative practice whereby patients and clinicians are in equal partnership in decision-making processes is required.[14] A critical component for a successful relationship of this type is access to and provision of robust clinical data.

With this new model of practice in mind, the previous methods of addressing the technical challenges of CCIS or ways of engaging clinician/ patient participation as separate identities is changing towards strategies that emphasise linking the socio-technical nature of CCIS together.[16,17] The key factor for future success has been identified as the ability to fit or align technology and work practices together,[18–20] with international research demonstrating that cross functional teams and co-operation are the key elements to achieving long- term sustainability for CCIS.[21–23]

The following section outlines the development of the Clinically Integrated System (CIS) Model. The CIS Model is a computerised interdisciplinary system that links evidence-based practice, clinical redesign, outcome management and participatory action research into a single framework of patient care delivery. While these philosophies have previously been used in health care, they have been used in isolation to one another. In order to enhance their potential to improve patient care, the notion was to interlink the innovations (the philosophies of care) with participatory action research (a collaborative approach) and IT (the tool) together with the aim of successfully diffusing innovations within and across the healthcare sector.

During this process the traditional view of gathering and using clinical data would be replaced with new interpretations on how to triangulate qualitative and quantitative data in order to address clinical and system problems. Some clinical examples from the Fractured Neck of Femur (#NOF) patient population are used below to demonstrate the impact of using a CCIS on patient care delivery.

## 2. What Constitutes Clinical Data

*It is more important to know the person who has the disease than the disease who has the person.* – Hippocrates.

In 2000, the CIS Model was introduced in the Orthopaedic and Palliative Care Services at New Zealand's Auckland City Hospital (ACH). Its introduction into clinical practice signalled a marked departure from the hospital's clinicians' original intention of using clinical pathways to improve patient care and as a means of gathering clinical data. Preliminary discussions about purchasing commercial clinical pathway templates raised concerns relating to patient complexity, for example, patients presenting with multiple problems would require multiple pathways. The possible loss of patient individuality was also discussed with queries around how a standardised template could accommodate patient input and special needs. The clinicians were asked what an ideal alternative solution would be, it became apparent that it was difficult for clinicians to distinguish between what they wanted and what was actually needed at a patient's bedside. This problem was compounded by the lack of a unified view as to which clinical data were important. However, the clinicians agreed on what they thought were the barriers to improving patient care. Fourteen themes emerged:

1. There was no clear overview of a patient's progress.
2. There was minimal evidence-based material to support clinical decision-making processes.
3. There was no immediate access to any available evidence-based material to support decision-making.
4. There was minimal understanding of by clinicians as to, costs associated with daily care activities.
5. There was no interdisciplinary team agreement on the minimum standards of care delivered.
6. There were no systems for concurrently capturing patient variances.
7. There were no systems for the concurrent analysis of patient outcomes.
8. There were no formal structures or processes for allowing or capturing daily patient/ relative feedback.
9. There were no longitudinal patient outcome data.
10. There were no interdisciplinary assessment forms.
11. There were no structures/ processes to prompt clinicians to follow up on the outcomes of care delivery.
12. There were no structures/ processes to identify clinicians requiring assistance with documenting care.

13. There were no structures/ processes for recording the actions and associated rationale for recommended care interventions.
14. There were no links between evidence, accountability for care delivery and outcomes.

These discussions provided a deeper understanding and clarification of what constituted clinical data, ie, it was not just a matter of number crunching. By combining the components of evidence-based practice, clinical redesign and outcome management into a singular structural research framework, and using the principles of participatory action research to guide the process the perception of, and potential for, using clinical data widened. With the emergence of this new philosophy the next step was to run a pilot project testing how it could work in clinical practice.

Wojner [24] states that at the beginning of a process improvement study one of the most important and interesting questions to ask is what do your patients look like? To verify clinician perceptions of care delivery clinical snapshots were undertaken. This involved tracking patients from admission to discharge, collecting qualitative and quantitative data throughout their hospital stay. This approach differed from other processes that advocate teams of clinicians meeting together to identify the daily activities of care that will form the basis for future changes.[25] There were significant advantages in taking these snapshots. Firstly, the results demonstrated wide variation between what clinicians thought was happening and the reality of clinical practice. This led to a growing appreciation of the need for data that simultaneously addresses system and patient care inadequacies. Secondly, team dynamics began to change. In particular, having information technologists as part of the group meant that new insights were gained as to how technology, ie, CCIS could help to resolve the identified gaps in patient health care delivery.

Having established a philosophical framework of care delivery, a search for software to support this concept was undertaken. Unfortunately, there were no commercially available products identified that supported the ability to link the new concepts of care together or to capture the anticipated changes in practice. In essence, the highly complex innovations that had been generated by the interdisciplinary team needed to be linked together via a sophisticated information infrastructure. Consequently, in-house software development was undertaken.

While the IDT acknowledged that computerisation of the Model had the potential to resolve its current difficulties, there were heated debates about the implications of introducing this new technology into clinical practice, particularly in regard to the idea of entering patient data concurrently and withdrawing pen and paper documentation.

This resistance was lowered by returning to the participatory action research approach. As discussions progressed it became clear that the barriers were not actually related to technical concerns, but related to the fear of losing the “ideas” that had been generated. These fears were allayed by actively involving the clinicians in the design phases of the computerised application.

The computerised version of the CIS Model was completed within three months. During this phase a new level of commitment was generated. Clinical participation increased as the clinicians watched their ideas being translated into viable computerised applications. The impetus for this renewed energy was reflective of Steanelli’s [26] observation that as knowledge generation is primarily tacit and characterised by context specific and personal interpretation, it is hard to formalise and communicate. In contrast, explicit knowledge can be easily transmitted through any systematic language. Therefore, the first part of the project may have been slower and more difficult as the IDT grappled with philosophical components of the CIS Model. The introduction of computerisation created a systematic language with the IDT abstract concepts turning into practical applications resulting in a new shared understanding of the CIS Model’s functionality and potential.

Having created the CIS Model prototype, informal networking between the ACH clinicians stimulated interest and requests from other departments to review the Model. Rather than discussing the concept of the CIS Model, clinicians were encouraged to immediately interact with the system by having a ‘hands of experience’. Consequently, clinicians quickly grasped the philosophy of the CIS Model as the concepts, such as the linking of evidence-based practice and outcome management, were visibly displayed.

In 2000, the CIS Model prototype was introduced at ACH. The following section provides some examples using the #NOF patient group to illustrate how the CIS Model contributed to improving organisational efficiency and patient care.

*It is a rule without any exception that no patient ought ever to stay a day longer in hospital than is absolutely essential for medical or surgical treatment.*

– Florence Nightingale, 1863

In 2000, a Ministry of Health benchmarking activity found that ACH had the highest length of stay (LOS) for #NOF patients in New Zealand. ACH clinicians believed that patient acuity was the primary cause for this difference but had limited data to support this view.

Following the introduction of the CIS Model into clinical practice all consecutive patients from January 2000 to June 2004 were divided into two groups: Group A had care delivery via the CIS Model and Group B did not. The study demonstrated a consistent reduction in LOS for Group A as opposed to Group B by 3.7 days. These differences were not confounded by patient age or sex, or the surgeon. By reducing the LOS significant cost savings were identified. Based on these outcomes it was estimated that if Group A had not been on the CIS Model and had similar LOS results to Group B the additional cost would have been approximately NZ\$3 million (1,448 patients x 3.7 days x \$580 per day).

In 2005, the CIS Model computer program was upgraded with the introduction of new initiatives, eg, emphasising proactive discharge which resulted in a continued decline in LOS (table 1). The implementation of the new initiatives was underpinned by increasing volumes of data that highlighted areas of adverse trends. For example, a greater understanding of why discharge delays were occurring was uncovered. While approximately half of all admissions were operated on within a 24-hour period, preoperative delays were still high. Prior to the CIS Model data collection it had been assumed that these delays were due to lack of theatres.

**Table 1: CIS Model Length of Stay Trends 2000–2005**

	2000	2001	2002	2003	2004	2005
Number of patients	345	317	304	337	334	307
Median age of patients	88	87	87	86	84	85
Median LOS (day)	11.5	12.8	9.6	10.4	10.1	8.6
Mean LOS ( day)	12.6	14.1	11.6	11.5	10.9	9.3
% of patients discharged by Day 7	22%	15%	23%	23%	25%	36%

However, the primary reason was clinically driven with patients being medically unstable which warranted more intensive investigations. These findings coincided with the discovery of significant under reporting of pre-existing co-morbidities and post-operative complications.

A patient documentation study was undertaken as part of plan to develop an Interdisciplinary Team (IDT) computerised patient peri-operative assessment form that would be incorporated into the CIS Model. A comparison between patient self-reports and current admission medical records showed that 83 percent of what patients self reported were not in the medical notes, with a 79 percent omission rate in the anaesthetic records. Examples of omissions included treatment for cancer, previous resuscitation, hepatitis carrier, allergies, and life threatening adverse reactions to anaesthetics. These conditions were verified in old clinical notes. Subsequently, an IDT form was developed which incorporated clinical, social and educational information. As part of this process patients received a copy of the completed IDT form for their future use.

Further documentation audits highlighted the problem of accurately capturing patient acuity. One hundred patients' notes were reviewed in a comparison study between the coded medical records and the CIS Model data. The CIS Model uncovered additional co-morbidities and post-operative complications in 22 patients resulting in additional revenue of NZ\$12,000 as the costs of these omissions were recovered. A further NZ\$12,000 was found through a coding error which had omitted the number of patients waiting for rehabilitation beds.

A wider appreciation of clinical complications and the impact on LOS and costs was achieved through the collection of concurrent automated outcome reports. For example, infection, anaemia, mobilisation and pain consistently appeared in the top seven post-operative variances resulting in an increased LOS and costs compared to the average LOS for # NOF patients (table 2)

**Table 2: Additional LOS and associated bed stay costs for four #NOF patient post-operative complications (extra cost) = (extra days stay) x (Number of patients) x NZ\$580**

	2000	2001	2002	2003	2004	2005	Total (\$,000)
<b>Infection</b>							
Average LOS	12.6	14.1	11.6	11.5	10.9	9.3	
Infection LOS	16.6	16.4	14.2	14.5	12.5	11.1	
Extra days stay	4.0	2.3	2.6	3.0	1.6	1.8	
Number of patients	102	117	89	79	76	55	
Extra cost	\$237	\$155	\$134	\$137	\$71	\$57	\$791
<b>Anaemia</b>							
Average LOS	12.6	14.1	11.6	11.5	10.9	9.3	
Anaemia LOS	15.4	15.8	14.4	12.3	12.9	9.5	
Extra days stay	2.8	1.7	2.8	0.8	2.0	0.2	
Number of patients	88	96	64	98	69	62	
Extra cost	\$143	\$96	\$103	\$45	\$80	\$7	\$474
<b>Mobilisation</b>							
Average LOS	12.6	14.1	11.6	11.5	10.9	9.3	
Mobilisation LOS	13.9	15.2	12.7	12.8	13.9	10.9	
Extra days stay	1.3	1.1	1.1	1.3	3.0	1.6	
Number of patients	220	218	185	93	45	118	
Extra cost	\$166	\$135	\$114	\$70	\$78	\$110	\$673
<b>Pain</b>							
Average LOS	12.6	14.1	11.6	11.5	10.9	9.3	
Pain LOS	14.5	14.6	15.0	15.8	11.9	9.8	
Extra days stay	1.9	0.5	3.4	4.3	1.0	0.5	
Number of patients	114	107	64	28	37	31	
Extra cost	\$126	\$32	\$128	\$70	\$21	\$9	

### 3. Conclusion

The CIS Model experience highlights the fact that the process of improved patient care delivery is non-linear with multidimensional impacts. The definition of what constitutes clinical data broadened during the Model's development ultimately leading to the interlinkage of care delivery, organisational efficiency, interdisciplinary teams, financial, patient and patient's family. This ultimately led to the production of new information enabling collective insights, which simultaneously embedded desired changes into clinical practice while developing innovations that benefited the patient.

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