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The Integration of Electronic Regulatory Manuals in Health Services Must Be More Reality than Rhetoric

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As corporate governance issues fill the headlines, Board Members, CEOs and Managers are coming under greater scrutiny to ensure the organisations they work for are compliant with a myriad of regulations and also deliver safe and efficient clinical services. State legislation, department of health directives, court cases and scholarly writings offer a multitude of rules, regulations, prohibitions, and interpretations that staff need to comply with. At times staff may experience difficulties in simply keeping up-to date with all of these notices. To further complicate this process, these notices may not be revised by external organisations simultaneously. As a result they have been found to contradict each other from time to time. In a recent case, the courts stated that the lack of knowledge by health practitioners of their regulatory obligations, will not absolve them or their organisation from delivering inappropriate clinical care. Subsequently, there needs to be integration of corporate governance processes that assist health professionals to keep up to date with their regulatory obligations. The integration of Electronic Regulatory Manuals ('ERMs') are useful tools in achieving and maintaining compliance with corporate governance obligations. As a result ERMs must be more reality than rhetoric.

The need for managing the quality of patient care is central to any organisation. One of the major dilemmas facing health professionals is how to coordinate administrative and clinical guidelines to ensure appropriate care is delivered. Integration is a management process that cuts horizontally across staffing functions, reaches vertically across clinical hierarchical lines, and involves management and staff to improve the efficiency and effectiveness of clinical care. This paper uses a case study to demonstrate that failure to integrate regulatory processes leads to disastrous patient outcomes. When legal proceedings are

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brought against health organisations, it is apparent that the judiciary will not only scrutinise health professionals but now also the appropriateness of their regulatory management system to determine the level of liability. Integration of regulatory management processes in health services appears to now have judicial support and consequently must be more reality than rhetoric.

Regulation in Health Care

There is vast array of legislation and regulatory notices that staff should be made aware of prior to providing health care. These documents include clinical guidelines, laws, regulations, policies from external health organisations and their organisations' own policies and procedures. At any one time notices may be provided by the State Health Department, Commonwealth Department of Health and Ageing, Regulatory Organisations, Medical Associations and a range of other sources. Managers, clinicians and administrative staff often have difficulties in keeping up to date with all of this information. It is certainly not uncommon for some of these updates to contradict each other and staff often experience difficulties interpreting and implementing these updates into their own service area or clinical practice.

Corporate Governance

The Australian health system has seen an expansion of health care regulatory enforcement, compliance activities and a heightened attention been given to the responsibilities of board members, CEOs and managers.[1] This expansion of compliance activity has been implemented to improve the quality of health service delivered. This has caused confusion for many health professionals as they try to grapple with the myriad of corporate governance obligations. This attention to corporate governance is rapidly becoming critically important to all health care organizations as they have to understand and meet their statutory obligations unique to the health system and then integrate it effectively across various disciplines.

What is Integration?

Integration of health care is seen as a major priority by all levels of government in Australia and internationally. It is also strongly supported by the non-government and private sectors. Integration as a term has a number of meanings.[2] At the Australian Health Ministers Conference in August 1999, the term *Integration* was defined to encompass activity which includes:

1) formal and informal linkages with other agencies and health service providers;

2) cooperation and collaboration in implementing specific interventions; and

3) formal sharing of care between, and across health disciplines and acute and community-based care settings.[3]

Evidence suggests that the benefits of an integrated health system include:

1) improved patient and population outcomes by reducing fragmentation of care through appropriate linkages between service providers and relevant agencies;

2) ensuring consistent evidence-based approaches to addressing health conditions and issues;

3) increasing the focus on addressing major burdens of disease are through strategies which focus on prevention, treatment and management regimes across health delivery settings; and

4) ensuring greater sustainability of the health system.

The following case review identifies what happens when there is no integration of corporate governance processes within a health service and how non-compliance to regulation can lead to disastrous patient outcomes.

Case Review

In the case of *Harvey v PD* ("Harvey case")[4] a New South Wales Court ordered a medical practitioner to pay over $700,000 to a former patient. In making this decision, the court identified a complete lack of appropriate management practices by a number of medical practitioners and an inadequate integration of clinical and administrative services that were not compliant with current corporate governance obligations. The court determined that this diminished corporate governance processes led to a diminished quality of patient care. This is an important Australian case because it establishes a legal precedent that the judiciary will now scrutinise not only health practitioners, but also the appropriateness of their regulatory management system.

Identification of Management Issues

The Court's analysis of the facts rather than the decision needs to be reviewed as it draws attention to the need of an integrated regulatory approach to health care. In the *Harvey* case there were three judges. All three justices were critical of the mismanagement of the patient's health information by the doctors and their staff. It was apparent that this directly resulted from the clear lack of understanding of the principles of privacy and confidentiality by all staff. The judges focussed on the failure of the doctors to advise, inadequate post-test counselling and mismanagement of their patient's health information. In particular, Justice Santow stated that:

> "it's about proper management of patients after they have been tested...the doctors were negligent in their management of the situation that was presented to them... the negligence was evidenced by their departure from, and ignorance of, established procedures which doctors are supposed to know and follow when dealing with HIV testing."[5]

In this case, had the medical staff been made aware of their corporate and clinical governance obligations then surely their clinical approach with the patient, the medical specialists and other health agencies would have been different. Clearly there should have been processes in place that sufficiently and adequately

coordinates and controls the accuracy of health information. Staff should have also been aware of the particular codes, guidelines and procedures that they should comply with to provide appropriate health services. If these governance processes had been in place, then an adverse patient outcome may not have eventuated. Integration of regulatory processes needs to be undertaken by individual health professionals and entire health organisations. Regulatory Manuals are designed to be a reference tool for the practitioner to create awareness of the requirement and to provide practical methods of complying with the myriad of regulations. The following part of this article identifies and outlines the approach taken by Plenty Valley Community Health.

Clinical Development

Plenty Valley Community Health ('PVCH') identified that the development of regulatory manuals differs in rigour, quality and standing within professions. For this reason, PVCH sought to comply with the English National Health Service's ('NHS') *Good Practice Booklet on Clinical Guidelines* and the Australian NHMRC's *Guide to the Development, Implementation and Evaluation of Clinical Practice Guidelines*. The NHS standards and NHMRC frameworks are often referred to as the benchmark in quality design. Both these documents have constituted a useful means of evaluating the authoritativeness of any given association guidelines, codes of practice and other relevant standards.

PVCH also took into account all relevant legislative requirements and assessed clinical governance obligations. Subsequently, the scope of PVCH's Regulatory Manual was extended to include the following elements and criteria.

1. Validity - the regulatory manual was based on all current available evidence, which should be correctly interpreted and reported.
2. Reproducibility - given the same evidence and methods of guideline development, other clinicians should arrive at the same recommendations and results.
3. Reliability - given the same clinical circumstances, different clinicians should interpret and apply the directions of the regulatory manual in the same way.
4. Cost effectiveness - the regulatory manual should lead to the delivery of health services that do not impose burdensome economic costs to the PVCH.
5. Representativeness - representatives of relevant interests groups should have participated in the development of the regulatory manual.
6. Clinical applicability - patient populations or services affected should be clearly delineated, as well as those not covered.
7. Flexibility - the regulatory manual should enable options to be appreciated as well as individual circumstances of patients.
8. Clarity - unambiguous language will be used so that it can be readily understood by clinicians and other staff.
9. Reviewability - regulatory manual should be reviewed and updated at predetermined intervals or to ensure legislative compliance to enable new research and changing clinical perspectives to be taken into account.
10. Documentation - the procedures used in developing the regulatory manual will be clearly described and thereby the processes which generated the regulatory manual should be transparent.
11. Amenability - the regulatory manual should include clinical audit information on ways in which adherence to them may be monitored

Theory in to Clinical Practice

PVCH therefore decided to create an Electronic Regulatory Manual ('ERM'). This ensured integration of regulatory processes across sites, services and staffing hierarchies as well as enabling seamless introduction of revisions as required. This was reviewed by the Physiotherapy team and introduced electronically. By using existing and new software applications, PVCH created a 'virtual hub' that can be accessed by all staff at anytime.

As detailed in Figure 1, PVCH has developed an ERM for the Physiotherapy team. This was the first pilot group to test such a product. As detailed, Quality Assurance Group receives corporate governance updates from a range of sources. These include ASIC, Health Regulation Boards, State Health Departments, law firms and a range of other sources. These updates are inputted into the ERM system. The PVCH Quality Assurance Group is then able to identify which specific PVCH policies and procedures are affected by these notifications and which health teams need to be notified. The ERM system has enabled efficiencies in clinical and administrative operations and enhanced service delivery. The most significant adaptation is legislative compliance. Using the PVCH ERM system has enabled the organisation to review legislation as it is passing through parliament. Using the ERM system, PVCH is able to review the impact that proposed legislation has on any and all service areas. Furthermore, business processes and change management planning can be undertaken at least 6 months in advance of the legislation coming in to effect. This means that PVCH is compliant from the commencement date of any governing legislation. The ERM system ensures all staff receive the most up to date information in relation to their service area. Regulatory processes are delivered and implemented directly into the clinical room. In this way, the legal and non-compliance problems experienced by the medical staff in the *Harvey* case are avoided.

Commentary

There appears to be great angst felt by health practitioners when they consider integrating or introducing regulatory and corporate governance systems in their health services. The

Harvey case was not viewed by the courts as simply a breach of privacy and confidentiality by medical practitioners. Rather, for the first time the courts actually assessed the appropriateness of, and compliance with, regulatory management processes. As a result, the *Harvey* case should be viewed as a 'wakeup call' for all health professionals to review their current corporate governance processes and ensure staff are aware of their compliance obligations. If integrated and implemented systematically, ERMs can improve not only compliance with regulatory obligations, but also the quality of patient care by improving the effectiveness, appropriateness, acceptability, accessibility, efficiency and safety of health services delivered. As a result, integration of ERMs in health services must be more reality than rhetoric.

[1] Queensland Government, National Health Performance Framework Paper 2001. http://www.health.qld.gov.au/nathlthrpt/framework.asp

[2] Sanford J. Grossman and Oliver D. **The Costs and Benefits of Ownership: A Theory of Vertical and Lateral Integration**, *The Journal of Political Economy*, Vol. 94, No. 4 (Aug., 1986), pp. 691-719.

[3] Queensland Health, Health Service Integration in Queensland, Position Statement June 2000 http://www.health.qld.gov.au/hssb/hou/intpolicy.pdf

[4] Harvey v PD [2004] NSWSCA 97 Unreported.

[5] Ibid at [16]

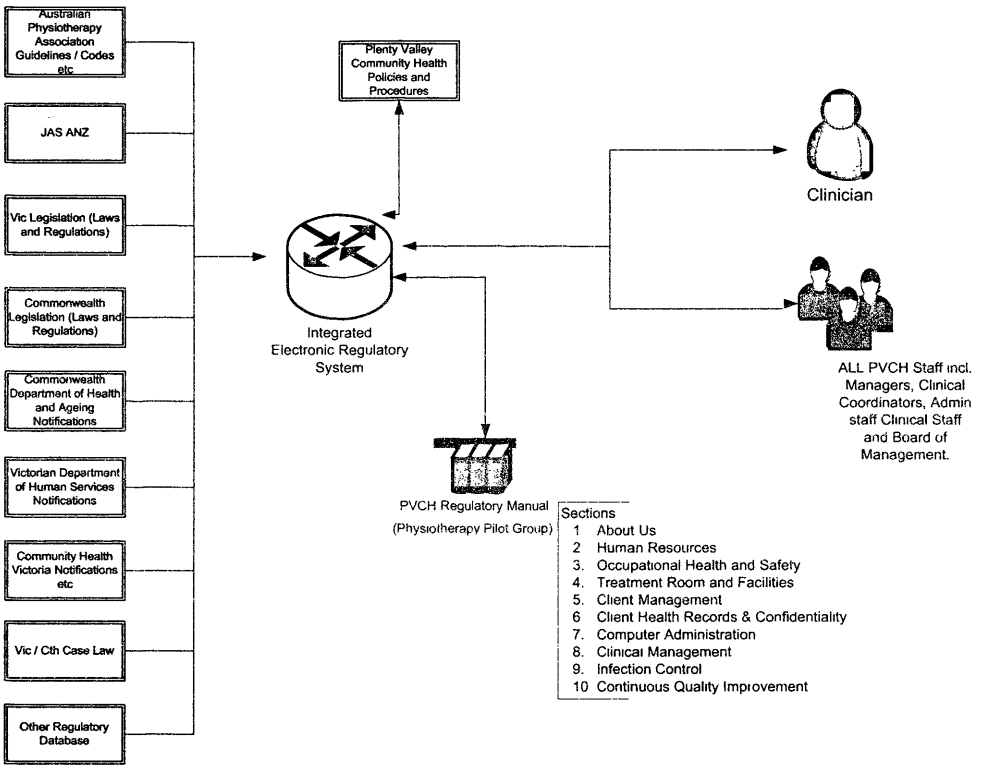

Figure 1. Regulatory Manual (Physiotherapy) Pilot Group

Internet Proxy Voting and the Australian Shareholder: Is there a need to take the technology further?

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Introduction

It has been suggested that the Internet will help to overcome the problem of shareholder passivity towards the contemporary corporation. Recent data supports this hypothesis: internet-proxy voting has steadily increased the participation of both retail and institutional shareholders at Annual General Meetings (AGMs) in Australia. This success has been taken as a cue for corporations to implement more advanced forms of technology, such as web-casts or bulletin boards, to further increase shareholder participation. However, evidence from the United States demonstrates that practical and psychological barriers make virtual meetings an unlikely replacement for the physical