Safe Introduction of New Interventional Procedures: A New Initiative in Hospital Authority

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Background

Progress in medicine and breakthroughs from bio-medical research have resulted in a rapid proliferation of healthcare technologies including drugs, equipment and interventional procedures.[1] They are often numerous, costly and holding great promises, with safety and efficacy yet to be fully established. Healthcare providers are thus under constant pressure to decide for timely introduction of appropriate and worthy technologies for benefit of patients, despite all the uncertainties involved.

Worldwide experience demonstrates that regulatory controls over emerging drugs and equipment are better established than for interventional procedures. It is not uncommon for the latter to involve intricate elements of innovation, new consumables, variations in application, and a high demand on operator skill to achieve the intended outcome. Such degrees of complexity often make the situation difficult to manage. As no interventional procedures are free from hazards, the decision to introduce a new procedure with its associated uncertainties is not a simply task. A number of government agencies and professional bodies have made attempts to devise assessment tools to manage this challenge,[2] in an effort to safeguard patient's wellbeing and uphold professional accountability.

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The Hospital Authority Scenario

In Hong Kong, the Hospital Authority (HA) has long established mechanisms to evaluate new drugs and equipment for safety and efficacy prior to their introduction into the system. Similar mechanism, however, is not available for interventional procedures. Section 22(e) (revised in June 1996) of the Professional Code of Conduct issued by the Hong Kong Medical Council stipulates that "The medical practitioner should consult and obtain approval from the relevant ethical committee in regard to the use of such surgical procedures, grafts, implants or medications". When the HA requested hospitals (or hospital clusters) to set up their own ethics committees in 1995, it was intended that they would deal with the introduction of new interventional procedures as well. Yet the prevailing practice is that only proposals on clinical trials would be considered in the hospital ethics committees. Out of the 12 major acute public hospitals surveyed in April 2000, few had established mechanism to evaluate new interventional procedures prior to their introduction, and most did not have explicit or sufficient documentation requirements for such reviews. Situation does not seem to be more assuring in the private sector (personal enquiry). Anecdotal reports that new procedure of unproven efficacy had been performed on patients highlight the need for an explicit mechanism in HA and perhaps Hong Kong as a whole.

Evolution of HAMSINP

In January 2000, the Coordinating Committee in Surgery reported to the Medical Services Development

Committee (MSDC) that a mechanism would be set up to vet new surgical procedures prior to their introduction into HA. Members of MSDC received the proposal with great enthusiasm. Thus, the Chairman, Dr the Honourable CH Leong requested an explicit mechanism to be established and implemented on the 1 January 2000 to cover all clinical specialties.

The 'HA mechanism for the safe introduction of new procedures' (HAMSINP) was designed to close a loophole in the existing system and to provide guidelines and tools for HA staff to appraise new interventional procedures and to document such activities. It was planned with the following principles in mind:

1. It is considered unethical to plan an introduction of new interventional procedure into the HA service without going through proper peer review.
2. The mechanism must not stifle clinical innovation but should, instead, facilitate timely assessment of new procedures aiming at their safe and effective introduction.
3. The mechanism would enhance accountability to public, protecting interests of patients as well as the clinicians and hospitals, through compliance with an impartial process that is explicit, transparent and benchmarked against international best practice.
4. The mechanism provides due recognition of staff initiative, originality and fosters spirit of shared learning.

Key results shall include:

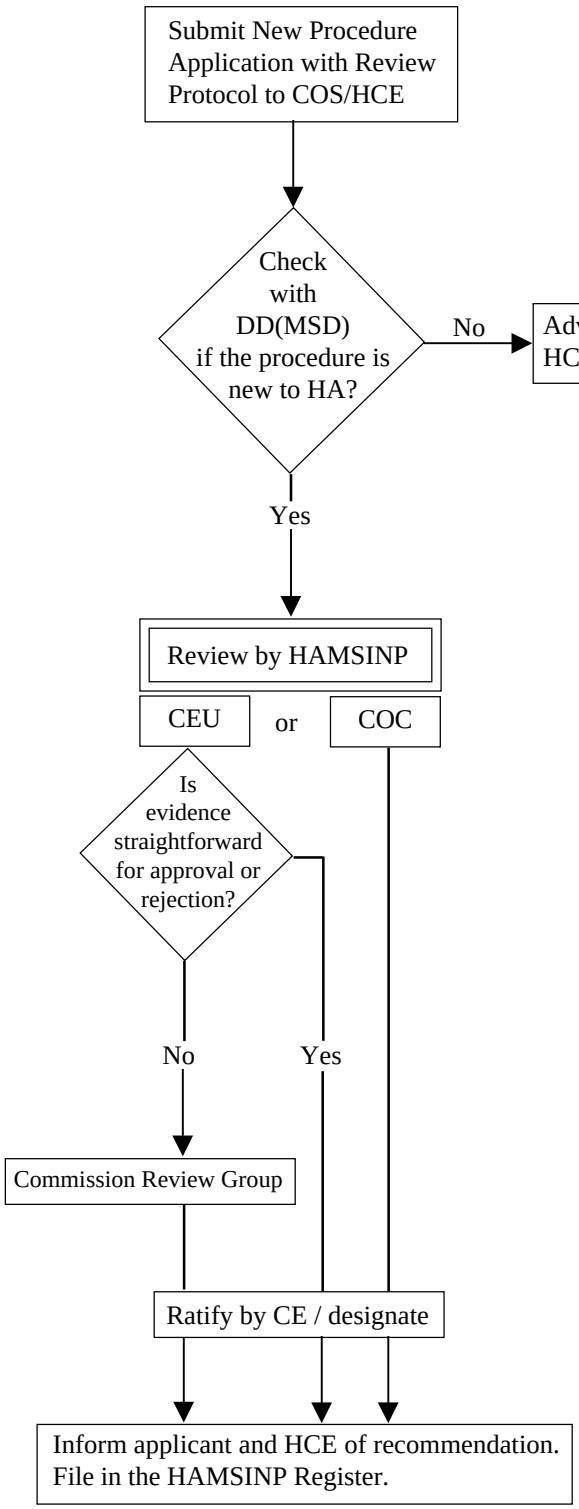
1. Establishing Standard Operating Procedures (SOP) for collecting, collating and analyzing evidence concerning the safety and efficacy of submitted new procedure, and making recommendations regarding appropriate method of introduction into the HA services.
2. Harmonizing vetting standards by providing a set of unified procedures and appraisal tools.
3. Establishing documentation requirements that permit retrospective evaluation of the conduct of the review and the quality of the decision reached.
4. Enhancing cooperation and implementation planning to minimise patient risks in going through many learning curves of individual operators and centres.
5. Setting up a central register to facilitate information dissemination.
6. Developing a culture of accountability through evidence-based decision making, independent peer review and procedural transparency.

The Approach

We scanned websites for similar set ups in the developed countries and conducted meetings to solicit inputs from leading surgical specialists from both Universities and HA hospitals. It was generally agreed that the Australian Safety and Efficacy Register of New Intervention Procedure - Surgical (ASERNIP-S)[3] was a model suitable for our adaptation. In April 2000, we were fortunate to be offered an opportunity by Pamela Youde Nethersole Eastern Hospital to test this model on an application of intracoronary brachytherapy.[4] We subsequently developed a set of SOP and appraisal tools using the evidence-based medicine approach.[5,6] These documents, grouped as HAMSINP during consultation, constituted a common platform of discussion whereby all interested staff could contribute their ideas. In developing the SOP, we took care to align the governance and management approval procedure with the existing accountability structure in the HA hierarchy (Figure 1).[7]

HAMSINP is application driven and its success is thus contingent upon professional integrity and a culture of accountability. Our professional obligation dictates that all clinicians must assess safety and efficacy issues before making changes or incorporates new innovations in interventional procedure to their practice. HAMSINP simply states these requirements and emphasizes the need for systematic searching and appraisal of evidence. The single unitary public hospital system in Hong Kong which, covers over 90% of the market, provides a unique opportunity to enable a healthcare technology assessment tool with high likelihood of success.

Noting that mutual understanding and trust are prerequisite for the successful implementation of HAMSINP. We would be holding more than 30 briefing



Abbreviations:
CE: Chief Executive
CEU: Clinical Effectiveness Unit
COC: Coordinating Committee
COS: Chief of Service
DD(MSD): Deputy Director (Medical Services Development)
HA: Hospital Authority
HCE: Hospital Chief Executive
HGC: Hospital Governing Committee
MSDC: Medical Services Development Committee

Figure 1. *An overview of the HAMSINP mechanism.*

sessions and open forum for major specialty Coordinating Committees, Hospital Governing Committees and frontline practitioners to solicit their comments.

What Have Been Confirmed in the Consultation Process?

During consultation, both heat and light were generated for HAMSINP. Concepts such as professional autonomy, public accountability and practicability were rigorously examined and debated upon among enthusiastic colleagues. No one was left in doubt of the principles and concepts of the proposed mechanism but many had shown concerns over how much could be achieved at the end. Many had pointed out difficulties such as resources constraint and a prevailing culture of competition among some hospitals that might obstruct shared learning.

HAMSINP is application driven. It is not a policing tool. The actual appraisal will be performed by peers utilizing methods established in evidence-based medical practice. This heavy involvement by clinicians should strengthen the basis and further promotes professional autonomy rather than limiting it as feared by some colleagues. HAMSINP would not infringe upon a clinician's sacrosanct privilege and duty in taking care of his/her patients. In unforeseen circumstances where a new procedure may be life saving, the accepted practice to "act in good faith" would prevail over a prescribed mechanism for normal use. Despite all considerations and efforts to design a "perfect" mechanism, the HAMSINP would need to evolve over the years to fully achieve its intended objectives.

Innovations and hypothesis that needs to be tested by clinical trials should be referred to the ethics committee for consideration. The latter's scope is much wider, covering issues such as bio-medical ethics, scientific values and quality standards in the designing, conducting, recording and reporting of clinical trials.[8] It is the authors considered view that the existing hospital ethics committee infrastructure needs further development to match our community's expectation.

Conclusion

The HAMSINP helps to close a "loop hole" in the existing system where some new procedures will escape proper assessment by bypassing the ethics committee. The limited experience we have gained suggested reasonable confidence on its feasibility and practicality. By making the best evidence and sound recommendations clearly documented and readily available, it will certainly facilitate better decision-making at all levels of healthcare in the Authority.

Readers interested in obtaining a copy of the SOP, and or providing any comments, should contact Dr SP Lim at splim@ha.org.hk.

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