Letters to the Editor

Introduction of New Interventional Procedures

Dear Editor,

Thank you for your publishing our paper[1] in your college journal as a special article. In your editorial[2] we note your views on the HA Mechanism for the Safe Introduction of New Procedures (HAMSINP) which we believe might be shared by some other colleagues. We would thus like to be given further opportunity to demonstrate that the perceived difference is neither fundamental nor substantive but one of proportionality and preference that is well within the tolerance of open minded intellectuals.

HAMASINP is a process control tool that bears no pre-judgement on the outcome of the application. By adopting an evidence-based approach and making the appraisal records available for scrutiny (and appeal) by any interested parties, its representativeness resides in the standard and rigour of appraisal and synthesis in the review process and not in the few chosen experts. The mechanism serves to require a standard of care before introducing a new medical interventional procedure to supplement or replace any existing treatments.

HAMSINP attempts to close existing gap in standards. Your editorial[2] suggested that both teaching hospitals have already established similar mechanism to approve new interventional procedures confirms that the extension of this requirement to the whole system is timely and appropriate. Hospital Authority (HA) has learned from these exemplary "bottom-up" initiatives to enhance professional accountability and patient safety and is applying them system-wide to maximize benefits. Indeed, the idea of HAMSINP when initially conceived by the Coordinating Committee in Surgery was modelled upon A-Sernip and the Queen Mary Hospital's therapeutic and technology sub-committee approach. When it was presented to the Medical Service Development Committee, members requested us to expand the mechanism to cover all clinical specialties so that patients receiving care in the public hospitals would all enjoy the same level of safety precaution that this mechanism can offer to the introduction of new interventional procedure.

The HK Medical Council also requires medical practitioners to handle new medical procedures with particular care. Under Part II (Convictions and Forms of Professional Misconduct which may lead to Disciplinary Proceedings) of the Professional Code and Conduct issued by the Hong Kong Medical Council, a whole section is assigned to new medical procedures. Besides other requirements, it stipulates that "medical practitioners when using NEW surgical procedures, grafts, implants or medications on patients should consult and obtain approval from the relevant ethical committee in regard to the use of such surgical procedures, grafts, implants or medications". In our understanding, there is no exemption to this requirement whether a new medical procedure is being introduced as a service or as part of a research. The Medical Council has examined HAMSINP and responded to HA that "the proposed HAMSINP is in general considered to be in line with the principles laid down in Section 8 'New Medical Procedure' of the revised Professional Codes and Conduct".

In view of all this developments, it is difficult for HA to justify a lassie faire approach that permits its hospitals to provide different standards of care and run the risk that some will fall short of the established professional code and conduct.[3] In reality, one either choose convenience and the risk that some of the new interventions introduced would subsequently turn out to be inappropriate (and possibly harmful), or the alternative of having process control that may cause a certain degree of "inconvenience" (and possibly delay), but an assurance of appropriateness of the new intervention introduced. Although HAMSINP will only be applied to a very small part of the clinical activities, the decision to have it set up in the HA system will have wide range of impacts including ethical, cultural and strategic political ones, We are aware of the opinion that considered HAMSINP (or any form of explicit review) to be a threat to the prevailing culture as it could compromise the perceived degree of autonomy currently enjoyed by our peers. Another equally valid description

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Opinions expressed are views of the authors and not necessarily the view of the editorial board or the Hong Kong College of Cardiology.

is that the mechanism serves to enhance professional autonomy by providing further justification and rationale for professional decision making using peer-reviewed evidence. Our difference here should be tolerable and I optimistically believe it would diminish with time.

The argument that formal review would delay the introduction of new technology and thus deprive patients of its benefit is appealing but unsubstantiated. Under normal circumstances, it takes anything from months to years to properly prepare for the necessary human resources training and facility support before we can responsibly and safely introduce a new interventional procedure into service. During our consultation with frontline colleagues, they also confirmed that a review not lasting more than 2 to 3 months would be acceptable. Therefore, providing an application is timely submitted, HAMSINP should not cause delay in its introduction. To avoid any possibility of depriving a patient from receiving an urgent therapy (even a new one) which is necessary to save life or prevent serious harm, the scope of HAMSINP is confined to those introductions that are "planned".[4] The burden of justification for exception to a responsible, planned introduction would be significant.

In April 2000, we had the privilege to test the concept on an application submitted to the hospital chief executive of Pamela Youde Nethersole Eastern Hospital for the introduction of intracoronary γ-brachytherapy. The review was completed in *a few weeks* and it did not alter the hospital's action plan. We have recently received another application from the Grantham Hospital on the use of ventricular assist device (VAD) for end stage heart failure as a bridge to transplant. While the review is still being conducted, the cardiac team performed that procedure as the clinicians considered it life saving for a particular patient. Apart from these 2 cases, we did not handle any other applications and thus could not have caused the 6 months' delay as described in your editorial. We would be most grateful if you can provide further identified detail relating to your alleged "delay". In our experience, HAMSINP has not interrupted any proposed activities. Moreover, by establishing a register accessible to all HA staff through electronic means and providing links to related web-sites, HAMSINP helps to spread knowledge and information. It has the potential of helping HA to acquire new technologies in the future, to facilitate coordinated dissemination of technology as well as inter-hospital learning. Readers who are interested in the mechanism can visit the HAMSINP web-site under the Hospital Authority Library Information System (HALIS).

Finally, HA acknowledged different levels of readiness between colleagues from various disciplines or hospitals and explicitly allowed hospitals to opt-out of the central mechanism if they prefer to develop their own models, providing that they fulfil the basic requirements spelled out in HAMSINP. So far, two hospitals have opted to stay out of the centrally coordinated review mechanism. Our initiative, though a new one in HA on a system-wide basis, is not an original innovation. Similar review mechanisms have been established in UK, Australia and also locally in teaching hospitals like QMH (? PWH as well as quoted in your editorial). Our initiative can be best described as a top-down follow-on effort building on an exemplary model which was developed from a bottom-up approach out of need.

Yours faithfully

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References

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2. Lau CP, Woo KS. Point of view: top-down or bottom-up? A cardiologist's view point on the proposed hospital authority initiative in safe introduction of new interventional service. J HK Coll Cardiol 2001;9:1-2.
3. The professional code and conduct. Accessible in the Hong Kong Medical Council web-site (http://www.mchk.org.hk/)
4. HA mechanism for the safe introduction of new procedures, document number CEU001, revision 1. Accessible in HALIS or request copy from the clinical effectiveness unit of HAHO.

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Dear Editors and Dr Chang,

We thank Dr D Chang's letter clarifying the role of the Hospital Authority Mechanism for the Safe Introduction of New Procedures (HAMSINP).

First, the editorial represents our view, which may not represent the viewpoint of the editorial board nor the Hong Kong College of Cardiology, as clearly documented in the disclaimer of the article.

Second, while we do not disagree that the HK Medical Council and the HAMSINP have similar intention to safeguard patient welfare, the Medical Council concerns with a professional conduct rather than the procedure of applying new interventional procedure to a HA hospital-wide level. Indeed, the Medical Council only requires approval of "relevant ethical committee" for an individual to deliver a new interventional procedure.

Third, we are pleased to learn the rapidity that the HAMSINP system can function, and the credit should go to the team and the director. We look forward to its continued efficiency. As we would like to clarify again, the HAMSINP, as we understand it is targeted to the logistics and safety of introduction of new (and already established) procedure at the HA hospital levels. For clinical trials on new devices/intervention, the hospital/university ethics committee would suffice to safeguard the welfare of the patients. We agree that there will be a balance between professional autonomy and service development on a territory wide level. We are very pleased to learn that the HA allows freedom of choice with individual hospitals deciding to use alternative approach to the HAMSINP system.

Yours sincerely

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