Format for Submitting Proposal

Title of the Proposal

Design and development of a post operative cardiac critical care simulator for training nurses

Member’s Details:

Name:
Sreekanth Nayak, Pavan Sridharan, Prof. J. E. Diwakar, Prof. B. Gurumoorthy, Prof. Dibaker Sen, Prof. J. Arakeri (IISc)
Julius Punnen, Devi Shetty (Narayana Hrudyalaya)
Sriram Sampath (St. Johns)

Address for communication: CPDM, IISc, Bangalore -12

e-mail: nsreekanthnayak@gmail.com, pavansridharan@gmail.com, bgm@cpdm.iisc.ernet.in

Phone numbers:
Landline:
Mobile:

Broad Area/Sector:
Medical Training/Education

Total cost (Details of budget with justification).

<table>
<thead>
<tr>
<th>Project Tasks</th>
<th>Unit Cost</th>
<th>No. of Units</th>
<th>Total Cost</th>
<th>Cumulative Cost</th>
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<tr>
<td>Setup Cost</td>
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<th>IISc contribution</th>
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<th>NH contribution</th>
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<td>Two doctors and nurses as required</td>
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**Abstract of the Proposal (Maximum 150 words):**

Summary of the activities to be carried out under the proposed proposal:

(If in phases, please give phase wise input needed and the output that you would be submitting to KKC after the completion of each phase).

We propose the design and development of a medical simulator for nurses to practice diagnosis and procedures that are carried out in a post operative cardiac critical care unit.

The product development of a medical simulator will be carried out. The sequence of activities is as follows-

1. Problem understanding and requirements identification - This information is collected from interviewing the stakeholders involved, namely nurses (who will use the product), doctors, hospital technicians. Further studies are done of hospital systems, infrastructure, procedures, competing
products etc. The result of this phase is a detailed set of requirements which the product will have to fulfil.

2. Concept generation and validation, prototype creation and testing- The product consists of physical representations of a human patient and the instrumentation found in the CCU. Both are associated by an electromechanical and computational back end. Thus, the concept generation and prototyping activities involve the design and building of physical modules, electronic circuitry and computer programs, and interfacing the three together.

After this is done, a database of medical scenarios will be created based on the nurses' training requirements. In parallel with these tasks, planning for manufacture and scalability is done.

Description of the Proposal:

- **Introduction (Maximum 200 words)**

The objective of the Nursing Training Simulator is to train the nurse to handle various scenarios that occur in patients in the post operative CCU. Since the nurse is usually present at the bedside, she should be able to keep an eye on the condition of the patient from the information available to her (vital signs, charts etc). More importantly, she should recognize the onset of clinical complications. Experienced nurses will typically be able to intervene to some extent. Other nurses would report the condition to them or the duty doctor. The simulator would serve as a platform for training on these abilities in a hands-on manner, without having to wait for the complications to arise in real patients. It should also reduce the training workload of experienced nurses, allowing them to spend more time in the wards. The system aims to be realistic yet affordable enough to supplement existing training facilities while making business sense for hospitals and institutes.

- **Includes birds-eye-view of the current status describing state/national/international scenario / factual analysis of the idea/ existing challenges and gaps.**

Medical simulators have been used for imparting medical training in the developed nations for several decades now, ranging from training common emergency procedures like CPR to more advanced and complex scenarios. However the high costs of procurement, infrastructure and maintenance render the use of these foreign medical simulators prohibitive for developing countries like India. In India, some organizations (such as the Manipal group and MS Ramaiah) in the medical education domain have invested and procured a number of simulators for meeting the needs of students in-house and conducting simulation workshops. Simulators can be an effective marketing tool for an institution for attracting students, academic partnerships etc. These simulators have a high cost for several reasons, primary being the exotic materials and R&D costs associated with replicating human tissue for sensory and physical response. Further, the number of devices required for training means that the savings from mass manufacturing will not lower the cost. The simulator that is being proposed here is different in several aspects. The well defined requirement of training nurses in a post operative environment allow for very specific functionalities. The product aims to increase the level of expertise of nurses in diagnosing and taking action in cases of emergency or complication thereby saving vital time and lives.

- **Explain regulatory bodies’ governing sectors’ existing norms/legal framework etc needed to be attended prior to making it possible to implement.**

The proposed product is to be used for training purposes, to be used by paramedical and nursing staffs that have had prior training. No part of the device is required to be in contact with a patient, even non-invasively. Nor is the device is required to be located in an actual ward or a hospital premises (however, this would be desirable). Therefore, regulations that govern medical devices should not apply. In the current state of development, the materials used are widely found in hospitals. Off the shelf computers and peripherals are certified from reputable manufacturers and wireless communication done over wi-fi, which is already in use in the wards.

- **Origin of the idea/recommendation (How different it is? what is new in the proposal? What is original in the proposal? )**
The device is based on ongoing project to develop an "Advanced ICU scenario Simulator" that is being carried out jointly between CPDM and St. John's Hospital, funded by the Department of Bio Technology (DBT) of the Government of India. The proposed device is based on the architecture of the ICU simulator, which is a platform with several physical and software modules that would provide capabilities as desired. The platform consists of a mannequin and the instrumentation that is present in an actual ICU. The mannequin houses several independent physical modules that are interfaced together by a computer. "Module" refers to an assemblage of components that are needed to simulate a particular medical procedure. Each one is built to ensure an accurate perceptual response, and contains sensors, transducers and actuators that will aid in the performance and monitoring of the procedure. The various modules are independent of each other, contained within the manikin and are only related via the computer. The proposed device is different from the ICU simulator in that it will be used to train cardiac post operative critical care nurses, therefore the medical procedures are different, the complications are different, and the training methods are different from those used to train doctors. The overall architecture is original, different from commercially available simulators in that the perceptual and physical response is not delivered by materials and configurations that closely mimic the human body. Instead stimuli are sensed electronically, processed by a computer and electronically triggered actuators deliver the required response. This allows the physical components to be made of easily available materials, which significantly bring down cost of procurement as well as manufacture. This approach also allows for customizability, allowing trainers to specifically build training programs based on their own requirements.

Significance of the proposal for Karnataka in terms of benefit, recognition, status, enhancement of knowledge

The proposal is an initiative to enhance skills that are required critically in India and around the world. The project involves two globally well known brands from Karnataka - Narayana Health and IISc, bringing together expertise in medicine and engineering respectively. With the support from the Karnataka Knowledge Commission, we aim to be a partnership of government-industry-university that successfully creates a product that is beneficial to society and humanity.

Objectives
(Illustrate the specific and overall objectives of the proposal)

Proposed is an aid to increase the competence and skill level of critical care nurses, with the overall objective of improving their ability to conduct timely intervention, saving precious lives. Specific objectives include:

1. Supplementing of medical education with more practical training without involving human subjects. This is done by challenging the student real time, observing how they react in terms of diagnosis and action taken.
2. Act as a platform for demonstrating various medical conditions- their symptoms, complications as well as corrective action without having to observe on an actual patient.
3. Improving the way assessment and benchmarking of nursing skills is done. Medical administrators will be able assess their staff as well as monitor their performance over a period of time.
4. To improve standardization in nurses’ training, as the functionality of the system is defined by a number of experts.
5. Allow for customization of the simulator such that doctors can create scenarios/situations based on their personal experiences and advancement in medical science.
6. A tool for "knowledge capture" from doctors and experienced healthcare professionals, and sharing between them. The learning of different conditions, their symptoms and complications can be composed in the form of scenarios that can be played out elsewhere, accessed remotely from databases.

Rationale
(Narrate the rationale of the proposal/idea)
The rationale behind the Nursing Training Simulator is to train the nurse to handle various scenarios that occur in patients in the post operative CCU. Since the nurse is usually present at the bedside, she should be able to keep an eye on the condition of the patient from the information available to her (vital signs, charts etc). More importantly, she should recognize the onset of clinical complications. Experienced nurses will be able to intervene to some extent. Other nurses would report the condition to them or the duty doctor. The simulator would serve as a platform for training these abilities in a hands-on manner, without having to wait for the complications to arise in real patients. It should also reduce the training workload of experienced nurses, allowing them to spend more time in the wards. The system should be simple and low cost, and yet realistic to make it effective and commonly available in hospitals.

Target Group
(Mention the target groups in terms of beneficiaries of the proposal, if implemented in terms of nature and number such as citizens, students, state govt departments, educational institutions, rural and urban areas, women, children, disadvantaged section of people, etc).
1. Cardiac critical care nurses
2. Hospitals which have cardiology departments
3. Medical educational institutes
4. Medical students
5. Nursing students
6. Healthcare workers in both urban and rural areas
7. Citizens who are heart patients, from all sections of society
8. Other establishments like the defence forces, PSUs with large number of factory workers, disaster relief bodies like NDRF, for emergency response drills and so on.

Support Needed
List out all the support needed (whose support is needed and describe ways of engaging/involving them and what would be their contribution).
As most of the development is between the engineering and medical experts, external support is not sought out at this stage of the project. However, for scaling and sustainability, support for setting up manufacturing infrastructure maybe required. Since this will vary with several factors such as materials and processes, experts can be brought in at a later stage.

Detailed Plan of Action-Implementation Strategies/Mechanism
Includes strategies or step-by-step action plan, with a timeframe, to implement the solutions/ideas including any policy change/amendment to existing law or making of new policy to facilitate implementation. Proposals to include the following:

- Constitution of committee/expert group/task force etc needed
- Stakeholders consultation-identify the stakeholders and number and type of consultation required
- Number of expert meetings/brainstorm sessions needed
- Implementation agency - single or multiple institutions/departments
- Piloting/field test, if required
- Any other strategy

A team of engineering and medical experts from the partner institutions have already been formed and implementation is underway. The project has progressed beyond the concept generation stage, in terms of structure and function of the underlying platform and principles of operation. Currently requirements, concepts and prototypes are being developed for the modules that provide the specific medical functionalities required. An overview of the product and its components has been described in an earlier section of this document. The strategy is to complete prototyping of the backbone physical and computational platform- iteratively demonstrating, collecting feedback and carrying out the necessary improvements. In parallel, requirements for the medical scenarios are being gathered from interviews with doctors and nurses. In this step, designers from the team are interacting with doctors and nurses in the frontline of post-operative cardiac care. Scenarios that would have to be captured by the simulator will be defined by the designers based on the observations and feedback from the doctors and nurses. These would have to be ratified by the doctors. The meetings between the medical experts and engineering partners are taking place as and when needed. Once the prototype has been completed, it will undergo testing in the hospital premises. A detailed time plan of the project is attached in the next session.

The proposed solution consists of the simulator platform with modules customized to suit the requirements of NH. Based on current requirements, the simulator platform consists of a central processing unit and a mannequin with the physical modules installed:
1. injection air bubble detection
2. anterior tibial pulse
3. chest rise and stomach distension
4. pupillary dilation
5. Calf swelling

The simulator will include the following interfaces to represent medical devices and critical care instruments normally present in the ward
1. Vitals Monitor
2. Ventilator (monitor and tubing)
3. Trainee interface module
4. Intra-aortic balloon pump (body and interface)
5. Syringe pump (body and interface)
6. Pressure transducer dome
7. Intercostal and mediastinal drains
8. Catheters, stethoscope, injections etc.
9. Intra Venous Fluid lines

The vitals monitor will display waveforms for ECG, ABP, SpO2, EtCO2 and their related parameters. All the variations of these waveforms for complications will also be included for identification exercises for the trainees as required. The ventilator monitor incorporates waveforms for the different modes - Volume control, pressure control, pressure assist and CPAP for multiple respiratory conditions.

**Sustainability**
**How can the initiatives be sustained?**

The initiative can be sustained by demonstrating the usefulness of the product to a wider audience. If this is successful, the medical fraternity should consider adopting simulation in medical training practices. The product is designed for affordability, it will be well within the reach of most medical establishments in India, whether educational institutions or hospitals. Besides the healthcare industry, establishments like the defence forces will benefit from it. Based on their need, the product can be purchased outright. If not, the product can be used to conduct simulation workshops, which will not only help recoup their investment, but also spread simulation-based medical training to other organisations and individuals from smaller hospitals, clinics. In this way, the initiative can achieve economic sustainability.

**How can the initiative/programme/scheme be integrated with departments' ongoing functions?**

### Duration

Overall time required for:
- Completion of the project Report;
- Implementation of the project with timeline for each action plan;

<table>
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<th>Month 2</th>
<th>Month 3</th>
<th>Month 4</th>
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<tbody>
<tr>
<td>Overall product definition (with NH/others.)</td>
<td>Feedback based corrections, alternate concepts</td>
<td>Critical Design Review</td>
<td>Feedback corrections/Prototype testing</td>
<td>Integration as per NH scenarios</td>
<td>Wet testing in hospital premises</td>
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<td>Preliminary Design Review</td>
<td>CE certification – product specific analysis</td>
<td>Custom modules prototyping</td>
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### Impact

Describe the impact or outcome of implementation of the idea on:
- KKC’s mandate in general;

- the target group in specific;

The immediate beneficiaries of this proposal will be nurses, as their competence and efficiency will increase. Experienced nurses will be freed of some training duties, and can concentrate on supervising wards. As a result, the doctors’ workload will be freed of more routine tasks. Better trained healthcare professionals improve the outcomes of medical procedures. Lower number of procedures lead to lowered costs, time spent per patient—freeing infrastructure to serve a larger number of patients more profitably, with a reduced number of complications and more lives saved are considered. Educational institutes will benefit as their students will be certified earlier, having
received better training. Healthcare professionals in rural areas will particularly benefit, as they can be continuously trained using a system that is periodically updated by the best doctors in urban areas. Thus, they need not work in large hospitals in urban areas to be exposed to the best training practices. The ultimate beneficiaries, however, will be common citizens seeking medical treatment from clinics and hospitals - better medical facilities will be made more available, and at a lower cost.

**Deliverables**
List out the final deliverables in terms of knowledge materials, reports, documentaries, etc., IISc will develop one prototype of the Nursing Training simulator for testing, evaluation and feedback by Narayana Hrudayalaya. The prototype will be demonstrated based on the manikin being developed in IISc. However, the simulator is modular as discussed above and therefore NH will have the option to either use the manikin from IISc or add the remaining elements in the simulator to a manikin of their choice. Once the simulator is accepted, a mutually agreed number of β-prototypes will be built for NH for further testing and deployment.

**Recommendations**
(Contains solutions/approaches/suggestions to address the identified gaps/or to overcome the challenges)
None so far

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Signature:

Date: 28/1/2015

Kindly send your proposals to the following address:

Member Secretary
Karnataka Knowledge Commission
Room No. 438-439, 4th Floor
Vikasa Soudha
Bangalore-560001
Email: admnkkc@gmail.com
Phone: 080-22268626/22267626