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Thai Nurses' Association
Of Thailand

The **2nd** International Nursing Research Conference
“Future Nursing Research and Innovation
for Sustainable Global Health”

to Commemorate the 125th Anniversary of the Birth of HRH Princess Srinagarindra

Jointly Organised by WANS, TNMC & NAT

Ethical Considerations of Emerging Nursing Research

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I have **no conflicts of interest** related to this
presentation.



Example of Ramathibodi Medical Innovations –created by nurses.

Development of Hemorrhoid Ligator removal for Internal Hemorrhoid

การพัฒนาอุปกรณ์รักษาโรคริดสีดวงทวารหนักชนิดภายในด้วยวิธีการใช้ยางรัด

โดย ฝ่ายการพยาบาล และภาควิชาศัลยศาสตร์
คณะแพทยศาสตร์โรงพยาบาลรามาธิบดี

IP

ประเภทสิทธิบัตร: อนุสิทธิบัตร

ชื่อการประดิษฐ์: อุปกรณ์สุญญากาศที่สามารถดูดจับและปลดปล่อยยางรัดที่อยู่ภายในอุปกรณ์นั้น

เลขคำขอ: 2403001846

วันที่ยื่นคำขอ: 20/06/67

ที่มา

โรคริดสีดวง(Hemorrhoids) เกิดจากการขยายตัวของหลอดเลือดขนาดเล็กส่วนปลายบริเวณเยื่อหุ้มช่องทวารหนัก รวมถึงมีการหย่อนยานของเนื้อเยื่อเกี่ยวพันของเยื่อหุ้มช่องทวารหนัก การรักษาสามารถทำได้หลายวิธี ตั้งแต่การดูแลตนเองโดยปรับพฤติกรรมการใช้ชีวิตควบคู่กับการใช้ยา การฉีดยา (Sclerotherapy) การจี้ด้วยเลเซอร์ อินฟราเรด หรือเครื่องจี้ไฟฟ้า การผ่าตัด มักจะใช้เมื่อการรักษาแบบอื่นไม่ได้ผลและมีค่าใช้จ่ายสูง การใช้ยางรัด (Rubber Band Ligation) เป็นวิธีรักษาโรคริดสีดวงทวารแบบผู้ป่วยนอกที่สะดวก และได้ผลการรักษาที่ดี

อุปกรณ์ที่ใช้ในปัจจุบันเป็นแบบโลหะใช้ซ้ำ มีปัญหาเรื่องการรัดได้ไม่ดีนักตรงตำแหน่งที่เหมาะสม เนื่องจากข้อจำกัดของขนาดอุปกรณ์ที่มีขนาดเล็กกว่าริดสีดวงทวารและการยึดจับในกรณีที่มีแผลเป็นจากการรัดยางครั้งที่แล้ว ทำให้การดึงรัดสีดวงมีภาวะแทรกซ้อนได้มากขึ้น

อุปกรณ์ที่ประดิษฐ์ขึ้นใหม่เป็นกระบอกสุญญากาศ สามารถแก้ปัญหานี้ได้ โดยมีแรงดูดเบากว่า และไม่ได้สัมผัสริดสีดวงทวารโดยตรง ทำให้ภาวะแทรกซ้อนที่เกิดขึ้นน้อยลง

การพัฒนา

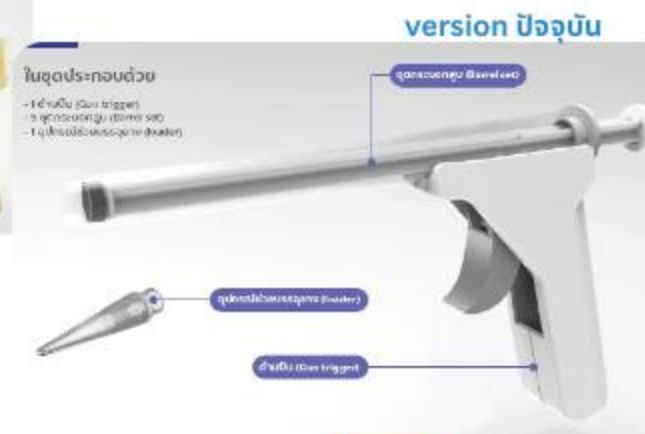
- ปัจจุบันด้ามยิงริดสีดวงที่ใช้งานอยู่ ผลิตจาก **สแตนเลส** ไม่สามารถซ่อมแซมได้ และไม่มีผลิตในประเทศไทย ราคาด้ามยิงริดสีดวงประมาณ 15,000 บาท/ด้าม คีม (forceps) ประมาณ 8,000 บาท
- ได้พัฒนาอุปกรณ์แบบใช้ **ครั้งเดียวทิ้ง (Disposable)** คิดค้นอุปกรณ์ที่ทำจากพลาสติกซึ่งสามารถใช้กับผู้ป่วยได้

การต่อยอดในอนาคต

- ผลิตอุปกรณ์ใหม่มาทดแทนอุปกรณ์เดิมที่ทำจากสแตนเลสที่กำลังจะขาดแคลนและราคาสูง
 - 1st target: Key Opinion Leaders (KOLs general surgeon) ใน sw.ย่านโยธี
 - 2nd target: sw.เอกชน
 - 3rd target: sw.รัฐ
- Channel: ผ่าน distributor เครื่องมือแพทย์ ซึ่งเป็นผู้ทำ sales & marketing strategy ผ่านผู้แทนขาย
- Price strategy: ราคาขายเข้า sw. 1,000-1,250 บาท/ชุด (เฉลี่ย 200-250 บาทต่อการรักษา) ประกอบด้วย ด้ามปืน ตัวหลอดยาง และกระบอก 5 ชิ้น บรรจุในซองฆ่าเชื้อ



version 1



version ปัจจุบัน

จุดแข็งของผลงาน

Single used Hemorrhoid Ligature Single used /Sterilized

คณะผู้วิจัย



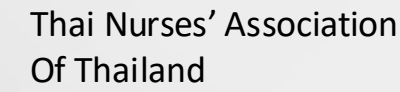
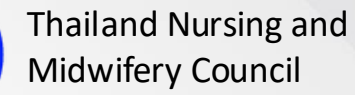
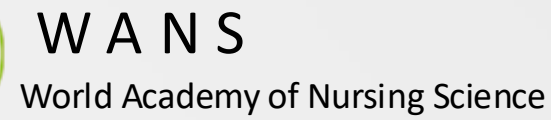
นางสาวเสาวรส พานิชย์วิสัย
ฝ่ายการพยาบาล



ศ.นพ.ไชยรัตน์ ทรัพย์สมบูรณ์
ภาควิชาศัลยศาสตร์



ศ.รท.นพ.จุมพล วิชาศรีศม
ภาควิชาศัลยศาสตร์

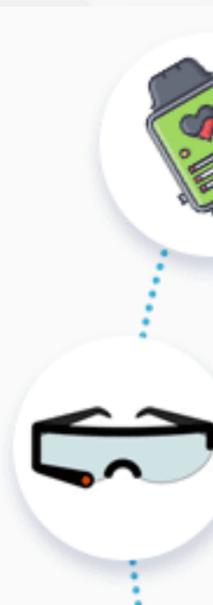


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- **Wearable and Portable Technology**
- **Robotics and Automation**
- **3D Printing**
- **Virtual Reality**
- **Telehealth**
- **Artificial Intelligence**

An illustration on the right side of the slide shows a green smartphone with a heart icon and a pair of blue VR glasses, both enclosed in white circles. A blue dotted line connects the two circles, suggesting a connection between mobile technology and virtual reality.



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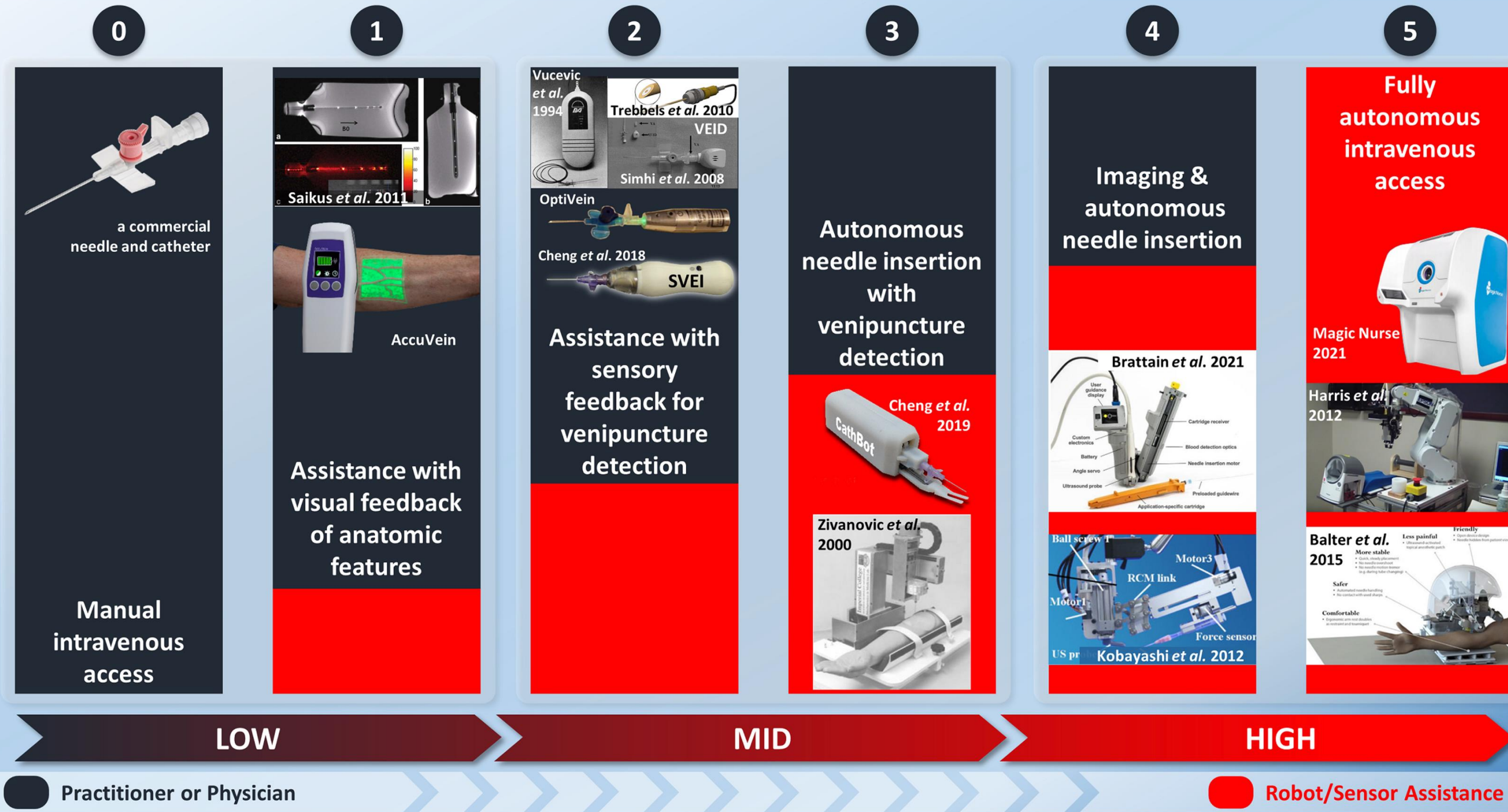
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LEVEL OF AUTONOMY IN INTRAVENOUS ACCESS SYSTEMS





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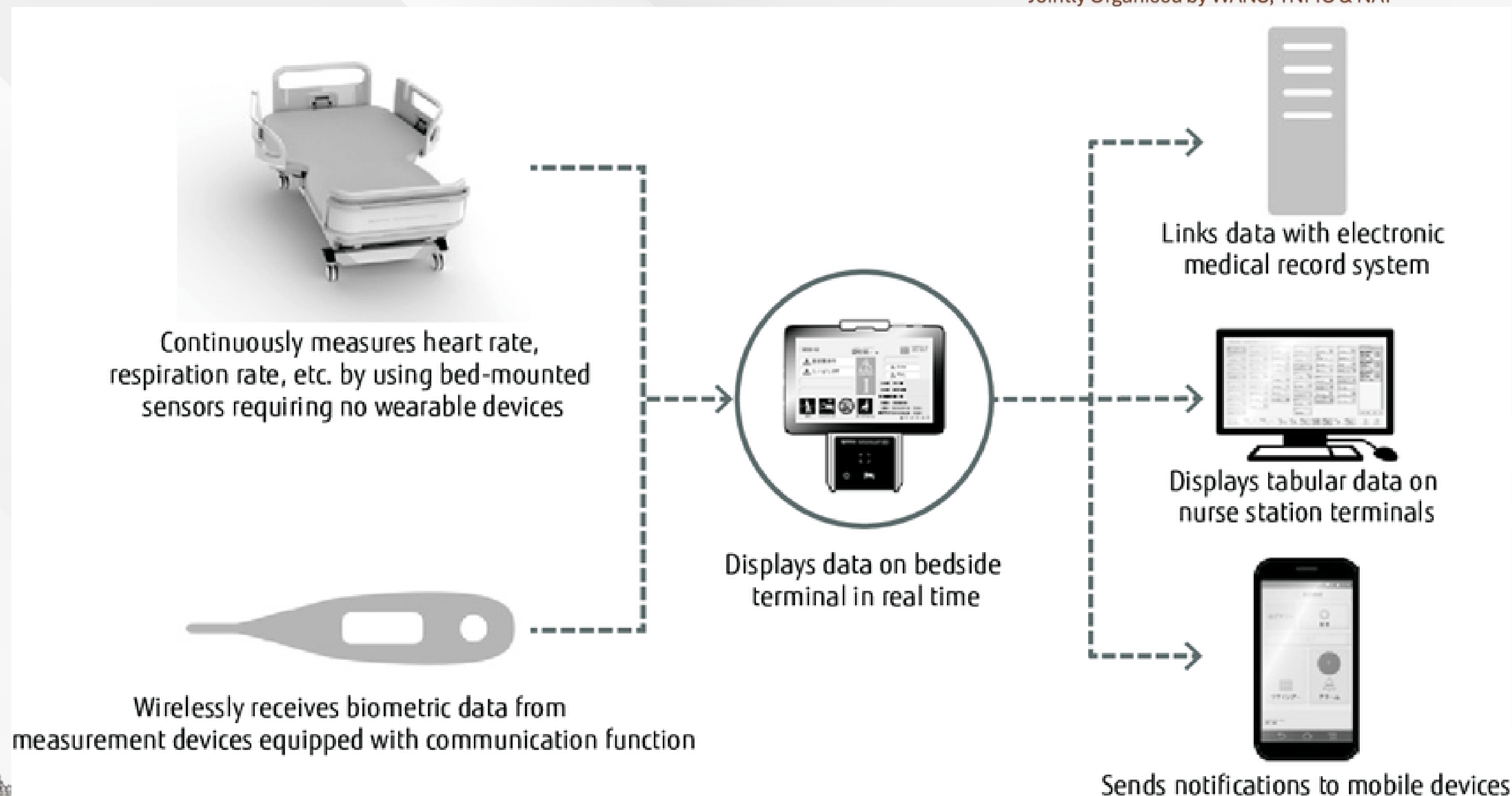


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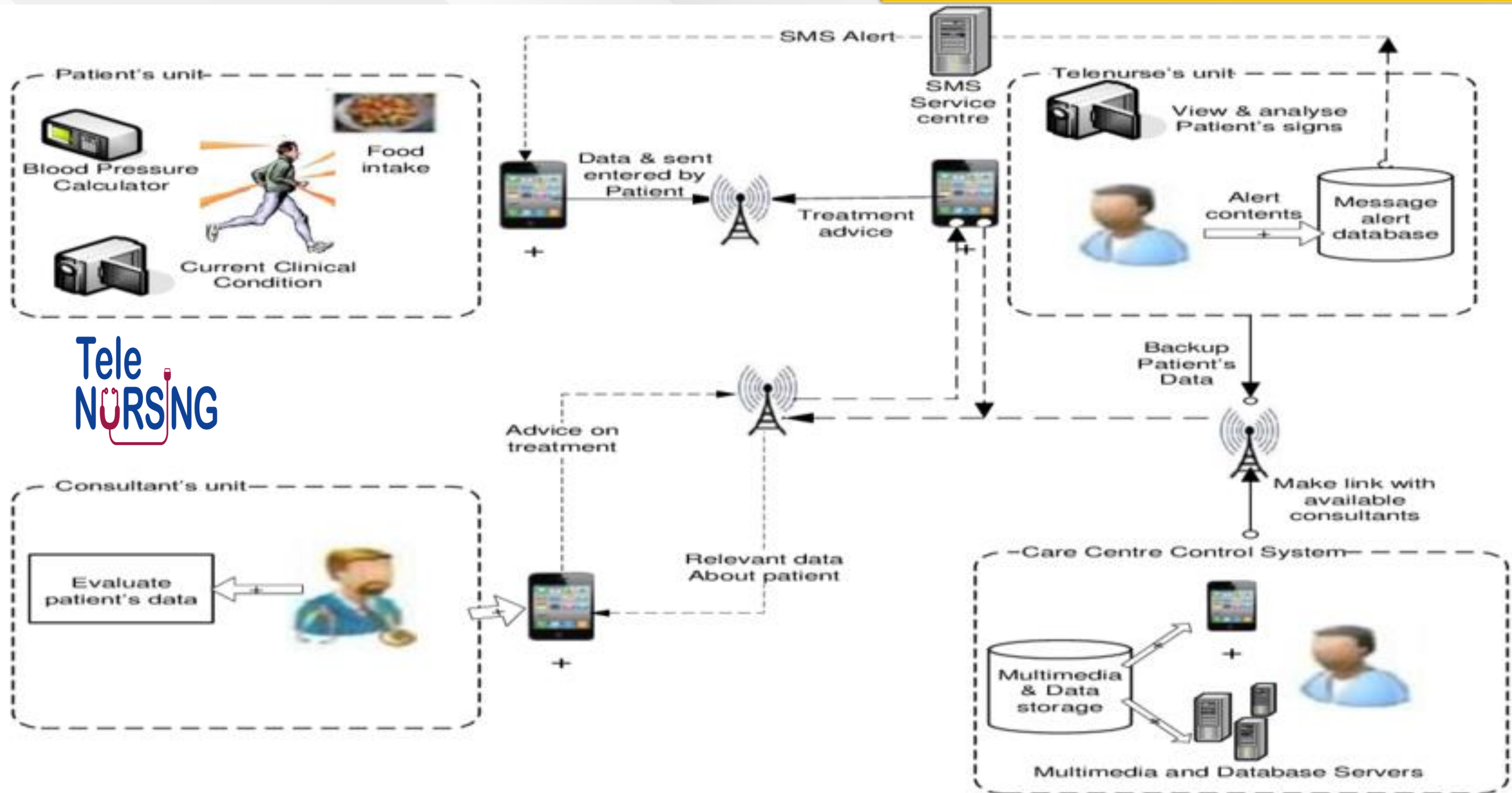
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Case Study

“A Randomized Controlled Trial of the AI-assisting radiological diagnostic software combining with the telemedicine in Mobile CT scan to improve the efficacy of emergency medical service for stroke patients.”

- Stroke: emergency condition, one of the common causes of death.
- 75% of cases are ischemic stroke.
- Early diagnosis and early intervention within 4.5 hours -> save life and get better recovery
- 1/3 of patients can access to health care facilities that have CT imaging and diagnosis can be confirmed by qualified radiologists.



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Case Study

- Mobile CT scan unit is introduced to improve the referral system and facilitate the early access to CT imaging, especially in the rural area.
- In-House AI-assisting radiological diagnostic software combining with the telemedicine consultation is developed and installed in the mobile CT scan unit.
- When the emergency system is alert and patient is suspected to have stroke attack, the ambulance will be sent from the nearest community hospital to the patient's house.
- **Objectives:** compare the effectiveness of Mobile CT scan unit with AI-assisted radiological diagnostic software and telemedicine service **versus** the existing stroke fast track system



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Case Study-continue

- PI: emergency physician & the director of the National Emergency Medical Service System.
- Ten provinces: community hospitals are >100 miles far from the tertiary centers are the target areas.
- Each tertiary hospital will receive two well equipped mobile CT scan units with resuscitated equipment and well-trained paramedic staffs.
- The paramedic staffs will be trained to get the informed consent from patients or LARs as appropriated.
- If the patient or LARs consent to participate, he will be randomized to get the new mobile CT scan unit protocol or the existing stroke fast track protocol.



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Case Study-continue

- The mobile CT scan unit will be sent from the tertiary hospital and meet the ambulance at the gasoline station within the halfway from the community hospital to the tertiary hospital.
- After the imaging is done, and ischemic stroke is confirmed, the paramedic staff will start the thrombolytic agent while the patient is in the ambulance.
- In case of hemorrhagic stroke and impending brain herniation, the endotracheal intubation will be inserted into the patient and operating room is prepared in advance before the patient arrives.



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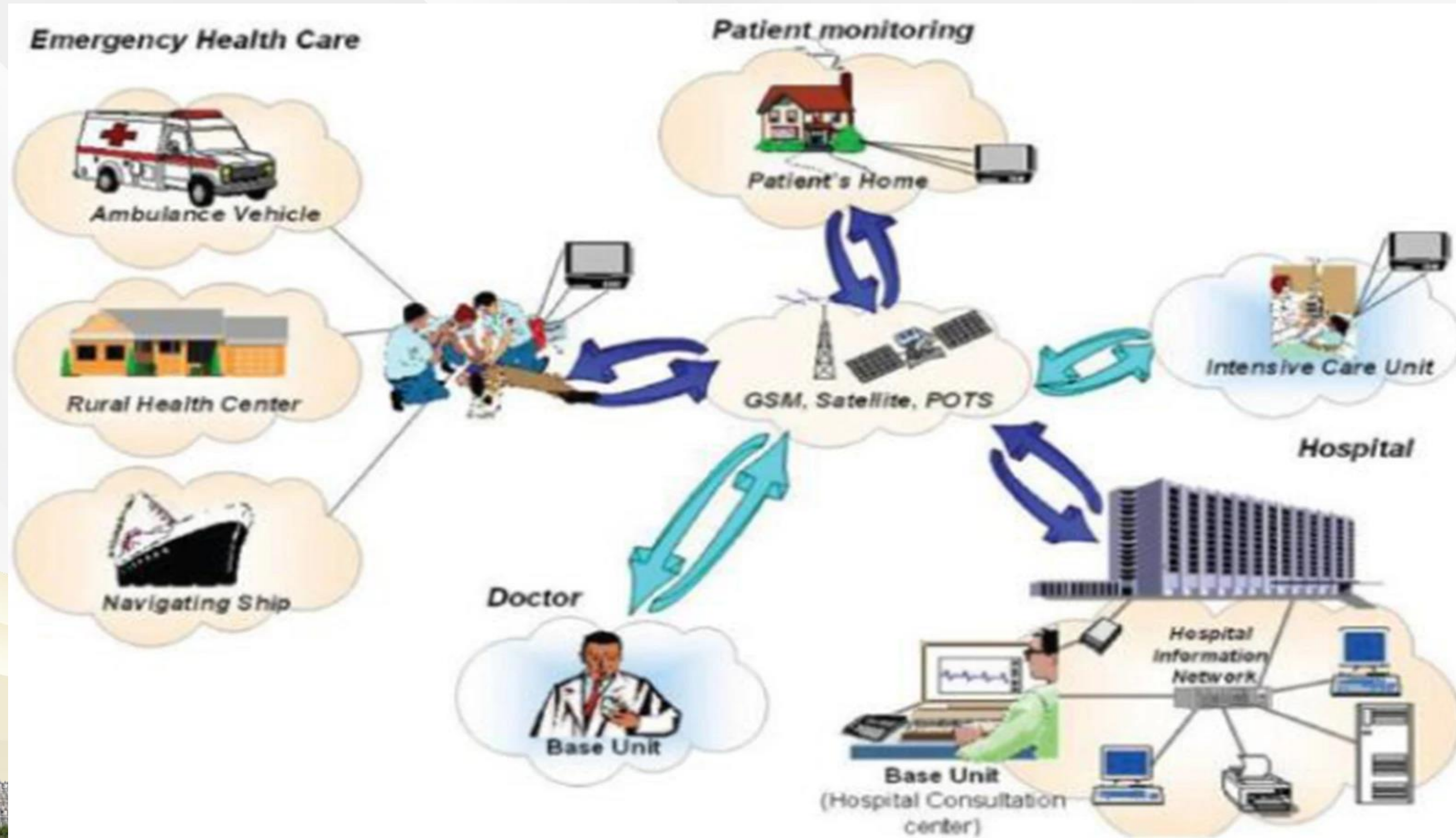


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Questions

- What is/are the investigational intervention(s)?
- What is/are the risk(s) of this study?
- What is/are the ethical issue(s) involved in this study?





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Questions

- What is/are the investigational intervention(s)?
 - Mobile CT scan Unit
 - In-house AI-assisted diagnostic software
 - Telemedicine





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Questions

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 - Mobile CT scan Unit
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 - Telemedicine
- What is/are the risk(s) of this study?
 - Software as a Medical Device->Verification process, cyber security
 - Stability of satellite system
 - Delay treatment





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Questions

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 - Mobile CT scan Unit
 - In-house AI-assisted diagnostic software
 - Telemedicine
- What is/are the risk(s) of this study?
 - Software as a Medical Device->Verification process, cyber security
 - Stability of satellite system
 - Device failure/Malfunction-> Delay treatment.
- What is/are the ethical issue(s) involved in this study?
 - Vulnerability
 - COI
 - Consent process in emergency research



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Conclusion

- Understand the classification of innovations or products
- When innovations meet the criteria for medical devices
 - Adhere with design verification and validation processes
 - Engage with regulatory framework of product development





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Thank you for your attention.

