Digital Postpartum Hemorrhage Management Device (DPHMD)

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Abstract

Baclground Postpartum hemorrhage (PPH) is an obstetric emergency caused by excessive blood loss that occurs most commonly after the placenta is delivered. PPH can lead to volume depletion, hypovolemic shock, anemia, which is the leading cause of maternal mortality worldwide. Maternal mortality rate in Ethiopia is among the highest in the world with 470 deaths per 100,000 live births. 94% of births in Ethiopia are estimated to occur at home and ten percent of maternal deaths are attributed to PPH. Now a days, physicians use visual estimation to calculate blood loss and provide fluid during delivery. This traditional method is subjective and generally inaccurate.Method In this project, after delivery blood loss measurement system integrated with fluid delivery and vital sign monitoring method is proposed. The collection and measurement system collects blood loss after delivery and measure the amount of blood loss. The management system continuously monitors the mother's heart rate, respiratory rate and blood pressure, and integrates the measured blood loss to make decision for providing appropriate fluid and medication necessary for the mothers. The fluid provided for mothers is also controlled automatically.Results The prototype was built and undergone through different tests and iterations. The proposed device was tested for accuracy, cost effectiveness and ease to use. 91.28% accuracy has been achieved and the prototype was built only with less than 210 USD.Conclusion The proposed design allows physicinas, especially those in low resource setting, to estimate blood loss and delver fluid accurately. This helps to reduce maternal mortality rate that may occur due to postpartum hemorrhage.

Background

Post partum hemorrhage (PPH) is defined as blood loss of 500 ml and above or 1,000 ml of blood within the first 24 hours following childbirth (1, 2). It is the most common cause of pre-mature mortality of women world wide. PPH is dangerous and life-threatening and can also lead to long-lasting health effects, including severe anemia (3). According to the 2013 World Health Statistics, the maternal mortality rate in low income, lower middle income, upper middle income and high income groups were 410, 260, 53, and 14/100,000 live births, respectively (4). More than 50% of all maternal deaths worldwide occurred mainly in Asian (India, Pakistan, Afghanistan) and three African (Nigeria, Ethiopia, and the Democratic Republic of Congo) countries (5). Major causes of maternal deaths are similar across low income countries, often obstetric in origin, and generally follow obstructed labor with or without rupture, hypertensive disorders (mainly severe preeclampsia and eclampsia), infection and hemorrhage (mainly placenta previa/abruption, urine rapture and postpartum hemorrhage) (4, 6). Ethiopia's maternal mortality rate is among the highest in the world with 470 deaths per 100,000 live births. It is estimated that 94% of births in Ethiopia occur at home. Ten percent of maternal deaths in Ethiopia are attributed to PPH (7).

Uterine atony, genital tract lacerations, retained placenta, uterine inversion, abnormal placentation, and coagulation disorders are the primary causes of PPH. Uterine atony, or lack of effective contraction of the uterus, is the most common cause of postpartum hemorrhage (3). Secondary causes of postpartum hemorrhage include retained products of conception, infection, subinvolution of the placental site, and

inherited coagulation deficits (8–11). The majority of these fatal obstetric complications occur during labor and immediately after birth. In the low income countries like Ethiopia, more than three-quarters of maternal deaths due to the direct obstetric causes occur during and after birth (4, 12, 13).

At term, the uterus and placenta receive 500–800 mL of blood per minute through their low resistance network of vessels. Maternal blood volume increases by 50% at the thrd trimester increasing the body's tolerance of blood loss during delivery (14). After delivery of the placenta, the uterus initiates a process of contraction and retraction, if it fails to contract, or the placenta fails to separate or deliver, hemorrhage occurs.

PPH can result in maternal complications like hypovolemic shock, disseminated intravascular coagulation, hepatic dysfunction, adult respiratory distress syndrome and renal failure (15). Organized diagnosis and management of PPH, including administration of uterotonic agents (16), controlled cord traction, and uterine massage after delivery of the placenta, is required to avoid maternal death.

The high frequency of PPH in the developing world is due to the lack of diagnosis and management methods as well as medications used in the active management of the third stage. A number of factors also contribute to less favorable outcomes of PPH in developing countries. Lack of experienced caregivers who might be able to successfully manage PPH if it occur and lack of blood transfusion services, anesthetic services, and operating capabilities also plays a role.

A well-defined stepwise approach is recommended for treatment of uterine atony, including drugs and mechanical interventions followed by surgery as a last intervention (3, 17, 18). The first diagnosis of PPH is performed by observing the amount of blood loss and the patient's clinical status. The amount of blood loss, the patient's level of consciousness and vital signs are continually assessed. Photospectometry is the gold standard blood loss measurement technique due to its accuracy. However, this technique is complicated, costly and impractical and it cannot be applied at all levels of healthcare and is more suitable for clinical research (19–21). Weighed soaked swabs or drapes after delivery are slos used, which proved to be effective for the early detection of PPH (22). However, this method substantially increases the workload of medical staff members and may not be suitable in a busy hospital setting. Bakri balloon (23), arterial embolization (24) and absorbable sutures (25) are other methods to manage and reduce PPH. However, most of the techniques are either expensive and complex to apply in low resources settings or are associated with complications.

Currently, in low resource settings blood loss during delivery is estimated manually through vsual inspection. Visual estimation of blood loss at delivery is subjective and generally inaccurate. Studies have showed that independent of the experience or skill level of the health care providers, visual estimation of postpartum hemorrhage blood loss has a 25% - 89% error of measurement (20).

In this project digitalized postpartum hemorrhage management device is designed to collect and measure blood loss, to monitor vital signs and estimate the amount of fluid required for medication to manage PPH at early stage. The proposed project method will be used as a decision support system for

physicians especially for those in low resorce setting where both the expertise and and medical devices are in scarce.

Methods

1. Concept Screening

Fout ideas has been proposed to come up with a solution for the management of PPH (Figure 1). These includes: auto transfusion, external pressure application on the uterus, locally fabricated under-buttok drape and diitalized postpartum hemorrhage manegemnt devic. The first idea was by an auto transfusion system that provides collection, measurement filtration and transfusion of blood loss (Figure 1a). The blood to be transfused will be determined by amount of hemoglobin in the blood. The second idea was uisng negative pressure on the outer part of the uterus to relax the uterus and stop the contraction of the uterus and reduce bleeding (Figure 1b). The thid idea was constructing under-buttock drape from locally available material. Locally fabricated under-buttock drape collects and measures amount of blood a mother is losing after delivery. This measuring device made of plastic and it is leveled to depict the amount of blood loss. The fourth proposed idea is digitaizing the blood loss collection and measurement system and by intergrateing it with vitals signs measurement amount fluid to be delivered can be estimated for proper management of PPH (Figure 1c).

2. Constraints and Proposed Solutions Evaluation

Absolute constraints for our design include: safety (while using the device there should not be any bad consequences like electric shock, pain e.t.c), decreasing number of physicians, durability, size, reliability (the ability to perform the intended purpose including measuring the blood loss, measuring vital signs, and controlling fluid delivery system) and cost effectiveness. These requirements are used to evaluet the proposed solutions. First each constraint were compared and a weight is evaluated. Table 1 shows the pairwise comparison chart. More emphasis has been given to accuracy, safety and decreasing number of physicians. Second concept screening was performed to evaluate each proposed solution against the crtiteria/constraints. As a baseline the digitalized postpartum hemorrhage managing device (DPHMD) is used. Therefore DPHMD is scored null (zero) against our criteria and others will are evaluated with respect to it. Each proposed solution is evaluated against the reference and if it is better, plus sign (+) will be assigned; if it is the same, zero (0) will be assigned and if it is worse negative sign (-) will be assigned for each criteria. Table 2 shows the concept screening process. In the third stage all values acquired during concept screening are multiplied by the corresponding weight which are acquired from the pairwise comparison chart. Based on this best proposed solution has been selected. Table 3 describes the pugh matrix for concept scoring and selection of best solution. This resulted DPHMD as the best proposed solution among brainstormed ideas.

3. Proposed Design

The Proposed solution includes blood loss collection and measurement system, Vital sign monitor (pulse rate and blood pressure), Processor unit (Arduino Mega microcontroller), flow rate monitor, display and alarm system. Inputs from the blood loss measurement system, vial sign monitor as well as essential parameters from the key-pad (age, weight) will be used to estimate the reccomeded fluid to be delivered. The alarm is used to notify the physicians in case of severe conditions. Under-buttock drape, which allows the blood loss to enter to the collection jar with out loss, was constructed from locally available material. Ultrasonic sensor is used to measure the volume of blood. Figure 2 show the functional blockdiagram and general blocdiagram of our proposed design.

The solenoid valve controls the amount of fluid to be delivered to the patient. Solenoid valve and flow sensor will stay on until enough fluid is delivered. The flow rate will be used to calculate the amount of fluid delivered. If the measured value is larger than the set value the solenoid value will be turned off automatically to prevent excess medication. Figure 3 show the slow chart of fluid medication controller.

Results

1. Final design

Different prototype iterations has been conducted to modify our design. Figure 4 shows parts of the Final design: (Left to Right: Top to Bottom) under-buttock drape for smooth flow of blood to the jar, collection jar and an ultrasonic sensor to collect and measure blood loss, heart rate and pressure sensor to measure the two parameters the two vital signs, a flow sensor and a solenoid valve to indicate flow rate and allow one directional flow of IV fluid, respectively and a display system.

The following components has been used in the final design: HC-SR04 Ultrasonic Sensor, Arduino uno, Flow Sensor YF-S201, Liquid crystal display (LCD), Buzzer, 4x4 Keypad, Plastic solenoid valve, Pulse sensor, Blood pressure sensor, Plastic jar, Drape, Plastic tube, Resistors, Potentiometer, Jumper wires, and USB cable. Figure 5 shows the final design of DPHMD.

Several tests and iteration were used in order to verify whether the design criteria and specification were fulfilled. Accuracy, cost effectiveness and easy to use are the parameters tested. Table 4 shows the test results.

Discussion

PPH can lead to volume depletion, hypovolemic shock, anemia, which is the leading cause of maternal mortality worldwide. The prevalence of PPH is disproportionately higher in low resource settings where there is limited access to skilled medical care and safe blood supplies. Despite the fact that it is largely preventable, by improving the quality of care, postpartum hemorrhage is the most common and most deadly form of obstetric bleeding (26). Initial treatment of PPH includes uterotonic medications such as oxytocin and misoprostol plus bimanual massage. However, proper collection and estimation of blood loss is required to manage PPH.

Visual estimation of blood loss including weighing of soaked pad is the current method for estimating amount of blood loss in low resource settings. This methodresults inaccurate conclusion about blood loss which may result misdiagnosis. Blood pressure and heart rate monitoring is key to hemodynamic assessment, with thresholds for systolic blood pressure (SBP) and pulse used in clinical trigger or early warning systems to prompt intervention (19, 27). However, using vital signs in isolation may lead to inaccurate decision since vital sign change due to PPH can be masked by the hemodynamic changes of pregnancy (28). The proposed design provides accurate and reliable measurement of blood loss as well as vital signs monitoring to detect and manage PPH.

Every design is preferable to be easy to use, accurate and low cost. Our design is simple and user friendly. The traditional manual PPH managing method is digitalized by incorporating vital signs monitoring and blood loss measurement in one system. This helps physicians to easily adapt the digitalized system with in less than 30 min training. The prototype costs only 210 USD making it affordable for low resource settings. The accuracy of the designed system is inspected by performing different tests with the assistance of the professionals. The blood loss collection and measurement system, vital signs measurement (on different subjects) and flow rate sensor and were tested. A total of 91.28 % accuracy has been achieved with five iterations on. The blood loss estimation was 98% accurate which is much better than the accuracy of visual estimation which was found to be 25%–89% accurate as reported in many studies (20–22, 29, 30). The proposed design provide high level of safety, which is free from electrical shock, contamination or infections and any type of hazardious radiation exposure.

Conclusion

In order to prevent complications, effective management of postpartum hemorrhage plays a huge role in treating and saving mothers suffering from PPH. Our Dgitalized postpartum management device can be used as a decision support system for physicians by determining the amount of blood loss and the patient’s level of consciousness through vital signs continuous monitoring. The prototype was built and undergo through different tests and iterations and it is 91.28% accurate. The proposed method will have a great impact in low resource settings where both the expertise and means is in scarce.

List Of Abbreviations

DPHMD—Digital Postpartum Hemorrhage Management Device

LCD—Liquid crystal display

PPH—PostPartum Hemorrhage

SBP—Systolic Blood Pressure

Declarations

1. Ethics approval and consent to participate

Not applicable

2. Consent for publication

Not applicable

3. Availability of data and materials

Not applicable

4. Competing interests

The authors declare that they have no competing interests

5. Funding

Resources required for this study were provided by the school of Biomedical Engineering, Jimma institute of Technology, Jimma University, Ethiopia.

6. Authors' contributions

All authors contributed equally in this study. All autors read and approved the final manuscript.

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Tables

Table 1: Pairwise comparision chart for constraint weighting

Constraint	Safety	Accuracy	Decrease number of physician required per patient	Durability	Size	Cost effective	Reliability	Total
Safety	×	0.5	0.6	0.7	0.6	0.5	0.5	3.4
Accuracy	0.5	×	0.6	0.7	0.6	0.6	0.5	3.5
Decrease number of physician required per patient	0.4	0.4	×	0.6	0.6	0.5	0.7	3.2
Durability	0.3	0.3	0.4	×	0.4	0.4	0.4	2.2
Size	0.4	0.4	0.4	0.6	×	0.5	0.4	2.7
Cost effective	0.5	0.4	0.5	0.6	0.5	×	0.4	2.9
Reliability	0.5	0.5	0.3	0.6	0.6	0.6	×	3.1

Table 2: Concept screening

Evaluation criteria	Auto transfusion	Externally applied pressure on uterus	DPHMD	Locally fabricated under buttock drape
Safety	_	_	+	+
Accuracy	+	+	+	0
Decrease number of physician required per patient	+	_	+	0
Durability	+	+	+	_
Size	_	+	_	0
Cost effective	_	_	+	0
Reliability	+	_	+	+
Sum +,0	4 (+)	3 (+)	6(+)	2 (+),4(0)
Sum -	3	4	1	1
Rank	5	3	1	2
Continue	No	No	Yes	Yes

Table 3: Pugh matrix for concept scoring and solution selection

Evaluation criteria	Weight	Auto transfusion		Externally applied pressure on uterus		DPHMD		Locally fabricated under buttock drape	
		Rating	Weight score	Rating	Weight score	Rating	Weight score	Rating	Weight score
Safety	3.4	4	13.6	3	10.2	5	17	5	17
Accuracy	3.5	4	14	2	7	5	17.5	3	10.5
Decrease number of physician required per patient	3.2	2	6.4	2	6.4	5	16	2	6.4
Durability	2.2	4	8.8	5	11	4	8.8	4	8.8
Size	2.7	2	5.4	4	10.8	4	10.8	4	10.8
Cost effective	2.9	3	8.7	3	8.7	5	14.5	5	14.5
Reliability	3.1	4	12.4	3	9.3	5	15.5	4	12.4
Total (%)		0.69		0.634		1		0. 804	
Rank		3		4		1		2	

Table 4: Test methods and results

Criteria	**Input**	**Method**	**Iterations**	**Result**
Accuracy	Blood volume	By using known amount of water	Five times	91.28%
	Heart rate	By using manual counting method	Five times	
	Blood pressure	By using existing method	Five times	
Cost effectiveness	Market analysis	Total components cost	_	210 USD
Easy to use	Operating procedure	30 min training for Physicians	-	Simple

Figures

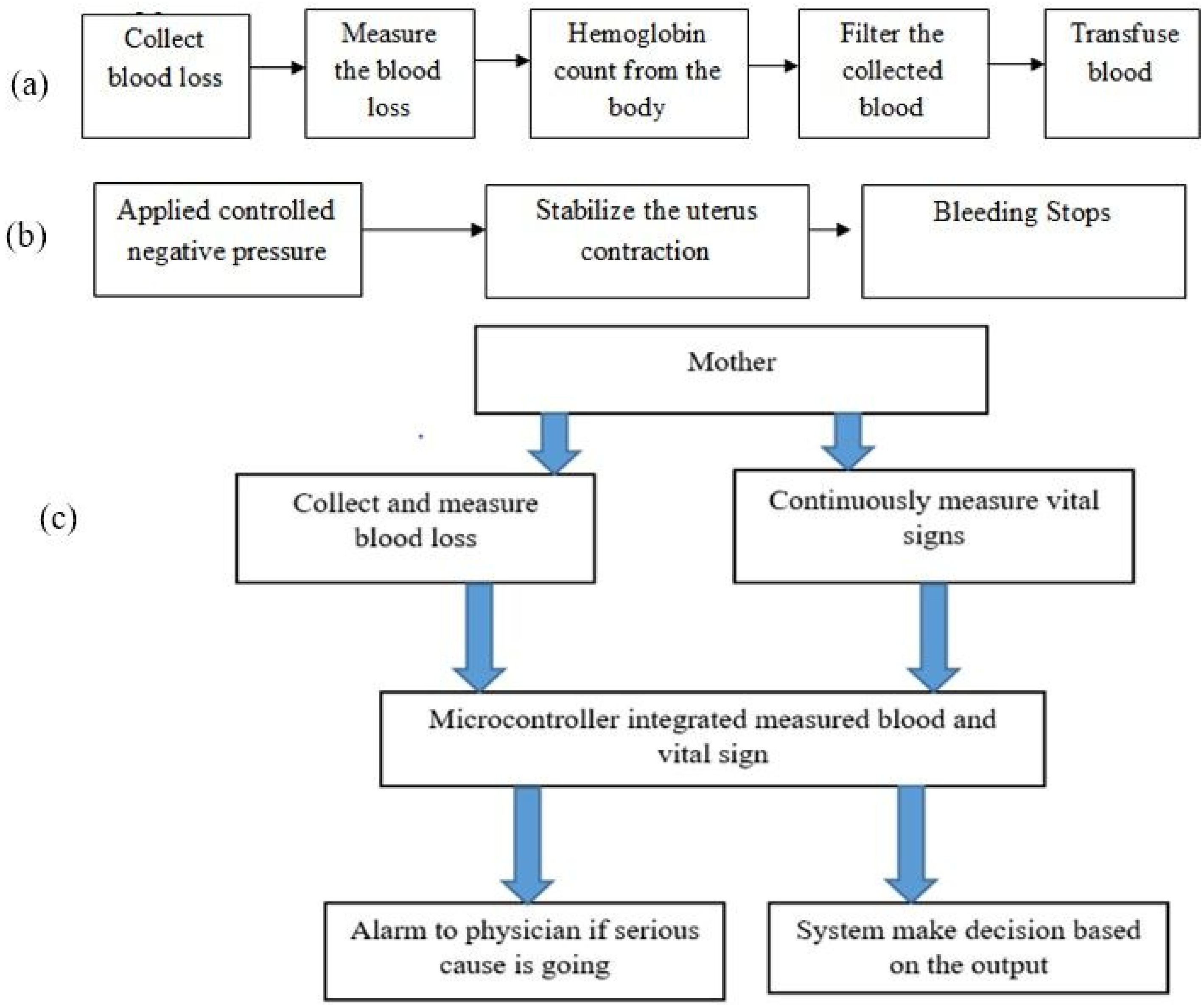

Figure 1

Proposed solutions for management of PPH: (a) Externally applied pressure on the uterus (b) Auto transfusion system (c) Digitalize postpartum manaegement device

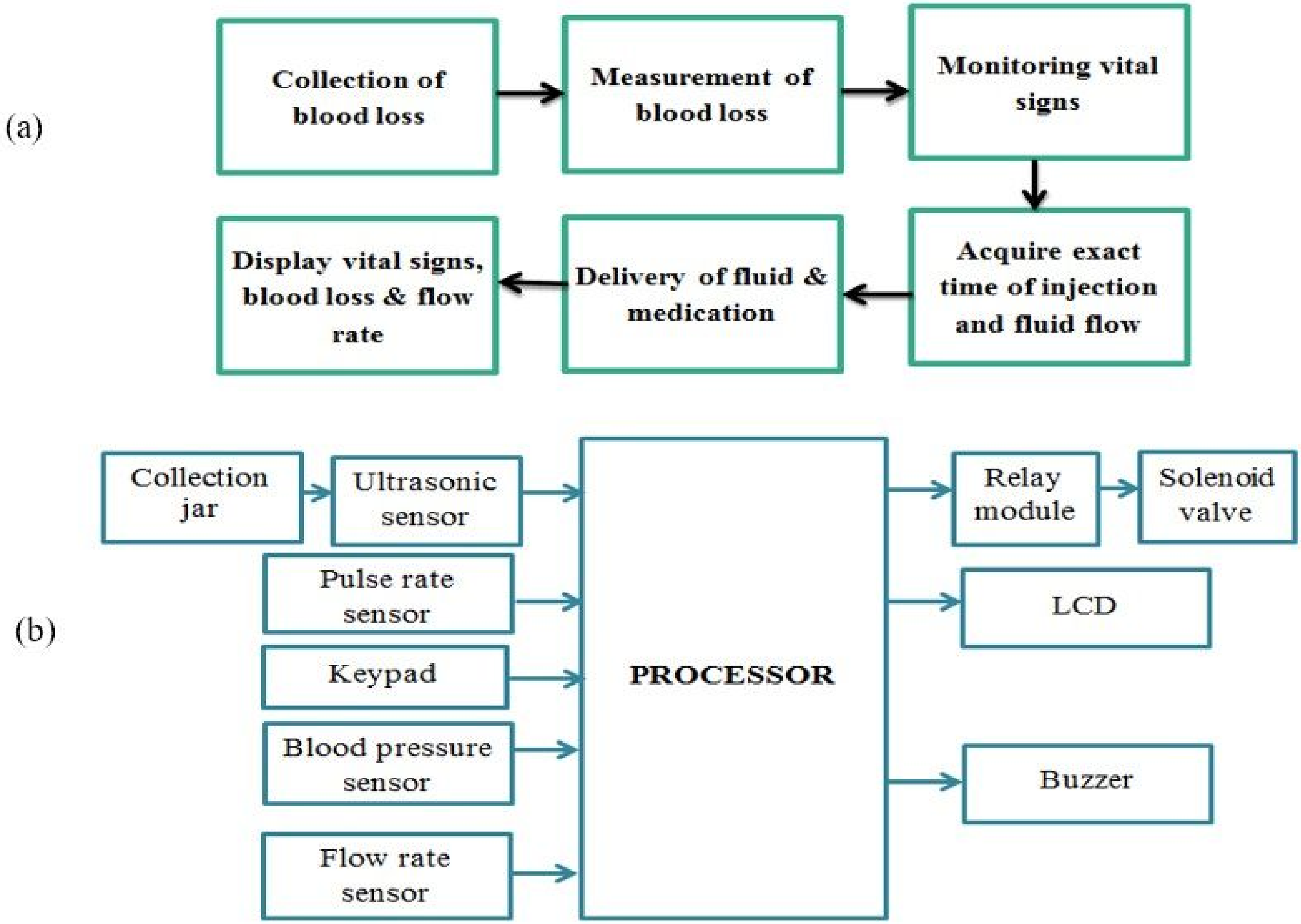

Figure 2

Functional and general block diagram of DPHMD

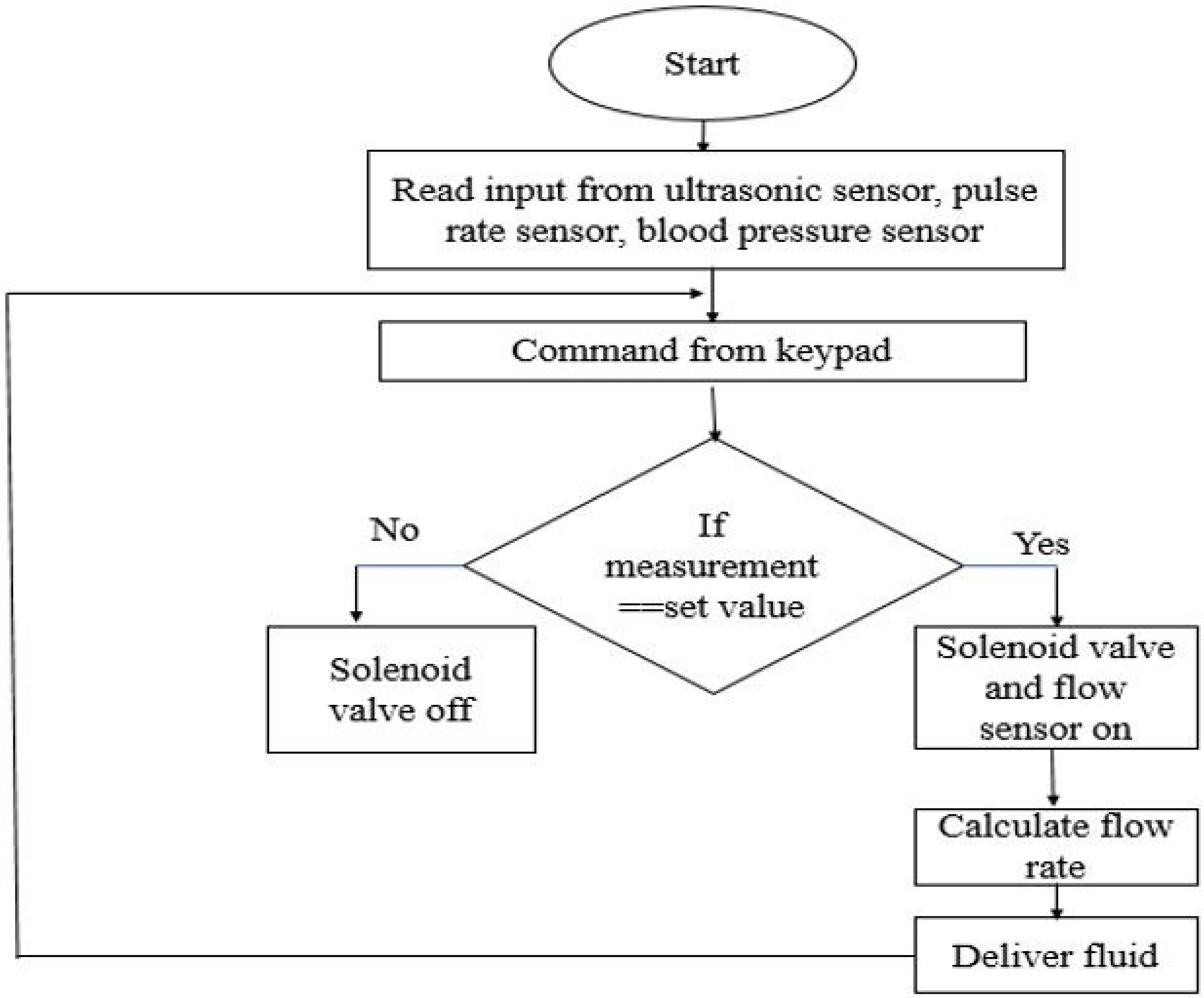

Figure 3

Flow chart of fluid medication ontroller

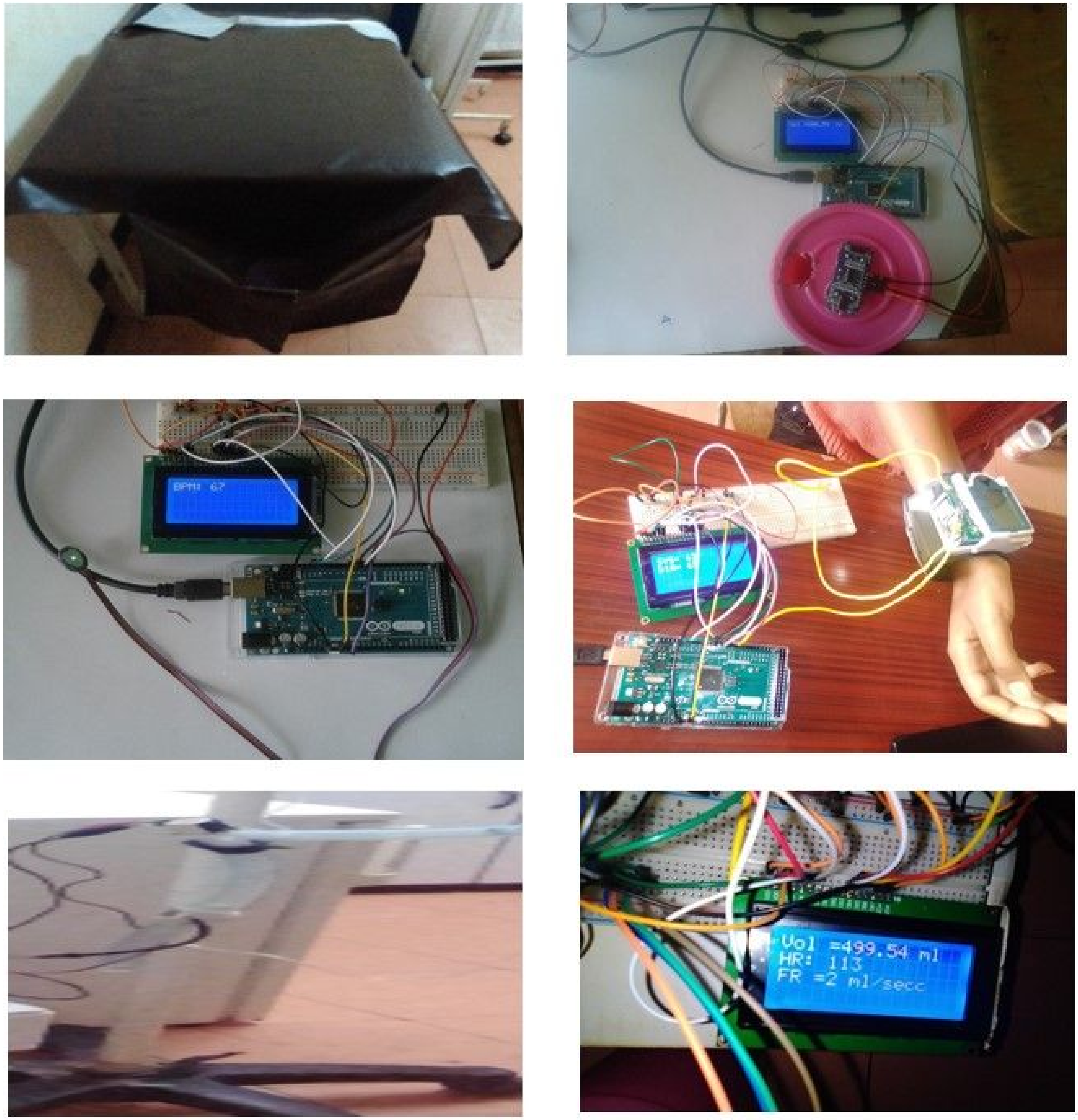

Figure 4

Componenets of DPHMD design

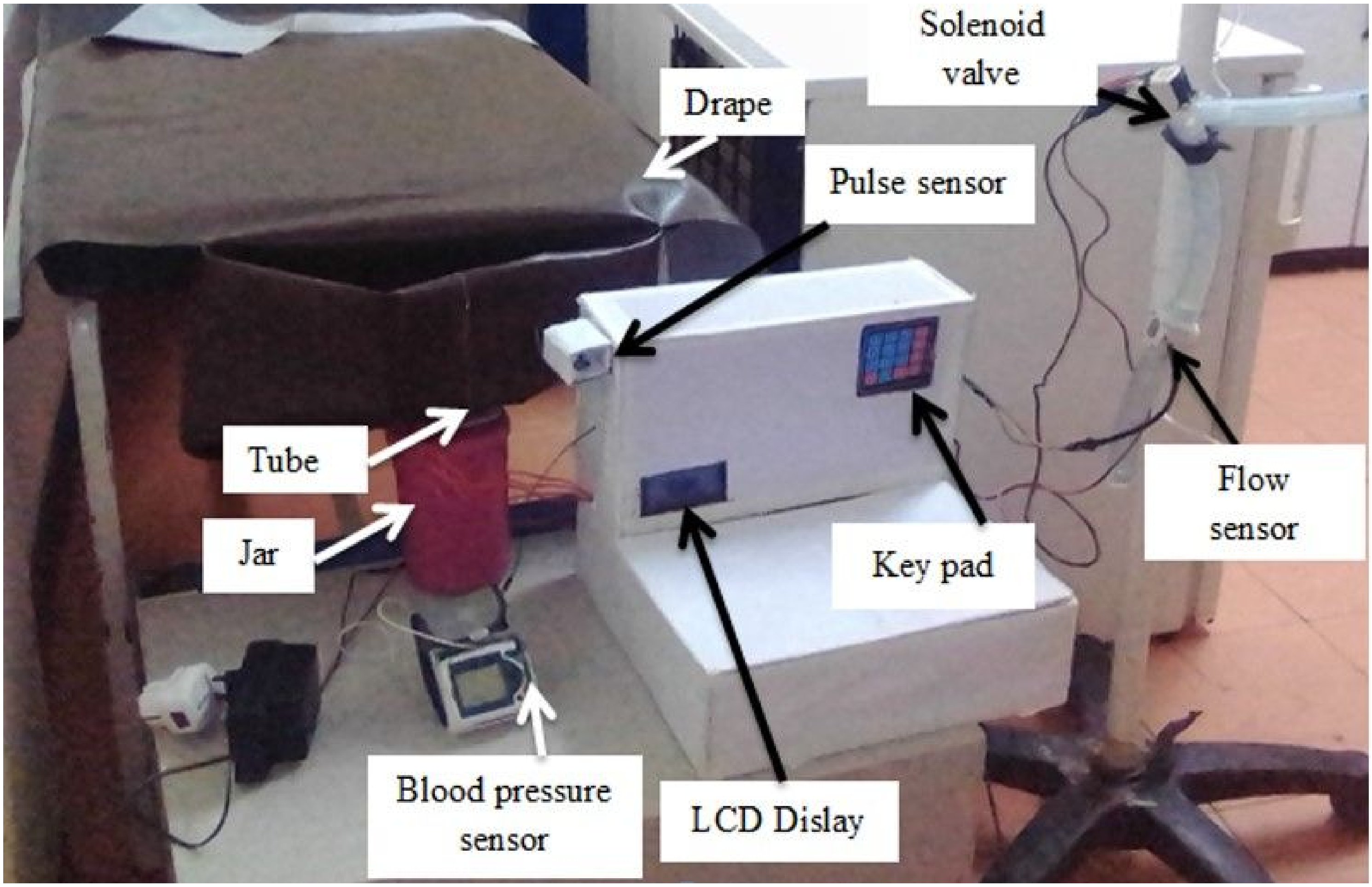

Figure 5

The final design of DPHMD