Chapter 15

An Electronically Controlled Gravity Feed Infusion Set for Intravenous Fluids

P.N. Makobore & M. Mulerwa

Background

In Africa, particularly Sub-Sahara Africa, access to quality healthcare continues to be a challenge and Uganda is no exception. The healthcare delivery systems remain inadequate to meet the needs of a growing population, raising concerns by policy makers regarding whether health services are being delivered efficiently (OAG, 2015). Unreliable supply chains for medical consumables, expensive medical equipment, irrational use and wide variation in the quality of health technologies are some of the leading challenges (Barry & Pathe, 2008). Medical devices are critical to health care delivery but access to them is often limited in African countries.

The largest hurdle in the Ugandan healthcare system is at the system level. Most of the limitations faced in hospitals are directly correlated with the economic state of the country and the lack of effective and sustainable mechanisms to provide adequate medical supplies and maintain equipment. Infrastructural deficiencies such as unreliable electricity supply and poor roads for transportation further compound the problem. The high clinician-to-patient ratio creates a need for robust automated devices that can alleviate the country-wide problem of limited health workers. The majority of equipment is donated and most of this equipment can be found in hospital dumping yards as a result of frequent breakdown partly due to inaccessibility of spare parts and because the equipment has not been designed for the Ugandan setting.

The Uganda Industrial Research Institute (UIRI) began to focus strategically on the design of innovative solutions to address gaps in the healthcare sector in 2013. UIRI is a centre of excellence for industrial research in the East African Community and a member of the World Association of Industrial and Technological Organizations (WAITRO). It was awarded this status in late 2013 during a heads of state summit held in Kampala, Uganda. The Institute is the Ugandan Government's lead agency for industrialisation, established by a Uganda Act of Parliament, under the auspices of the Ministry of Trade, Industry and Cooperatives and as of 2017 under the Ministry of Science Technology and Innovation. The Instrumentation Division was founded in 2011 to undertake applied research and development in the area of electronics. The Instrumentation team comprises electrical and computer engineers and the

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focus has become the design of non-invasive medical technology. Through institutional-level collaborations with Makerere University's College of Health Sciences, Columbia University in New York, and Oxford BioHorizons Ltd. UK (a company specialising in technology in medicine and biology), the Instrumentation Division has embarked on the design of affordable medical devices for Sub-Saharan Africa and other low-income settings. The design process is inspired by the Stanford Biodesign approach (Yock, et al., 2010). The first two phases of the latter approach, namely identify (uncovering clinical needs and the cycle of care) and invent (brainstorming solutions, rapid prototyping, concept development and intellectual property consideration) have been adopted. The invent phase also captures electronics design, development and testing. The third phase – implement – has been applied partially, in particular, strategy development in terms of clinical validation and exploring sources of funding. Business modelling, regulatory approval, reimbursement, and charting the market potential are still in progress.

Uncovering a priority clinical need

The Instrumentation team decided to focus their efforts based on areas of specialty, availability of resources, and the area with the highest need with few people innovating on the topic. With the team having experience in hardware design, rapid prototyping of electronics and systems design, it was natural to lean towards the design of non-invasive medical technology. This focus was further refined to maternal and child health. Uganda continues to experience health system challenges and poor social determinants of health that have slowed the improvement of women's and children's health. Difficulty in accessing quality services, a shortage of trained and motivated healthcare professionals, and shortages of essential drugs and medicines contribute to high mortality and morbidity rates (WHO, 2011).

The overall goal was to improve significantly healthcare outcomes for a high priority clinical need in a vulnerable population. Design considerations were not limited to functionality, performance and usability, but included infrastructure such as access to reliable power sources, and design for lack of power, which is a common occurrence in rural health facilities.

Having successfully carried out a needs survey across four regions in Uganda (northern, central, eastern and western) and in four major regional referral hospitals, health centres, and the national referral hospital, the team was able to identify numerous clinical needs and gaps related to existing medical equipment. After formulating a list of top priority needs, the team proposed solution ideas. To achieve general consensus on a particular idea, decision

criteria and a decision matrix tool were used to enable team members to vote on and rank the most compelling need. The decision matrix was based on the following criteria:

1. *Impact*: what are the numbers involved? How many people's lives would be improved or saved by the proposed intervention?
2. *Feasibility*: Does the team have the requisite skills and partners to implement the proposed design, are there available resources?
3. *Low cost*: What percentage of the raw materials can be accessed locally? Can we make this particular design affordable and accessible for hard-to-reach health facilities?
4. *Priority*: From the perspective of the clinicians, is the need high in priority?

The strategic focus was to innovate for maternal and child health as this group is the most vulnerable in low- and middle-income countries. The severity of the situation was mapped out to determine the best starting point, taking into account the availability of financial resources for implementation. Two methods were used, namely literature reviews and baseline studies; the latter involved several visits to health facilities that included the national referral hospital, Mulago, regional referral hospitals, and health centres in western, eastern and northern Uganda. Studies revealed a persistent challenge in improving child mortality. The leading direct causes of under-five mortality include neonatal conditions (prematurity, asphyxia and infection), malaria, diarrhoea and pneumonia (WHO, 2010). The majority of children presenting for treatment often exhibit advanced disease stage symptoms and usually require immediate intravenous therapy. The FEAST trial estimates that over 10% of children admitted to East African hospitals are in shock due to treatable disease and require immediate infusion therapy (Maitland, et al., 2011). It is important that infusion therapy be administered correctly to ensure timely treatment and safety, especially for sick children, to prevent morbidity and in the worst cases mortality; however, this requires a syringe pump to accurately control intravenous (IV) fluid administration (Graz, et al., 2008). Based on preliminary findings, infusion appeared to be a neglected area with limited interventions.

The WHO recommends syringe pumps as an essential medical device that should be present in all district hospitals for the care of neonates (WHO, 2015). Due to their cost and complexity, commercial syringe pumps are often not readily available in low-resource settings, where the majority of neonatal deaths occur (Lawn, et al., 2006; FDA, 2010). In the absence of syringe or infusion pumps, fluids are delivered with gravity-driven IV drip systems (Slusher, et al., 2012) which neither control nor regulate fluid flow; thus accurate volumes, which are critical for infusion therapy in children, are not guaranteed. Imprecise flow rate control and lack of monitoring with these devices present a risk of over- or under-hydration (Almroth & Latham, 1995).

Existing solutions

To avoid designing an already existing solution and infringing on existing patents, and to better understand why certain design considerations had been avoided in available solutions, an investigation of existing solutions and technologies was carried out. Solutions for both developed and developing countries, their advantages, associated limitations and the reasons why some were not adopted, were systematically examined. The available solutions are described below.

Infusion/elastomeric pumps

Infusion/elastomeric pumps and burettes are commonly used to regulate delivery of IV therapy to paediatric patients in developed nations. Although infusion pumps are accurate and deliver fixed volumes, they are too costly and not appropriate for healthcare settings in many developing countries. Priced over US$1,000, infusion pumps require routine maintenance, expensive consumables that are not generally available in the developing world, and electrical power that may not be reliable, making them unsuitable for the developing world.

DripAssist™ flow monitor

The DripAssist™ is a device that allows users to monitor gravity fed infusion therapy and respond to an alarm to ensure that the infusion rate remains constant. Although the device does not control the rate of infusion, it provides clear and simple feedback, allowing users to clearly see how their drip tubing set is functioning (Ssekitoleko, et al., 2015). Initially used as a veterinary device, it has been piloted to improve the administration of medications during labour to prevent postpartum haemorrhage, preeclampsia and eclampsia in low-resource settings. The device has been clinically piloted in Haitian clinics on expectant mothers who received oxytocin and magnesium sulfate intravenously (Pedagogy Infusion Online Learning System, 2017).

Acuset IV flow controller

The Acuset IV Flow Controller is a reusable IV flow controller which is intuitive to use even by relatively untrained operators (Medicine Mondiale, 2008). The controller regulates drug delivery by rotation of a dial to the expected setting. However, it neither dynamically adjusts nor maintains the rate of flow at a given/set degree of constriction, resulting in slight variations in flow rate as the drip bag is being emptied owing to external atmospheric conditions and hydrostatic pressure.

Burettes/fluid giving sets

Burettes deliver measured volumes of fluid or medication. They are however impractical for use in low-resource settings because they are single-use, in addition to not being very accurate. Specifications for burettes and fluid giving sets are based on the performance of the drop orifice in delivering a specified volume of fluid (usually within ±10%), and not the rate, as this is dependent on the clinician regulating the appropriate flow rate for the therapy. Research has shown that when manually regulated, fluid delivery flow rate variances of ±20% (error between prescribed and actual flow rates) occur in 80% of intravenous administrations, inclusive of burette administration (Kolko & Intlekofer, 2016). Such flow rate errors escalate to errors in the overall volume delivered to the patient.

Understanding the challenge

The team embarked on field trips to collect primary data and information that would essentially guide the design process for the identified challenge of improving the quality and affordability of infusion. Four major regional referral hospitals – Mbarara, Fortportal, Mbale, Gulu and Soroti – and three health centres – Bukuku, Lamogi, Amuria – were visited during the first two quarters of 2017. The objective of the study was to uncover challenges related to infusion therapy, inadequacies with existing infusion pumps or controllers if available, the reasons why infusion pumps break down, the maintenance regimen, and the desired features of a device that could potentially address these gaps.

The team met and interviewed various stakeholders, including physicians, nurses, patients, carers and biomedical technicians. Interviews were aided by a questionnaire that served as a guiding tool to collect both quantitative and qualitative data. The end goal was to design for the end user based on the data that was collected. In addition to interviews, the team observed clinicians' day to day activities i.e. observing the work flow in an emergency ward and clinicians interacting with medical equipment. The observations uncovered additional challenges that were missed during face-to-face discussions. Access to inventories of medical equipment and discussions with biomedical technicians revealed the reasons why equipment fails.

Data from the maternal and paediatric wards at the eight health facilities revealed the following challenges.

Paediatric ward challenges with infusion

1. Due to a lack of infusion pumps or controllers that are critical for intravenous delivery of IV fluids and drugs, these are currently being manually administered; on average more than 60 infusions are carried out daily.
2. Over- and under-infusion are common due to severe workload challenges; it is difficult to maintain and monitor the prescribed flow rate manually due to the high number of children admitted.
3. Inadequacy of consumables e.g. fluid giving sets and drugs lead to an additional financial burden on the patient who is required to purchase the needed materials.
4. There is a shortage of blood from the blood bank to infuse anaemic children; over 85% of children are anaemic and require blood transfusion.
5. The ward is severely congested due to the overwhelming number of children requiring admission.
6. Severe cases of shock in children are usually referrals from smaller community health centres.

Maternal ward challenges with infusion

1. There is a lack of infusion pumps or controllers that are critical for intravenous delivery of oxytocin or misoprostol; improper infusion of these drugs can cause rupture of the uterus or birth asphyxia for the neonate.
2. Blood transfusion for mothers experiencing postpartum haemorrhage or with ectopic pregnancy is a necessity, however there is a limited supply of blood; a possible solution could be recycling of blood to re-infuse into the mother.

Conceptualisation

In response to the identified need for an infusion device that regulates infusion therapy, the Electronically Controlled Gravity Feed Infusion Set (ECGF) prototype v1.1 has been designed; the ECGF automatically regulates the drop rate for infusion therapies for drugs and fluids and provides the minimum safety features for implementation in a hospital setting. Figure 1 shows the four modules that make up the ECGF device.

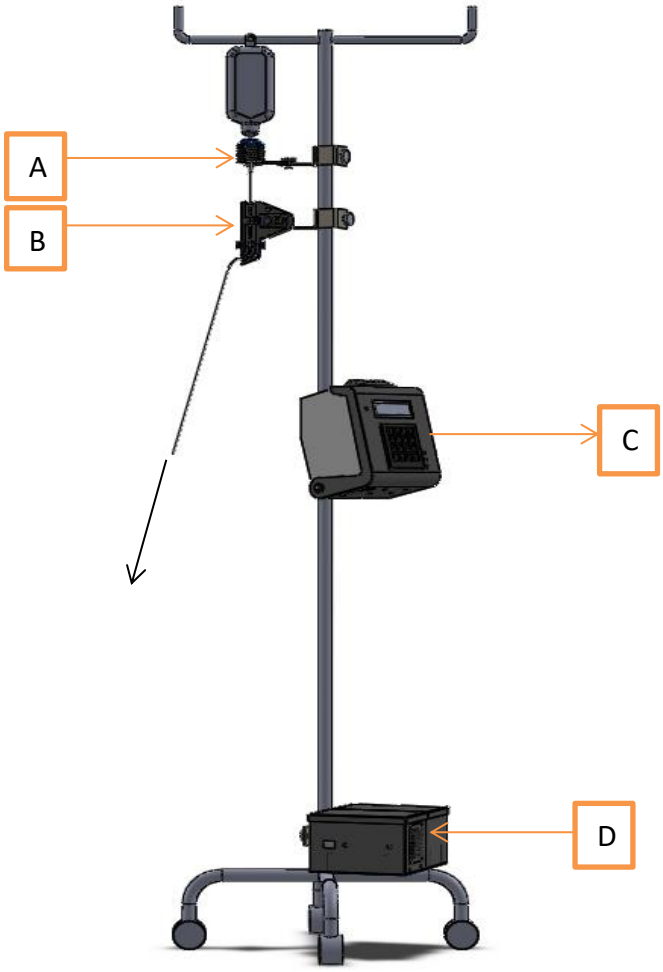

Figure 1: Modules of the electronically controlled gravity feed infusion set (ECGF); A: Drop rate detector, connects to the infusion set drip chamber and monitors the drop/infusion rate; B: Drop rate controller, clamps onto and constricts the infusion tube to regulate the infusion rate; C: User Interface, to allow the user to input parameters for the therapy that include infusion bag size, size of the fluid giving set, volume to be infused and infusion time; D: Power supply for the ECGF device.

System overview

Micro-processor/logical unit

The logical unit is the heart of the system and it receives input from all the various peripheral units (analog to digital converter, counter, USART, keypad, memory, switches), and algorithmically processes the inputs and transmits instructions to the actuators/output units (Ssekitoleko, et al., 2015).

Drop rate detector module

This module is responsible for the drop rate detection. The module comprises a light source and a photo-cell. Signals from the photo-cell are transmitted to the processing/logical unit.

Drop rate controller module

This module is responsible for effecting the change desired as per instructions from the logical unit resulting from the feedback from the monitoring module. An appropriate constriction of the drip line/tube results in an adjustment/continuance of a drip/flow rate. It also caters for air bubble and occlusion detection.

User interface

The user interface provides the user with vital information and provides alerts indicative of system performance or status as well as allowing for human–machine interaction by way of various input options.

Comparison with infusion pumps on the market

The ECGF is comparable in functionality with some of the infusion pumps on the market in terms of performance and safety features. The ECGF has been tested for flow rates 15–300ml/hr. Further development will refine accuracies for slower and faster flow rates. Clinically most flow rates fall within the tested range. Table 1 compares the ECGF with the Hospira A+ Infusion System.

Table 1: Comparison between the ECGF and the Hospira A+ Infusion System

Development	Hospira A+ Infusion System	ECGF
Subassemblies	1 part	4 parts
Supply chain complexity	0% local materials	80% local materials
User training	Minimum 2–3 weeks	4 hours (intuitive and easy to use user interface)
Power consumption	High (35VA)	Low (6VA)
Maintenance support	Costly and limited	Affordable and locally available
Battery life	Approx. 6 hours	Approx. 8 hours
Delivery accuracy	±5 (1–999mL/hr), ±10(0.1–0.9mL/hr)	±1 (15mL/hr – 300mL/hr) for preclinical tests on v1.1 prototype
System alarms	Air-in-line, air-in-line backpriming, low battery, occlusion, turn to run, flow detector, VTBI complete or dose end	Low battery with status LEDs, occlusion, flow detector, VTBI complete or dose end
Added value	None	Solar system can be used for battery charging & hospital lighting
Selling price	~US$1300–3000	~US$100

Design and manufacture

The ECGF is an embedded system application designed to perform a specific function. Embedded systems are a combination of computer hardware and software that are programmable with a fixed capacity that includes electrical and mechanical components. These systems are designed for a specific function or for specific functions within a larger system. The design of the ECGF therefore comprises both software and hardware design processes.

AutoCAD software, EAGLE, was used to design the schematics of the ECGF electronic circuits and the layout of the printed circuit boards. Proteus software was used for simulation and debugging of the electronic circuit before preliminary hardware prototyping using breadboards, oscilloscopes and power supply units. During initial prototyping, electronic components were mounted on a breadboard, the microcontroller was programmed to perform specific functions and the circuit output was analysed. Additive manufacturing specifically 3D printing was particularly useful for the intricate parts of the device, in particular variations of specific parts were printed for testing, towards achieving an optimal design. SolidWorks software was used for the casing design of the drop rate detector and the drop rate controller and printed using a 3D printer. The microcontroller was from Microchip Technology Inc.; a PICkit 3 was used for programming and Integrated Development Environment (IDE) software called MPLAB for the firmware. The firmware underwent verification and validation tests to ensure that it performed as specified. The Instrumentation Division complies with the coding standard for critical systems (Doering, 2004).

After the circuits have been verified and validated to function as required, the final stage of the development of the device was the manufacturing process that consisted of etching and milling the printed circuit boards and manufacturing of the casings for the drop rate detector and drop rate controller using a 3D printer. The drip stands were fabricated using mild steel in compliance to standard BS 3619:1976 for mobile infusion stands (British Standards, 1976). Figure 2 shows in-house manufacturing of the ECGF user interface.

Figure 2: In-house manufacturing of the ECGF user interface

Preclinical studies

In order to verify the accuracy of the ECGF prototype v1.1 a test setup was used in compliance to the standard IEC 60601-2-24 for medical electrical equipment (IEC, 1998). The standard contains particular requirements specifically for the safety of infusion pumps and controllers. The ECGF v1.1 is categorized as a drop rate controller, however, the updated standard has a heavy focus on regulation of volume to be infused in addition to the drop rate (IEC, 2012). The next version of the ECGF (v2.0) will include design for regulation of volume to be infused.

The ECGF device is designed to operate in a drop rate scope between 5–100 drops/min which is equivalent to a flow rate of 15–300ml/h, assuming a 20 drops/ml IV giving set. According to the baseline studies conducted in the eight health facilities, this range covers all the required IV infusions for the target group (children under the age of five). The testing parameters for infusion delivery to cover the operating scope of the device are shown in Table 2.

Test case 1 and 2 are compliant with the required infusion rates for accuracy tests mentioned in the standard IEC 60601-2-24 (IEC, 1998). Each delivery rate test was repeated three times.

Table 2: Test cases for infusion accuracy tests				
Test case #	Drop rate r [1/min]	Flow rate f [ml/hr]	Infusion time [min]	Infusion volume [ml]
1	5	15	180	45.0
2	20	60	180	180.0
3	50	150	180	450.0
4	75	225	180	675.0
5	100	300	180	900.0

To ensure reliable results, new infusion set tubing, a new cannula needle and a new solution bag were mounted before each test run. During the test period the total drop count N_x and the corresponding total infusion time stamp t_x were collected every 12s via RS-232 serial interface to a separate data assessment computer using RS-232 terminal software.

Test results

Through the calculation of the actual drip rate Q_i from the collected data of all conducted tests, it was possible to plot the start-up graphs for each test case. As an example, Figure 3 shows the progression of the actual drip rate Q_i over the test period T_0 (the first 2 hours) performed with a desired drip rate r of 20 drops/min (test case 2).

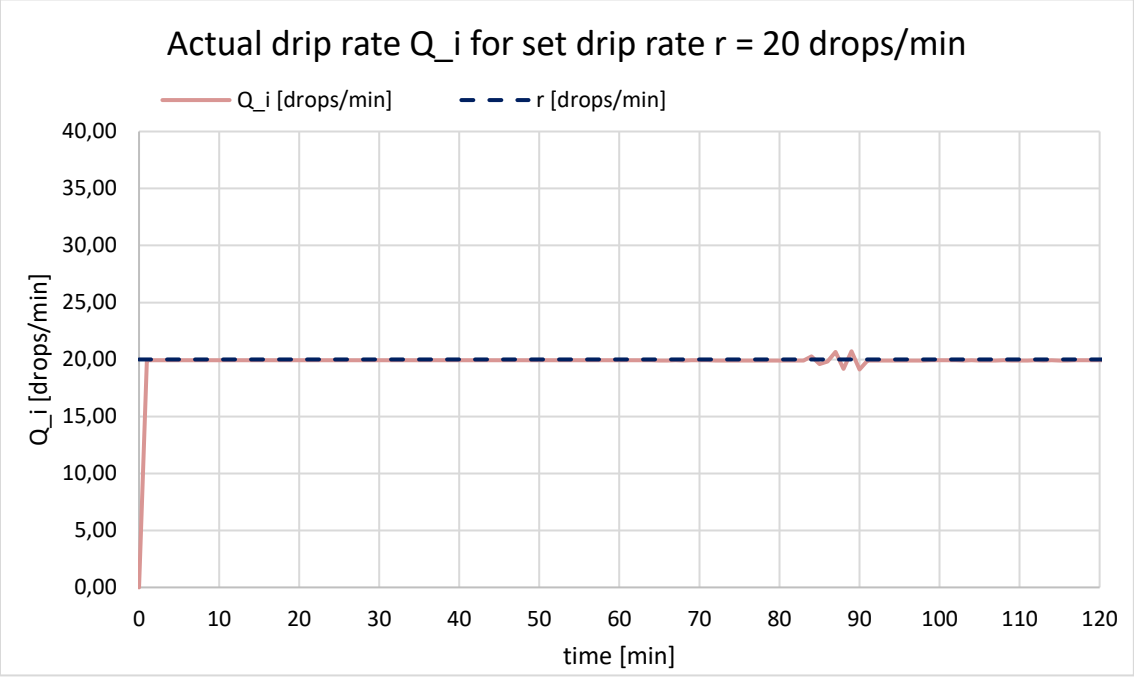

Figure 3: Plotted start-up graph of the actual drip rate Q_i for a set drip rate r of 20 drops/min for test period T_0 of 120 min

All tests conducted with the ECGF prototype v1.1 showed the ability of the ECGF device to deliver fluids with a relatively high degree of accuracy. See Table 3 for an overview of all test results per test case. Neither the overall mean percentage error E_total for the entire test period nor the percentage errors A and B for the second and the last hour of the test period respectively show values greater than ±1%.

Table 3: Overview of preclinical test results

Test Case (TC)	R (drp/min)	Q_total [drp/min]	E_total [%]	Q_T1 [drp/min]	A_T1 [%]	Q_T2 [drp/min]	B_T2 [%]
1	5	4.987	–0.257	4.977	–0.468	4.966	–0.671
2	20	19.931	–0.343	19.917	–0.415	19.918	–0.412
3	50	49.801	–0.398	49.786	–0.428	49.762	–0.477
4	75	74.698	–0.402	74.684	–0.422	74.660	–0.453
5	100	99.585	–0.415	99.566	–0.434	99.555	–0.445

Conclusion

The Instrumentation Division at UIRI has developed the ECGF in response to a demonstrated clinical need to improve the safety and efficiency of delivering intravenous fluids to children. In-house design and development enabled the design team to iteratively test and design the first version of the ECGF device that is acceptable for clinical use. The public health impact of the device will be a contribution to safer and less labour-intensive delivery of drugs to patients by reducing the clinician time involved in manual regulation of the rate of fluid flow. The potential impact will be lives saved, alleviation of the human resource burden, improved usability of an infusion medical device and improved patient care. The Uganda Industrial Research Institute plans to develop a feasible implementation plan to scale up this and other medical device innovations to improve access to quality medical devices and alleviate the shortage of appropriate medical equipment in Uganda and other similar developing country settings.

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