

Feasibility and barriers to implementing the Jada System for postpartum haemorrhage treatment in Rwanda: a qualitative study

Elyse Ihirwe

elnis65@gmail.com

University of Global Health Equity

Sara Della Ripa

University of Global Health Equity

Jason Bell

Organon

Robert Ojiambo

University of Global Health Equity

Vincent Dusingizimana

Centre Hospitalier Universitaire de Kigali

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Abstract

Background.

Postpartum haemorrhage (PPH) is a leading cause of maternal mortality worldwide, and the burden is greatest in low and middle income countries, where access to timely emergency obstetric care is limited. The Jada System is a device that uses vacuum induced haemorrhage control to induce uterine contraction and control bleeding due to uterine atony. Although effective, it is not yet available in most low and middle income countries. This study aimed to assess the feasibility of implementing the Jada System in Rwanda, including its usability and the readiness of the health system.

Methods.

A qualitative case study was conducted using semi structured focus group discussions and in depth interviews with healthcare providers at primary, secondary and tertiary levels of care, and with national key informants. Health facilities were purposively sampled across public and private sectors and urban and rural areas. Maternity ward tours guided by a structured checklist were used to assess facility readiness. Participant characteristics were summarized descriptively, and interview data were analyzed inductively using iterative thematic analysis.

Results.

A total of 33 participants were included: 13 midwives and 5 nurses (89% female, 11% male), 12 physicians (25% female, 75% male), two government decision makers and one key opinion leader. Four themes were identified. First, incorporating Jada into existing protocols was considered likely to add benefit to care. Second, providers and experts generally preferred Jada to existing methods, although limited familiarity and comparison with more familiar alternatives may influence its acceptability. Third, implementation was seen to depend on supporting systems, including affordability, reliable availability, training, adequate staffing and technical support such as regulated suction. Fourth, administrative approvals at multiple levels and advocacy were regarded as necessary. Both midwives and doctors were identified as potential users.

Conclusion.

The Jada System appears compatible with existing PPH management protocols and practice in Rwanda, and was generally preferred to existing methods. Implementation is likely feasible but will depend on inclusion in national protocols, training, regulatory approval, affordability, reliable availability and local advocacy. These findings contribute to efforts to improve equitable access to life saving maternal health technologies in low and middle income settings.

Trial registration.

Not applicable.

Background

Postpartum haemorrhage (PPH) is the leading direct cause of maternal death worldwide [1]. The World Health Organization defines it as blood loss above 500 mL after a vaginal birth, or above 1000 mL after a caesarean section, within 24 hours of delivery [2]. The most common cause is uterine atony, when the uterus fails to contract adequately after the placenta is delivered, which accounts for roughly 70% to 80% of cases [3, 4]. PPH affects an estimated 14 million women each year and is responsible for about a quarter of maternal deaths globally [5].

The burden is far from evenly shared. The overwhelming majority of maternal deaths occur in low and middle income countries (LMICs), where PPH accounts for more than two thirds of them [6, 7]. In Rwanda, PPH prevalence in some settings has been reported to reach 25.2%, and it is responsible for approximately 22.7% of the country's maternal deaths, with uterine atony as the leading cause [8].

The harm extends well beyond mortality. When a mother becomes seriously ill or dies, families suffer socially and economically: children's nutrition, mental health and schooling all tend to decline, survivors may develop lasting trauma, and households can be pushed into hardship by medical costs and lost income [9, 10, 11, 12]. Because PPH is largely preventable and treatable, much of this suffering is avoidable, which is part of what makes it such a pressing target for health systems [13]. Addressing it also aligns with international commitments, including Sustainable Development Goal 3.1, which aims to cut the maternal mortality ratio to below 70 per 100,000 live births by 2030 [14].

Rwanda offers an encouraging backdrop. The country has cut maternal deaths dramatically, from roughly 1,160 per 100,000 live births in 2000 to around 249 in 2019 to 2020, through investments in emergency obstetric and neonatal care, family planning, community based health insurance and national campaigns such as the White Ribbon Alliance and the Campaign on Accelerated Reduction of Maternal Mortality in Africa [15, 16, 17, 18]. This track record suggests a system that may be receptive to new tools that save mothers' lives.

International guidance emphasizes active management of the third stage of labor to prevent PPH, and, once atonic bleeding is established, a mix of pharmacological options such as uterotonics and tranexamic acid, and non-pharmacological measures including uterine massage, bimanual compression, uterine balloon tamponade (UBT) and surgery [2, 19]. Each carries limitations, and in many LMICs shortages of equipment, staff and infrastructure leave women exposed to complicated bleeding and death [20, 21].

The Jada System takes a different approach. It applies low level vacuum inside the uterus to trigger a physiological contraction that controls bleeding from atony, an approach known as vacuum induced

haemorrhage control (VIHC) [22]. Despite promising evidence, the device is available mainly in high income countries and has not reached most of sub Saharan Africa, where the burden of PPH is greatest, even though some of its early in human testing took place in LMICs such as Indonesia and Uganda [23, 24]. That gap is precisely the kind of inequity that a feminist, intersectional reading of global health draws attention to: at the meeting point of gender, geography and economic position, women in the Global South can face the steepest barriers to high quality health technologies [25, 26].

Against this background, this study wanted to understand whether and how the Jada System might be brought to Rwanda. We asked three questions: where Jada could fit within existing PPH treatment protocols; which levels of care meet the minimum requirements to use it, and what barriers providers foresee; and which providers could be trained to use it, and what that training would involve.

Methods

Design and approach

This was a qualitative case study built around semi structured focus group discussions (FGDs) and in depth interviews (IDIs), a design well suited to teasing apart the interacting factors that would shape whether Jada could work in Rwanda [27]. We approached the work through a feminist methodology and an intersectional lens, which we chose deliberately so that the views of people often left out of technology decisions, such as midwives and providers in rural facilities, would come through, and so that we would not simply assume the device fits the Rwandan context [25, 28, 29]. Because Jada is not used in Rwanda, we showed a short manufacturer's demonstration video and passed around a demonstration device during each session, which helped participants respond with their own context in mind.

Setting

The study took place in Kigali City and the Eastern Province of Rwanda, chosen to represent urban and rural areas and because both have high numbers of live births [30, 31]. Rwanda's health facilities are organized into primary (community health workers, health posts and health centers), secondary (district hospitals) and tertiary (provincial and referral hospitals, including teaching hospitals) levels (Fig. 1) [8, 32, 33]. The Ministry of Health (MoH) regulates the system while the Rwanda Biomedical Center (RBC) oversees the implementation of health decisions, and we included both, along with the Rwanda Society of Obstetricians and Gynaecologists (RSOG), to capture the perspectives of decision makers [34, 35].

Sampling and participants

We used convenient purposive sampling to select facilities, a key opinion leader (KOL) and government decision makers, diversifying sites by PPH knowledge, birth volume, PPH rates and urban or rural location [36]. Six facilities were included:

- one urban public referral and teaching hospital;
- one urban private referral hospital;
- one rural public district hospital;
- one rural public provincial hospital;
- one urban public health center; and
- one rural public health center.

The decision maker group comprised one MoH professional, one RBC professional and one obstetrician KOL. At facilities, we separated FGDs by profession, with nurses and midwives in one group and doctors in another, to reduce the pull of professional hierarchy on what people felt able to say. Each FGD had two to three participants, in line with recommendations for team based discussions, and where a group had only two people we added an IDI to be sure enough was captured [37, 38]. Altogether the results draw on 8 FGDs and 12 IDIs. We judged that saturation, meaning the point at which information began to repeat, had been reached across facility levels [39].

Inclusion criteria

- Health facilities with maternity wards in urban and rural areas.
- Maternity department professionals (nurses, midwives, residents, medical officers and doctors) at health centers, district, referral and teaching, and private hospitals.
- MoH and RBC professionals and an obstetrician KOL with 10 or more years of experience in the Rwandan health system.

Exclusion criteria

- Facilities with fewer than three staff meeting the professional criteria.
- Professionals at their site for less than six months, or who had never managed PPH.
- Decision makers in post for less than six months, or unfamiliar with PPH or device regulation, and retired obstetricians.

Data collection procedures

After securing ethics and MoH approvals, we obtained facility level approvals from General Directors or local institutional review boards, who then referred eligible providers. Sessions ran for about 25 to 40 minutes during work breaks, and were held in English or Kinyarwanda according to each participant's preference, with the option to respond in French as well. Trained bilingual and trilingual data collectors helped conduct Kinyarwanda interviews and translate. During each session participants watched the Jada demonstration video and handled a demonstration device. With consent, sessions were audio recorded for transcription; where a participant declined recording, one or both principal investigators

(PIs) took detailed notes and checked them together afterwards for reliability. Where General Directors agreed, PIs toured maternity wards to look at the technical realities firsthand, for instance the presence and condition of suction machines.

The PIs developed three interview guides specifically for this study; the guides have not been published elsewhere and are provided in full, in English, as Additional File 1 - Interview Guides. Guides were developed for the following respondent groups: 1) healthcare providers (FGDs and IDIs), 2) Key Opinion Leaders (KOLs) in obstetrics (IDIs), and 3) decision-makers familiar with device regulations and clearances (IDIs) (supplementary file). Each guide collected participant characteristics and included fewer than ten open-ended questions mapped to the study objectives. Before data collection began, all three guides were pre-tested with two medical doctors, one KOL, and one decision-maker, each with more than six months of experience in maternal deliveries or maternal health. These pre-test interviews were used only to refine the interview process and were therefore not included in the study's data.

Moreover, a structured maternity ward checklist was developed with reference to the Jada System's instructions for use and recorded suction sources, oxytocin storage and refrigeration, the presence of PPH kits or carts, and materials for improvised condom-catheter UBT, all of which served as indicators of facility readiness [22]. The Jada System is a proprietary device (Jada System, Organon).

Data management and analysis

Participant demographic data were entered into a restricted access spreadsheet and summarized descriptively in IBM SPSS Statistics version 20. Audio recordings were held on password protected devices and in a restricted folder; transcribers produced verbatim transcripts and translated them into English where needed. The PIs de identified and cleaned the transcripts and imported them into Dedoose version 9.0.90 for analysis [40]. Working independently at first, the two PIs wrote memos and codes, then pooled their analysis frequently, built a codebook iteratively and generated themes, which they finalized through iterative thematic analysis [41, 42]. We practiced reflexivity throughout and documented our own positionality, one PI being a Rwandan pharmacist working in emergency blood delivery and the other a non-clinician biomedical engineer with prior experience of the device, so that we could keep our biases in view. Maternity ward checklists were compiled into a summary table to validate and triangulate what providers told us.

Results

Participant characteristics

Thirty three people took part, drawn from six health facilities, MoH, RBC and RSOG. Nineteen (57.6%) identified as female and 14 (42.4%) as male, with a mean of 7.15 years of experience (range 0.5 to 20). Roles were strongly gendered: 89% of nurses and midwives were female, whereas only 25% of

physicians were, and all three key informants were male (Table 1). We grouped data by gender so that we could look at potential biases and power dynamics.

Table 1
Participant and study site characteristics.

Characteristic	Category	Male	Female	Total
Sample size, n (%)		14 (42.4)	19 (57.6)	33 (100)
Years of experience, mean (range)		6.07 (1 to 20)	7.95 (0.5 to 20)	7.15 (0.5 to 20)
Affiliated setting, n (%)	Ministry of Health	1 (3)	0 (0)	1 (3)
	Rwanda Biomedical Center	1 (3)	0 (0)	1 (3)
	RSOG	1 (3)	0 (0)	1 (3)
	Urban public health center	0 (0)	3 (9.1)	3 (9.1)
	Rural public health center	1 (3)	2 (6.1)	3 (9.1)
	Rural public district hospital	1 (3)	5 (15.2)	6 (18.2)
	Rural public provincial hospital	3 (9.1)	3 (9.1)	6 (18.2)
	Urban private referral hospital	3 (9.1)	3 (9.1)	6 (18.2)
	Urban public referral and teaching hospital	3 (9.1)	3 (9.1)	6 (18.2)
Area of Practice, n (%)	Decision-Making Key Informants	3 (9.1)	0 (0)	3 (9)
	OBGYN	2 (6.1)	0 (0)	2 (6.1)
	OBGYN Resident	4 (12.1)	0 (0)	4 (12.1)
	Junior Medical Officer	1 (3)	0 (0)	1 (3)
	General Practitioner	2 (6.1)	0 (0)	2 (6.1)
	Intern Medical Doctor	0 (0)	3 (9.1)	3 (9.1)
	Unit Manager Midwife	0 (0)	2 (6.1)	2 (6.1)
	Midwife	1 (3)	10 (30.3)	11 (33.3)
	Nurse	1 (3)	4 (12.2)	5 (15.2)

RSOG, Rwanda Society of Obstetricians and Gynaecologists.

Maternity ward readiness

We completed tours at five of the six facilities (Table 2). Four of five had a working suction source, though at one rural health center the pressure gauge range looked unsuitable for Jada. None of the facilities stocked condoms for improvised UBT in the maternity ward, and none had a dedicated PPH kit or cart, although all had a general emergency trolley or cupboard. All five had refrigeration for oxytocin on or near the ward.

Table 2
Maternity ward checklist findings.

Facility	Suction	Condoms for UBT	PPH kit or cart	Oxytocin refrigeration
Urban public referral and teaching hospital	Yes, one portable machine	No	No, emergency trolley present	Yes
Urban public health center	No	No	No, emergency cupboard present	Yes
Urban private referral hospital	Yes, one portable machine, plus wall suction at each labor bed	No	No, emergency trolley present	Yes
Rural public provincial hospital	Yes, two portable machines	No	No, emergency trolley present	Yes
Rural public health center	Yes, but gauge may exceed Jada range (over 150 mmHg)	No	No, emergency trolley present	Yes
Rural public district hospital	Tour not available	-	-	-
Summary	4 of 5 had suction but 1 was out of range	0 of 5 had condoms available in the maternity ward	0 of 5 PPH specific kits, 5 of 5 general emergency trolleys or cupboard	5 of 5 had refrigerator on or near the maternity ward for oxytocin storage

UBT, uterine balloon tamponade; PPH, postpartum haemorrhage.

Analysis produced four themes and their sub themes (Table 3). Every FGD and IDI was quoted at least twice, and illustrative excerpts below are labeled by setting, provider group, and gender and interview type.

Table 3
Themes and sub themes.

Theme	Sub-Themes
1. Incorporating Jada into existing protocols would likely add benefit to care	Placement of Jada in protocols
	Potential users of Jada
	Benefits of Jada in the management of PPH
2. While providers and experts prefer Jada over existing methods, biased perceptions may affect preferability	UBT usage and comparison to Jada
	Some confusion about Jada's intended use and mechanism
3. Despite its benefits, some supporting systems may be needed	Affordability
	Device availability
	Training & sufficient staff
	Technical support
4. Administrative approvals at various levels and advocacy will be required	Approvals required for implementation
	Advocacy needed for adoption

Incorporating Jada into existing protocols would likely add benefit to care

Placement of Jada in existing protocols

Participants reported following national protocols for the management of PPH, and most who spoke about placement preferred early use of Jada, which we defined during analysis as a preference to use the device no later than the failure of first line uterotonics or uterine massage (Fig. 2). Some would use it immediately after failed uterotonics, before measures such as uterine packing.

"You know, when you give uterotonics and you don't succeed, this could be the next step instead of packing like we do." (Rural public provincial hospital, doctors, FGD)

Others who follow uterotonic failure with bimanual compression similarly saw Jada following the failure of uterotonics.

"I think it can be better to introduce the device after seeing that the uterotonics are not working, like where you need to do the bimanual compression. Then I think it's better if you can just introduce the device." (Urban public referral and teaching hospital, midwife, female, IDI)

In one discussion, participants added that some maneuvers are more theoretical than routinely practiced, which reinforced a preference for early use.

“Frankly speaking, all those maneuvers are not done in practice. In theory they are written like that but are less likely to be followed that way. After doing the massage and the uterus is not contracting and you know the cause, I would immediately use this, because going in those steps you'll be delaying.” **(Rural public provincial hospital, midwives and nurses, FGD)**

A minority preferred late use, defined during analysis as use beyond the steps that follow uterotonics, seeing Jada as a replacement for UBT after second line options such as aortic compression.

“The step I would use this? Exactly the same as the way we use UBT, after medication, bimanual compression, and aortic compression.” **(Urban public referral and teaching hospital, midwife, female, IDI)**

Views on caesarean birth were mixed. Because the demonstration video showed only vaginal birth, caesarean use arose only occasionally; some would use Jada after a caesarean if it came sterile, while others felt suturing and manual compression would be faster once the uterus was visualized.

“As long as they told us if you're having the atony, you suture quickly and press and hold the uterus back to help it contract. So I don't know if I would prefer this one to suturing.” **(Rural public district hospital, doctor, female, IDI)**

Potential users of Jada

Most participants felt both midwives and doctors should be able to use Jada, emphasizing that PPH is managed as a team.

“PPH requires teamwork. It will not be only for doctor or midwife. Even the midwife can use it. So for me everyone: doctor can use it, midwife can use it, according to how you are working in teamwork.” **(Urban public referral and teaching hospital, doctor, male, IDI)**

Midwives were repeatedly identified as the likely primary users, being closest to mothers during the early phases of PPH, especially at health centers where doctors are not present.

“They are the ones who deal with many cases because at health center level there are no doctors. So if they can be trained, that's when we would see the effectiveness of the device.” **(Rural public provincial hospital, doctors, FGD)**

Midwives themselves expressed confidence in learning the device, and a decision maker at the RBC echoed this.

“Midwives and nurses, because what we do is more complicated than inserting this instrument. We usually manage PPH, why can't we use it. We have been trying to use the more complicated version, UBT, so there is no reason why we can't use it.” **(Urban public health center, midwives and nurses, FGD)**

Two concerns about midwife use were raised, both by physicians at tertiary facilities where doctors are more consistently present. One related to the cost of the device and who should decide to use it; the other to ensuring atony is correctly diagnosed before use, though that physician still considered trained midwife use acceptable.

“Midwives properly trained and given the appropriate timing for insertion can use it. But in a tertiary hospital like ours, it should be the decision of a physician, when we feel the uterus is not responding to conventional management.” (Urban private referral hospital, doctors, FGD)

Benefits of Jada in the management of PPH

When asked about the hardest parts of managing PPH before being introduced to Jada, many participants described staff shortages and the stress of emergencies.

“When it's night shift, there are few staff. When you have a PPH case being the only one at work, first of all this is a case that can induce you to panic, because you think it could claim the life of this woman.” (Rural public health center, midwives and nurses, FGD)

After being introduced to Jada, participants felt it could ease these pressures because they expected it to be quick and simple to use, and could help save lives and prevent hysterectomy.

“If we have it, we can save the women not only by saving them but also by saving their uterus, because we still have many hysterectomies.” (Urban private referral hospital, doctor, male, IDI)

Many contrasted Jada favorably with the improvised condom catheter UBT, which must be assembled under pressure. Participants reported that purpose built UBT devices are not available in Rwanda and that condoms and catheters are improvised when needed.

“This equipment can help us in our daily life because it is easy to use and does not consume time, and the previous ones are like arrangements, such as going to search for condoms.” (Urban public health center, midwives and nurses, FGD)

There was particular emphasis on the value of Jada at lower level health centers, which manage many births, cannot perform surgery, and often refer complicated cases onward.

“PPH is frequent and lethal. It can be better when these devices are made available not only to hospitals but also to health centers, because most PPH cases happen at health centers.” (Rural public district hospital, doctors, FGD)

While providers and experts prefer Jada over existing methods, biased perceptions may affect its preferability

UBT usage in Rwanda and comparison to Jada

Participants reported that condom catheter UBT is the only UBT method available and is included in national guidelines for an atonic uterus after medical management, before surgery, and when transferring a patient. Yet its use was described as rare, and it seldom arose without prompting.

"It's very rare to reach that step. In fact, for all these 14 years I've been here, we only did like two UBTs." **(Urban public referral and teaching hospital, midwife, female, IDI)**

Participants described several difficulties with UBT, including the skills required, uncertainty about whether it is working, and the risk that it conceals ongoing bleeding.

"Sometimes you may not even know if it is successfully in place and if it is responding. And another thing, for UBT it may even hide the hemorrhage, you see?" **(Key opinion leader, RSOG, male, IDI)**

Against this backdrop, many compared Jada favorably, valuing that it induces uterine contraction rather than only applying pressure.

"This device is easy to use, it doesn't require many techniques. And another thing, you brought uterine contraction, which is necessary. Otherwise, with UBT you'll be just pressing the vessels without a single initiation of the necessary uterine contraction." **(Rural public provincial hospital, midwives and nurses, FGD)**

Confusion about Jada's intended use and mechanism

Confusion arose in several sessions, usually after the English language video. Referring to the animation showing blood being evacuated, some participants first thought Jada was intended to suction retained products rather than to collapse an atonic uterus.

"The way I have seen this video, I saw that it's like removing the blood remnants collected into the uterus or removing any other tissues stuck there." **(Rural public provincial hospital, doctors, FGD)**

The confusion usually cleared once the interviewers explained the VIHC mechanism.

"I understand that if the uterus was bloated due to fluids and blood accumulated, it can draw it out and allow the uterus to contract. I have understood that it is possible." **(Rural public district hospital, midwives, FGD)**

In one outlier discussion at a private tertiary hospital, midwives remained sceptical, concerned that suction might draw blood from open vessels and worsen bleeding, though they were still willing to try the device.

"We are dealing with open vessels in PPH. When we are using this Jada, we see that it is for removing the clotted blood, so those vessels will still be open and the mother will still bleed." **(Urban private referral hospital, midwives, FGD)**

Despite its benefits, some supporting systems may be needed

Affordability

Affordability was raised repeatedly, from rural providers to government experts. Estimates of what patients could pay ranged from under one US dollar in rural public settings to 100 to 200 USD in the private tertiary setting, and concerns centered on insurance coverage, the single use design, and differences in ability to pay between sectors and settings.

“Our clients who have PPH are economically unable to afford it; if the device's price is not covered by Mutuelle, they will likely not use it.” **(Rural public provincial hospital, doctors, FGD)**

Providers in rural public facilities described the tightest constraints.

“If you look at the financial status of the clients we receive, it would be better if the client would not pay higher than 500 Rwandan francs.” **(Rural public district hospital, midwives, FGD)**

The private tertiary facility offered a higher range but noted that cost still deters use, drawing an analogy to epidural analgesia.

“We have epidural available, but it's not insurance covered and very few people use it because of cost. So it would be the same for this one. It saves lives, but in the end they may not compensate for the cost.” **(Urban private referral hospital, doctors, FGD)**

Device availability

Availability concerns spanned national procurement and facility level stockouts, amplified by the single use design. A key informant cited tranexamic acid as a cautionary example of something listed but not reliably supplied.

“Tranexamic has been added to the essential list, but it's not yet available for low level. So it's on the list, but not really available.” **(Decision-making key informant, RSOG, male, IDI)**

At the facility level, stockouts were a specific worry, and a few participants candidly acknowledged that a single use device might be reused in practice given cost pressures.

“Like now you brought one and maybe we used it, and there is no other one. It would be better to have it in enough quantities with no stockouts.” **(Rural public district hospital, doctors, FGD)**

Training and sufficient staff

Training was seen as essential, and participants described it in three parts: theory on PPH and atony, simulation on manikins, and supervised practice on real cases, with midwives and doctors trained

together.

"Something that can be a barrier is when we are not trained. We cannot practise anything not trained."

(Urban public referral and teaching hospital, midwife, female, IDI)

"Give us simulation training on manikins and then real-time practice on two or five patients. You can train champions and after, those champions would teach others."

(Rural public provincial hospital, midwives and nurses, FGD)

Estimates of training length ranged from one to seven days, with midwives tending to suggest longer and physicians shorter timeframes.

Technical support

Because Jada is not supplied with a suction source, participants at health centers, where suction is limited, suggested it be provided together with a suction machine.

"We immediately refer her to district hospital as we do not have the suction machine. When you bring this device, don't forget even the aspirator."

(Urban public health center, midwives and nurses, FGD)

Higher level facilities had suction available, though its routine use was reportedly declining as newborn aspiration shifts to other devices.

Administrative approvals at various levels and advocacy will be required

Regulatory approvals

Key informants described a pathway beginning with approval by the Rwanda Food and Drug Authority, followed, for public sector use, by addition to the national essential medicines list and inclusion in national guidelines, after which procurement can proceed.

"As long as it is accepted by our regulatory bodies, Rwanda FDA, and it is evidence based, we are committed. Maternal health is our top priority. We need really innovative approaches."

(Decision-making key informant, RBC, male, IDI)

One MoH informant noted that inclusion in WHO guidelines would help national adoption but was not strictly required once the Rwanda FDA had approved the device.

"While we rely on WHO recommendation, if Rwanda FDA approves then it's still okay to use, so we can still use Jada in Rwanda."

(Decision-making key informant, MoH, male, IDI)

Procurement and distribution

In the public sector, devices are procured through Rwanda Medical Supply, and a device from a single manufacturer would follow a single source tender, with the budget and specifications set by the RBC in partnership with the MoH.

“A one-source tender can be used if the device is produced by one company, and an open tender if it is sold by many companies to allow for competitive pricing.” (Decision-making key informant, MoH, male, IDI)

Participants noted that procurement can be a bottleneck, again citing tranexamic acid, and concluded that advocacy is needed to keep new supplies moving.

Advocacy

Advocacy was seen as inseparable from approvals and necessary at both government and facility levels. The MoH and RBC were viewed as the strongest advocates for new maternal health technologies, with the RSOG also playing a role, and advocacy for insurance coverage through the Rwanda Social Security Board was seen as important.

“We have to advocate to the insurers, especially the Rwanda Social Security Board, in which around 95 percent are insured. We need to make sure this is really insured.” (Decision-making key informant, RBC, male, IDI)

Facility level advocacy was emphasized so that lower level health centers, which report to district hospitals, are not left behind, and participants repeatedly urged that the device be brought to Rwanda soon.

“No decision can be made by the health center without the hospital permission, so we are asking you to communicate with our superior and teach them too, so they consider our thoughts.” (Urban public health center, midwives and nurses, FGD)

“What we can add is to request you to advocate for it, so it is brought sooner.” (Rural public health center, midwives and nurses, FGD)

Discussion

Providers and decision makers in this study saw the Jada System as broadly compatible with how PPH is managed in Rwanda, and generally preferred it to what they currently use, while pointing clearly to what implementation would require. It is worth keeping in mind that these views come from people who saw and handled the device but did not use it clinically.

What participants described about current practice mostly matched Rwanda’s national PPH guidelines, and their preference for using Jada early, once uterotonics fail, suggests a natural insertion point in the existing cascade [43]. The consistent view that midwives would be among the primary users, particularly at health centers, is notable given the usual professional hierarchy, and it points to a real opportunity:

with task appropriate training and clear indications for use, midwife led use could be feasible where doctors are not immediately on hand [48].

The preference for Jada over UBT deserves a careful reading. Because purpose built UBT is not available and the improvised version is seldom used, some of that preference may reflect dissatisfaction with an unfamiliar alternative as much as the merits of Jada itself [44]. The early confusion about how VIHC works reinforces the point that clear, language appropriate training on the mechanism will matter, both for uptake and for correct use.

The supporting systems that participants raised including affordability, dependable supply, training and staffing, and technical support such as regulated suction, echo well documented determinants of whether a technology takes hold in LMIC health systems, and can be read through a staff, stuff, space and systems lens [49, 50]. Affordability and insurance coverage stood out because without inclusion in Mutuelle de Santé and other schemes, public sector uptake looks unlikely, and the single use design raises questions of both cost and disposal [45, 51]. Health centers, which manage many births and where suction can be unreliable, deserve particular attention so that the women at highest risk are not the ones left behind.

The pathway participants described, from regulatory approval through essential medicines listing, guideline inclusion and procurement, highlights several points where advocacy will be decisive [46]. History offers encouragement because sustained advocacy was central to expanding access to HIV medicines in LMICs, and participants saw a similar role for advocacy at government and facility levels [52, 53]. The risks of single source procurement, together with Rwanda's openness to foreign investment, also suggest there could be value in exploring regional or in country manufacturing to improve availability across sub-Saharan Africa [23, 47].

Ultimately, when effective innovations fail to reach LMIC markets, it is a matter of social justice, all the more so where the early in human testing took place in LMICs. Prioritizing affordable access in those settings is consistent with widely endorsed principles of research ethics [24, 54].

Strengths and limitations

The study's strengths include the range of facility levels, sectors and locations, the inclusion of decision makers and a KOL, triangulation through maternity ward tours, independent dual coding, and explicit attention to reflexivity. However, as limitations, we could not assess cost effectiveness, and a dedicated cost analysis across levels is warranted. Moreover, participants were reacting to a device they had not used, and although we showed a video and a demonstration device, the video was in English only, which we mitigated by explaining in participants' preferred languages. Time with busy providers was limited, which capped how deep some discussions could go, and within FGDs there was a risk that people gave shallower answers alongside more senior colleagues, which we tried to reduce by separating professions. Some doctors already knew of Jada, which may have shaped their responses. Finally, both

PIs could not attend every session, so intercoder agreement on some ward tours was not possible, and the insider and outsider dynamic between the two PIs may have influenced how participants responded. Even so, the perspectives gathered here offer useful insight for any future effort to bring Jada to Rwanda and comparable settings.

Conclusions

Bringing the Jada System to Rwanda appears feasible, and it was welcomed by the providers and decision makers we spoke with, who saw it as compatible with existing PPH protocols and preferable to what they currently use. Turning that into reality will take inclusion in national protocols, structured training that combines theory, simulation and supervised real case practice and is shaped by Rwandan providers, regulatory approval and essential medicines listing, dependable supply and affordability including insurance coverage, and technical support, especially regulated suction at health center level. Advocacy and administrative approvals across several levels will be central to adoption. We recommend a post market study that includes patients' own perspectives, alongside a cost analysis across levels of care, and we argue that access should be prioritized in sub-Saharan African settings, above all where Jada was first tested in humans, as a matter of equity.

Abbreviations

FGD

Focus group discussion

IDI

In depth interview

KOL

Key opinion leader

LMIC

Low and middle income country

MoH

Ministry of Health

PI

Principal investigator

PPH

Postpartum haemorrhage

RBC

Rwanda Biomedical Center

RSOG

Rwanda Society of Obstetricians and Gynaecologists

UBT

Uterine balloon tamponade

VIHC

Declarations

Ethics approval and consent to participate

Ethics approval was obtained from the University of Global Health Equity (UGHE) Institutional Review Board (reference UGHE/2022/002). Additional approvals were granted by the Rwandan Ministry of Health (NHRC/2023/PROT/011) and by the relevant institutional review boards or authorities of the participating facilities (University Teaching Hospital of Kigali (EC/CHUK/085/2023), King Faisal Hospital (KFH/2023/077/IRB), Rwamagana Provincial Hospital (14/208HOP/RGNA/2023), Rwinkwavu District Hospital, Kayonza District and Kibagabaga Hospital). All participants gave written informed consent to take part. Consent forms were available in English and Kinyarwanda, and consent was sought at the facility level and again directly from participants before each session. All methods were carried out in accordance with relevant guidelines and regulations.

Consent for publication

Not applicable. The manuscript contains no individually identifiable data, and all quotations are deidentified and cannot be traced to individual participants.

Availability of data and materials

The qualitative datasets (interview transcripts) generated and analyzed during the study are not publicly available in order to protect participant confidentiality, but de-identified excerpts are included in this article and further information is available from the corresponding author on reasonable request and with appropriate approvals.

Competing interests

In the interest of full disclosure, SDR is a named inventor on patents related to the Jada System. We declare that these disclosures did not influence the reporting of the study's findings. EI declares no competing interests. Neither author is currently affiliated with Organon, the manufacturer of the device, nor does receive financial incentives from Organon.

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Authors' contributions

EI and SDR conceived and designed the study, collected the data, carried out the analysis, and drafted and revised the manuscript. Both authors contributed equally to this work, and both read and approved the final manuscript.

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Authors' information

EI is a Rwandan pharmacist with experience in emergency blood delivery services and health systems across Rwanda. SDR is a biomedical engineer and advisor who has worked in the PPH field since 2016. This study was completed in partial fulfillment of the Master of Science in Global Health Delivery at the University of Global Health Equity.

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Figures

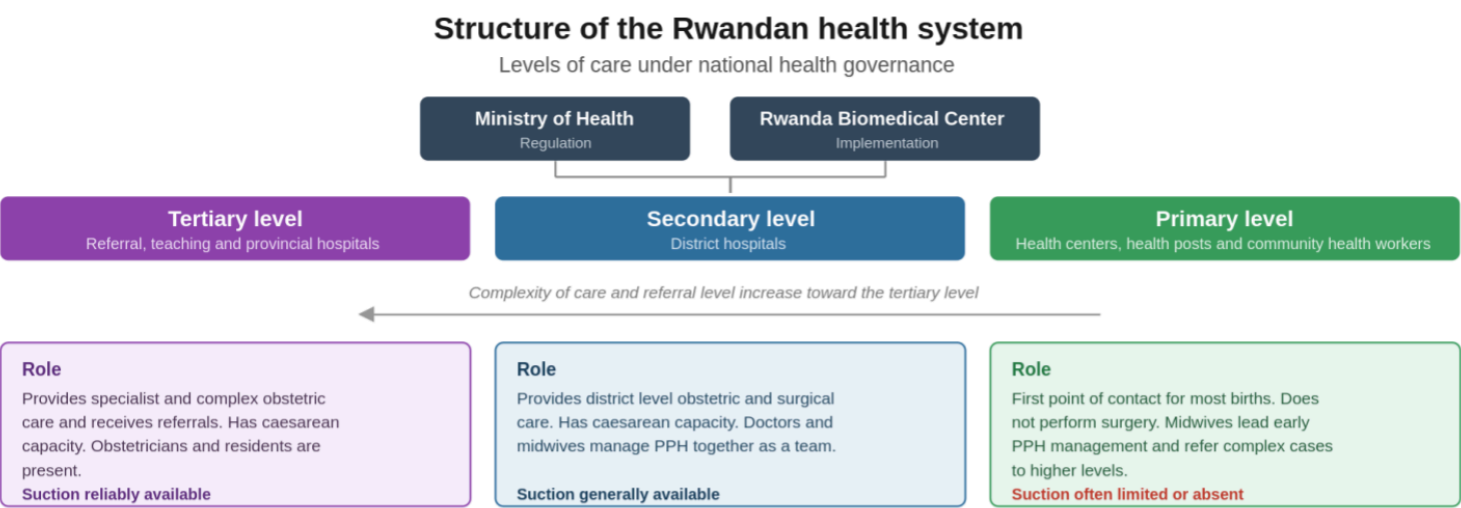


Figure 1

Structure of the Rwandan Health System

Management of atonic postpartum haemorrhage in Rwanda

National guideline steps, with the points where participants preferred to place Jada

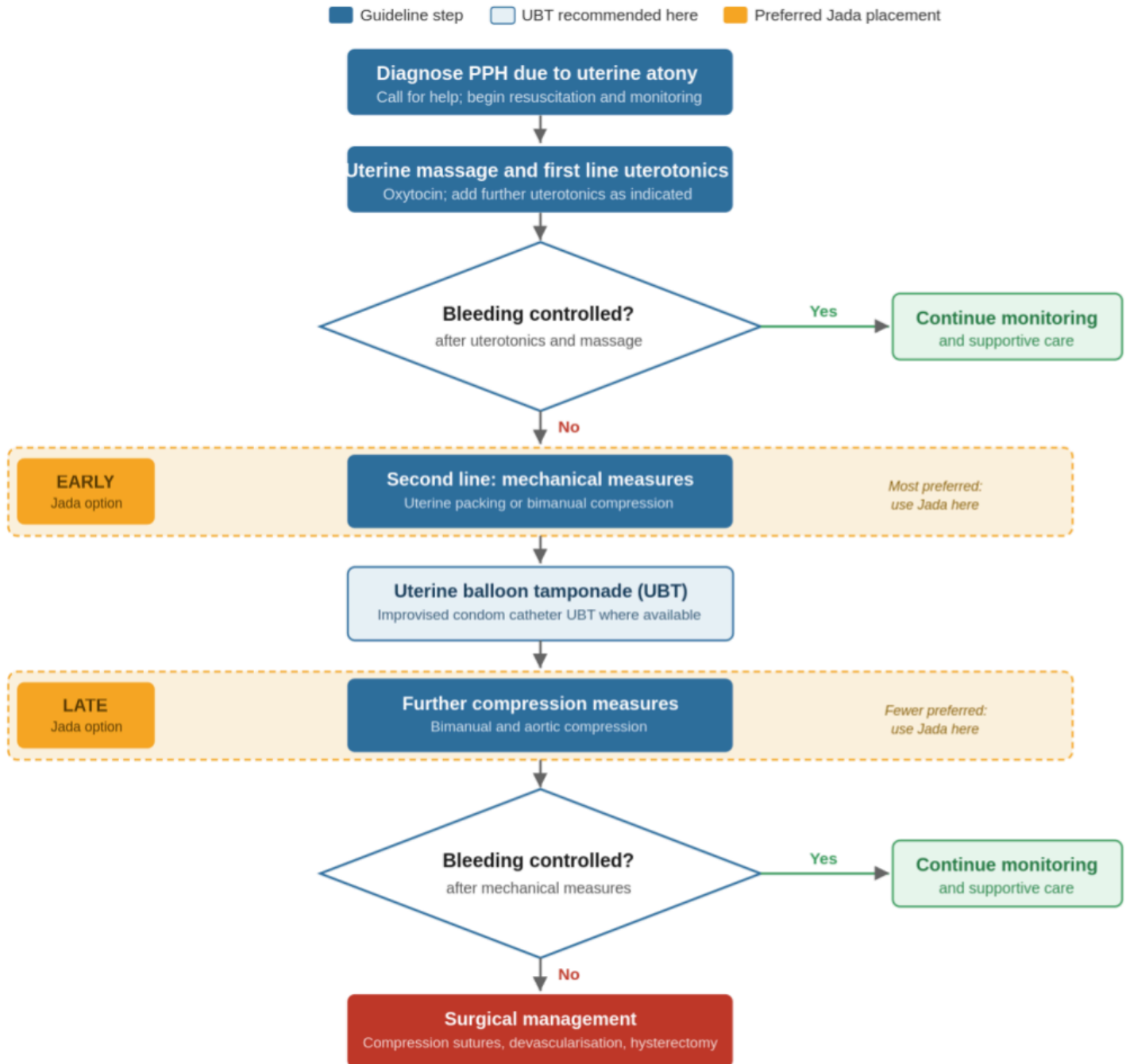


Figure 2

Management of atonic postpartum haemorrhage in Rwanda, showing where participants preferred to place Jada

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