Title of Study: Feasibility Testing of a Urinary Drainage Bag Securement Device to Improve Patient and Clinician Ambulation Experiences

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Feasibility Testing of a Urinary Drainage Bag Securement Device to Improve Patient and Clinician Ambulation Experiences

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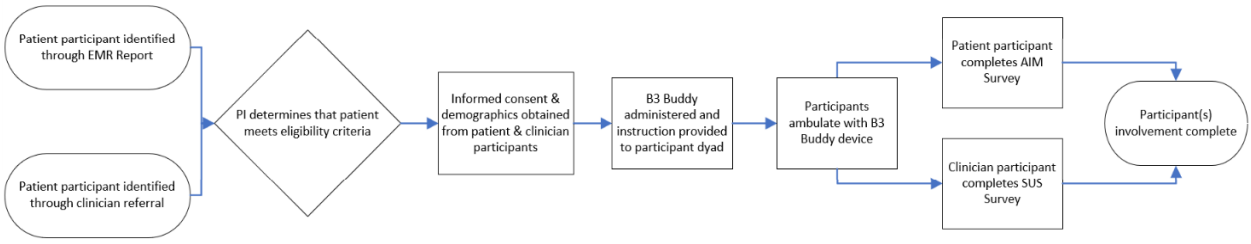
I. Study schema



II. Project overview

There are currently no devices designed to secure a urinary drainage bag, also known as a foley bag, while a patient ambulates. To address this, a urinary drainage bag securement device called the Bag Below Bladder (B3) Buddy was invented by the research team. The B3 Buddy is not intended for diagnosis, prevention, or treatment of disease, or affects any bodily functions or structures. The purpose of this study is to determine the feasibility, which will be measured by usability and acceptability tools, of the B3 Buddy in securing urinary drainage bags while patients ambulate.

III. Objectives

Objective 1: To evaluate the acceptability of the B3 Buddy, from the patient's perspective

- Endpoint- Acceptability will be determined with the Acceptability of Implementation Measure (AIM) tool. The B3 Buddy will be considered acceptable if at least 70% of patient participants find the device acceptable, which will be calculated by survey responses.

Objective 2: To evaluate the usability of the B3 Buddy, from the clinician's perspective

- Endpoint- Usability will be determined with the System Usability Scale (SUS). The B3 Buddy will be considered usable if the overall mean score is 68 or greater, which will be calculated by survey responses.

IV. Background and Rationale

Keeping a urinary drainage bag below the bladder is the standard of care to maintain urine flow and inhibit urinary backwash into the bladder (Stratton & Zieve, 2021). Despite the use of modern urinary drainage bags for over 60 years, clinicians find workarounds for drainage bag securement. Clinicians may use items, like disposable gloves or tourniquets, to tie around an IV pole to create a makeshift hanger for the urinary drainage bag (Appendix 1). Other situations may include the clinician hooking the drainage bag into their pant pocket while assisting the patient in ambulation (Appendix 2). It has been observed that patients also hang their drainage bag from their shirt pockets (Appendix 3).

A. Invention

The research team invented the B3 Buddy to hold urinary drainage bags in an optimal position while patients ambulate. We have developed a conceptual model of this device through The Ohio State University's Innovation Studio. Our team created Computer-Aided Design (CAD)

drawings and 3D printings of the B3 Buddy (Appendix 4). We have disclosed this invention through the Technology Commercialization Office and have submitted a provisional patent to protect the intellectual property of this device. The College of Engineering's Center for Design and Manufacturing Excellence has been contracted to complete the final design phase and manufacturing of the device.

The B3 Buddy is designed to be a flexible, easy to utilize, safe, and nonsignificant risk device to help patients and frontline clinician's keep urinary drainage bags at an appropriate level. This device will be disposable so that there is no risk of contamination between patients. This device can adapt to a variety of patient situations. Since there are many different urinary drainage bags out on the market, the B3 Buddy demonstrates its versatility using a dual-function "select-a-size" tailed hook on one end and a strong clamp on the other. It is designed to hang off the patient's gown, clothing, IV pole or ambulatory assistive device while securing the drainage bag on the other end.

The research team will conduct a feasibility study on the B3 Buddy, using validated measurement tools in usability and acceptability. Usability can be defined as a measurement of a product to achieve its intended purpose with effectiveness, efficiency, and satisfaction in a specified context (Bitkina et al., 2020; Brooke, 1995; Schmettow et al., 2017). The System Usability Scale (SUS) (Appendix 5) is a popular usability scale developed by John Brooke in 1986 (Brooke, 1995), and will be a tool used in this study. Acceptability can be defined as how the end-user reacts to the device (Bowen et al., 2009). Weiner et al. (2017) developed the Acceptability of Implementation Measure (AIM) (Appendix 6), which has been validated to be a psychometrically sound tool and will be used in this study to measure acceptability.

B. Significance

This study is significant because results from this study may inform the final development of the B3 Buddy. Determining end-user acceptability and usability is an important initial step to ensure that the B3 Buddy mitigates the problem it was designed for, without spending unnecessary time and resources. The results of this study will hopefully affirm that this innovation enhances the experience of patients and clinicians' ability to keep urinary drainage bags in the optimal position during ambulation.

Hypothesis: The Bag Below Bladder (B3) Buddy will enhance the ambulation experiences of patients with urinary catheter bags and clinicians that care for them.

V. Methods

A. Study design

This project is designed as a feasibility study where both usability and acceptability will be measured on a convenient sample. The sample will include 20 patient participants to test acceptability and 20 clinician participants to test usability.

B. Participant selection

1. Recruitment procedures:

The study will take place on inpatient units, where there are approximately 34 patients per unit. Clinician participants may include nurses, patient care associates, physical therapists, occupational therapists, or therapy assistants. A total of 20 patient participants and 20 clinician participants will be recruited. The researchers will run a report through the organization's

Electronic Medical Record (EMR) to identify patients that meet inclusion criteria (listed below). A secondary recruitment technique will be applied through in-servicing potential clinician participants who frequently engage with eligible patients so that they may reach out to the PI if interested in participating in the study (see in-service materials Appendix 7). After IRB approval, in-services will take place during monthly unit meetings for information sharing and awareness of the study. Likely the first in-service will be provided the following month after IRB approval. After identification of eligible patient participants, the PI will communicate in-person with the patient to inquire if they have interest in participating in the study (see script Appendix 8). If the patient is interested, the PI will then communicate with the clinician to inquire if they are also interested in participating (see script Appendix 9). To ensure accrual of 20 distinct patient participants and 20 distinct clinician participants, all participants will only be allowed to participate once.

2. Inclusion/Exclusion Criteria:

Inclusion criteria for the <u>patient participant</u>:

- Must be English-speaking
- Able to comprehend and agree to consent
- Able to read and complete the AIM survey
- Be willing to participate using the B3 Buddy device
- Have an indwelling urinary catheter or urostomy device connected to a drainage bag
- Have no restrictions in ambulation

Inclusion criteria for the <u>clinician participant</u>:

- Must be English-speaking
- Able to comprehend and agree to consent
- Able to read and complete the SUS survey
- Be willing to participate using the B3 Buddy device
- Have a professional role in assisting patients in ambulation in normal workday activities

Exclusion criteria:

- Those patient participants that have more than one urinary-like drainage bags will be excluded. This exclusion is due to the limited prototype samples available to the research team. Limiting one device for one patient with multiple drainage bags may not allow for accurate assessment of the B3 Buddy device.

3. Informed consent process:

- *Patient participant*- Consent and demographics (Appendix 10 and 11) will be obtained after both patient and clinician dyad express interest in participating in the study. The research team will administer the consent and demographics to the patient participant through an electronic tablet in the patient's inpatient, private room using a REDCap-based electronic consent form.

- *Clinician participant*- After the patient participant's consent and demographics has been obtained, the clinician participant will be sent an email with a link containing the consent and demographics survey (Appendix 12 and 13) using a REDCap-based electronic form.

Both participants' consent forms (Appendix 10 & 12) will be obtained using a "yes" or "no" along with a typed name and electronic signature via mouse or touch screen. Upon completion of the consent encounter, participants will be provided with a copy of the consent document by a printed copy of the consent form or providing participants with a with the web link to the appropriate version of the consent.

VI. Study procedures

A. Explanation of the intervention.

Patient participant- There will be a short instructional session on what the patient should expect during the use of the B3 Buddy (see script Appendix 14). Although the securement of the device will be done by the clinician assisting the patient, patients may have the opportunity to participate in the discussion. They will be instructed to attempt to ambulate the length of the hallway outside their inpatient room, which is approximately 90 feet, while utilizing the B3 Buddy. After the completion of their ambulation experience, their clinician assisting them in ambulation will remove the B3 Buddy and return the urinary drainage bag to its standard position.

Clinician participant- The same instruction, that was given to the patient participant, will also be provided to the clinician participant (see script Appendix 14). The PI will share securement techniques of the B3 Buddy to the patient's clothing, gown, IV pole, or ambulatory assistive device. Dependent on which end was used in the previous step, the other end of the B3 Buddy will then be secured to the urinary drainage bag itself. Because the B3 Buddy device is adaptable to a variety of different clinical situations and types of drainage bags available in the market, the clinician may select which securement end would work best. Examples of different ways to use the B3 Buddy may include, but not be limited to:

- the clip end is secured to the patient's gown or clothing and the drainage bag may be secured via the securement hook; for bags without hooks, the tailed end of the B3 Buddy may be looped around the strings or preexisting holes of the drainage bag (Appendix 15)
- the tailed end is looped around the patient's IV pole and the clip end is attached to the urinary drainage bag (Appendix 16)

Clinician participants will be instructed to assist the patient in ambulating the length of the hallway outside the inpatient room, which is approximately 90 feet, while utilizing the B3 Buddy. After the completion of the ambulation experience, the clinician will remove the device from the patient and secure the urinary drainage bag to the standard position.

At the completion of the ambulation experience, the PI will provide an electronic tablet to the patient participant to complete the 4-item questionnaire AIM survey (Appendix 6). The PI will send an email of the REDCap link of the SUS survey to the clinician participant (Appendix 5; Appendix 19). If the PI has not received the survey response within 3 business days, the PI will send a reminder email if the survey responses have not been received (Appendix 20).

B. Study Calendar

Overall study calendar (Appendix 17)- The research team anticipates a total of 6 months to complete the study, which will include pre-screening, screening, device testing, and end of trial phases. After IRB approval, the PI will provide in-services about the B3 Buddy study at unit and departmental staff meetings in the pre-screening phase to encourage secondary recruitment strategies (in-service materials Appendix 7). Review of inclusion/exclusion criteria, recruitment of participants, informed consent, and demographic information will be obtained during the screening phase. During the device testing phase, the B3 Buddy device will be deployed to the participant dyad with bedside instruction provided by the PI. The study will end when the participant dyad completes the appropriate surveys and the PI collects the B3 Buddy device.

Patient and clinician participant recruitment and user testing will take approximately 3 months. After accruing 20 subject dyads, one month will be allocated for data analysis and an additional two months to disseminate findings.

Participant time commitment- Patient participants can anticipate being involved in the study for a total of 17 minutes and clinician participants can anticipate being involved for a total of 20 minutes, when actively participating (Appendix 18). The participants' time in the study will end once they submit their survey responses.

VII. Data collection and management process

A. Data to be collected

- *Patient participants*- Demographics (age and gender; Appendix 11) and AIM survey responses (Appendix 6)
- *Clinician participants*- Demographics (age, level of education, hospital role, and years of healthcare experience; Appendix 13) and SUS survey responses (Appendix 5)
- *Recruitment log*- A recruitment log will be used to organize information regarding eligible patients. Information collected will include the patient's room number, MRN, type of urinary drainage device, activity order/restrictions, and language/English-speaking status. (Appendix 21)

B. Data collection

For both patient and clinician participants, consent, demographics, and (AIM and SUS) survey responses will be captured through REDCap. REDCap is a secure, web-based, HIPAA-compliant, data collection platform with a use management system allowing project owners to grant and control varying levels of access to data collection instruments and data for other users. REDCap was developed by Vanderbilt University, with collaboration from a consortium of institutional partners (including OSU), as a software toolset and workflow methodology for electronic collection and management of research and clinical trial data.

C. Data storage and protection

The PI will assign each patient and clinician participant dyad the same number code. The codes will be assigned chronologically throughout the duration of the study, one through 20, with an "a" to indicate the patient participant and "b" to indicate the clinician participant. For example, a participant dyad of a patient and clinician would be identified as 8a and 8b. The PI will deidentify all participants by substitute codes for personal data by keeping a list that matches each participant's name and personal information. Only the PI will know the correspondence of the participant names with the deidentified number code, which will be stored on a secure password protected computer server. The information from REDCap, containing the consent and survey results, will also be stored on a secure password protected computer server. Deidentified data will be shared with study personnel only for the purposes of analyzing and disseminating findings.

D. Quality control procedures

The PI will have each patient and clinician participant name and will code each participant chronologically, one through 20. For the remainder of the study, other members of the research team will only see these specific coded, participant identification number. All documents and participant information related to the study will be kept strictly confidential. For both types of participants, this information could be used to identify the participants. There may be circumstances where this information must be released. For example, personal information

regarding their participation in this study may be disclosed if required by state law. At the end of the study, the PI will delete all personal participant contact information.

VIII. Human subjects information

A. Potential risks and benefits

The B3 Buddy poses no significant risk to participants as it does not provide life-sustaining treatment or therapies in its absence or application. We anticipate direct benefits of having a practical device to support the position of a urinary drainage bag below the bladder while a patient is ambulating. Another benefit in participating in this study is to provide the opportunity for patients to utilize a device that is not yet available for public use and provides a simple solution in keeping a urinary drainage bag at the optimal position while ambulating.

There is a risk of the device unclipping or untethering from its secured surface, causing the urinary drainage bag to fall on the ground. This is no different than the standard of care, which may require the end-user to hold the urinary drainage bag or place it on a make-shift securement device (e.g. clinician pocket, patient pocket, tied glove or tourniquet around an IV pole; Appendix 1-3).

An inherent risk is the breach of confidentiality. Only members of the research team will have access to the de identified results. The research team will work to ensure that no one sees participants' survey responses collected electronically via REDCap without approval, but because this study will be using the internet, there is a chance that someone could access a participant's online responses without permission. In some cases, this information could be used to identify the participants. Each participants' information will be coded to reduce this risk so that other people cannot view their responses. There will be no stored hard copies of the of the clinician consents, demographics, or survey responses.

B. Protections against risk

Each participant may refuse to participate in this study without penalty or loss of benefits to which they are otherwise entitled. If they are a student or employee at Ohio State, their decision will not affect their grades or employment status. Each participant records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices.

C. Reporting of adverse events

We anticipate no significant adverse events as this study poses minimal risk as outlined above under potential risks and benefits. If an event does occur, the PI will be notified of the situation and the data and safety monitoring plan will be followed (see page 9, Section X).

D. Premature removal of participant

A participant can be removed from the study at any time and may choose to voluntarily withdraw. The PI will be notified of a participant's withdrawal or removal; the reason for the withdrawal or removal will be noted in the PI's record keeping.

E. Study termination procedures

At the end of the study, the PI will delete all personal participant contact information, along with excel sheets that include coded participant names. If the PI who manages this data leaves the

university prior to the end of this study, another member of the study team will gain access to this information with plan to delete.

F. Completion of study

Participant involvement in this study will be concluded after submission of the AIM or SUS survey response via REDCap. After the completion of the ambulation experience, the PI will collect the B3 Buddy device.

IX. Statistical Methods

Statistical methodology and calculations have been reviewed and performed by statistician and co-investigator, Dr. Loraine Sinnott.

A. Sample size calculations

According to the Food and Drug Administration, testing a medical device requires at least 15 test participants for adequate human factors validation testing (2016). This allows for assessment of whether the device is effective for the intended users. We are oversampling for attrition or other factors that may suspend the ambulation experience. It is supported by usability experts of the SUS tool that 12-14 participants are an adequate minimum sample size to determine usability (Sauro, 2011; Tullis & Stetson, 2006). Additionally, each prototype device will be designed for single-patient use and cannot be applied to another participant. The research team has been provided funding to create 20 devices. This sample size will inform future research and goals.

B. Data analysis plan

The primary outcomes of this research are estimates of the proportion of patients who find the device acceptable and the expected value of clinicians' perceptions of usability of the device.

Acceptability: The AIM (Appendix 6) will measure acceptability. The AIM's four items have 5-point Likert scales, ranging from 1 (for 'Completely disagree') to 5 (for 'Completely agree'). Higher number indicates greater acceptability. If a patient marks three or more items with at least a '4', the patient's overall AIM score will be graded as '1'. Otherwise, the patient's overall AIM score will be '0'. The device will be considered acceptable if at least 70% of patients have AIM scores of '1'. Should that happen, the total width of the confidence interval for the true proportion of patients finding the device acceptable will decrease as the acceptability proportion increases. For a sample size of 20 patients, the maximum width will be 0.40. For example, if the observed proportion is 0.7, the confidence interval will be 0.43 to 0.83 (a width of 0.4, the maximum). If the observed proportion is 0.8, the confidence interval will be 0.59 to 0.93 (a width of 0.34).

Usability: The SUS (Appendix 5) will measure device usability. The SUS's ten items have 5-point Likert scales, ranging from 1 (for 'Strongly disagree') to 5 (for 'Strongly agree'). Half of the items require reverse scoring. An overall SUS score will be obtained using an algorithm that transforms the sum of responses of the ten items to a score with a range of 0 to 100. Higher scores indicates a perception of greater usability. To obtain the overall mean SUS score, we will take each individual SUS score, add them together, and divide by the number of participants. The average SUS score across all studies is 68, which indicates that any SUS score above 68 is considered above average (Sauro, 2011). Scores 60-70 are considered "okay," scores 70-80 are considered "good," scores 80-90 are considered "excellent," and scores greater than 90 are the "Best Imaginable" (Bangor et al., 2009). It is the hope of the research team to obtain an overall mean score of 68 or greater. Bangor et al. (2008) reviewed statistics from 206 studies

that used the SUS. They found that the typical standard deviation across the studies was 18.0. Assuming a standard deviation of 18.0 is observed in this study, with a sample of 20 clinicians, the confidence interval for the true SUS mean will be the observed study mean +/- 8.42.

In relationship to the endpoints, the findings of this study will inform the research team if the B3 Buddy invention suits the needs the end-user. It's our goal that the B3 Buddy will meet both objectives of demonstrating acceptability and usability. If either objective(s) does not meet the goal, there may be an opportunity (with IRB approval) for the research team to perform a simple qualitative study to determine end-user needs to improve the device. Possibly redesigning the B3 Buddy so that it meets the end-user needs.

X. Data and safety monitoring plan

The data and safety monitoring plan will involve the continuous evaluation of safety, data quality and data timeliness. Investigators will conduct continuous review of data and patient safety at their study team meetings established by the principal investigator. The PI will review responses of the trial where applicable at these meetings and determine if the risk/benefit ratio of the trial changes. In the unlikelihood that an adverse event would occur, the event will be reviewed by the PI to determine if the trial should be terminated before completion. All adverse events will be submitted as part of the summary report. The PI will submit a summary report, at least annually, that will be reviewed by the committee per the IRB of record as per the policies of the IRB.

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