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**UNIVERSITY OF SAN DIEGO
Hahn School of Nursing and Health Science**

DOCTOR OF NURSING PRACTICE PORTFOLIO

by

Yen Tse Kim, BSN, RN, DNP Student

A portfolio presented to the

**FACULTY OF THE HAHN SCHOOL OF NURSING AND HEALTH
SCIENCE UNIVERSITY OF SAN DIEGO**

**In partial fulfillment of the
requirements for the degree**

**DOCTOR OF NURSING PRACTICE
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Final Manuscript

**MANAGING END-OF-LIFE PAIN USING A RECTAL
MEDICATION ADMINISTRATION DEVICE**

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MANAGING END-OF-LIFE PAIN USING A RECTAL MEDICATION ADMINISTRATION DEVICE

Abstract

Approximately 75% of the terminally ill will experience pain during the dying process. Oral opioids are the mainstay of pain management; however, patients are often unable to tolerate oral medications at the end of life and will need an alternate route of medication administration. Rectal administration is an appropriate alternative. End-of-life patients unable to tolerate oral pain medications were switched to the rectal route using a rectal medication administration device for pain management. Although only four patients participated in the pilot project, all patients experienced a decrease in pain level. Pain medication administration using a rectal medication administration device is a viable alternate route and is low cost, easy to use, and effective for dying patients for whom oral medication administration is not appropriate.

KEYWORDS:

End-of-life issues, pain management, rectal tube, rectal medication
administration device, end-of-life symptom management, hospice

Managing end-of-life pain using a rectal medication administration device

In 2013, the National Hospice and Palliative Care Organization estimated 1.5 to 1.6 million patients had received hospice care¹. Ensuring a good death is a major challenge for healthcare providers². Six major components of a good death include pain symptom management, clear decision making, preparation for death, completion, contributing to others, and affirmation of the whole person³. Approximately 75% of terminally ill patients will experience pain at the end of life⁴. Pain is a common symptom during the end of life; therefore, pain management is a key element in end-of-life care. “Good management of physical symptoms allows patients and loved ones the space to work out unfinished emotional, psychological, and spiritual issues, and thereby, the opportunity to find affirmation at life’s end”^{5(p.1059)}.

Pain control is a challenging task for end-of-life care, and, unfortunately, pain is often untreated or undertreated⁶. Effective pain management may necessitate a variety of control strategies⁶. Groninger and Vijayan emphasized the necessity for strong opioids for effective analgesia

in dying patients⁷. Oral opioids are the preferred method of pain management in hospice care⁸; however, end-of-life patients are often unable to tolerate oral routes due to loss of consciousness, inability to swallow, fear of aspiration, or too many medications. Warren noted that “persistent inability to utilize the oral route is most common when death is imminent”⁹(p. 378).

These patients will need an alternate route of medication administration, and the rectum provides a viable alternative. The rectal route has several benefits including low cost, consistent and predictable absorption of medications, ease of use, and good symptom management¹⁰. Rectally administered medications are as effective or, in some cases, more effective than oral medications¹¹. The rectal route has a rapid onset of action, is safe, easy, and generally painless, and there is no risk of aspiration. Rectal administration also bypasses first pass metabolism and the protein peptide drug delivery system¹². Almost all oral medications can be given rectally¹³, and oral medications are significantly cheaper than other forms, such as sublingual, transdermal, or intravenous.

The Local Problem

Currently, patients unable to tolerate oral medications are switched to sublingual or subcutaneous routes (SQ). The transdermal route is not considered for pain management in end-of-life patients, due to the long period required for sufficient absorption to achieve pain relief. For example, Fentanyl patches can provide adequate pain control but take approximately 12 hours to become effective. Such delays are not acceptable for patients in the last hours to days of life⁶. Similarly, sublingual (SL) medications are not always effective in end-of-life patients for a variety of reasons. Some of these reasons include inadequate absorption of SL medications in patients with extremely dry mucus membranes, inappropriate use of SL medications by caregivers, or pocketing of medications in patient's cheeks, which poses a risk for aspiration. Subcutaneous (SQ) medications are effective for end-of-life pain management; however, supplies and medications for the SQ route are expensive. Due to these many factors, a need for an alternative route for pain medication management between the oral and SQ routes was identified in the hospice setting.

Each patient that is placed on a subcutaneous button is a patient that would be eligible for a rectal medication administration device (RMAD).

Patients using a subcutaneous button are placed in crisis care, meaning that they need daily follow up by a provider and sometimes a bedside nurse for symptom management. The number of crisis care patients and the number of patients using a subcutaneous button each month was tallied. Over a 3-month period, the number of patients on crisis care ranged from 42 to 45, and the number with a subcutaneous button ranged from 13 to 19. During the time period, at least a third of the patients on crisis care were using subcutaneous buttons.

Patients unable to tolerate oral medication administration were being changed from oral directly to subcutaneous pain medications, the only other routes available were sublingual or transdermal routes, and not all medications are effective via those routes. Patients often waited a long time before subcutaneous medications could be started. Subcutaneous button supplies need to be ordered and were often not stocked in case managers' supplies. Subcutaneous medications need to be ordered and picked up or delivered from the pharmacy, which could take six hours or longer. These patients needed a faster alternative as a possible step between the oral and subcutaneous routes.

Purpose

The purpose of this evidence-based project was to improve end-of-life pain management in hospice patients experiencing uncontrolled pain using a rectal medication administration device.

Ethical Issues

Approval to implement the project was obtained from the administration of a large southern California hospice organization. In addition, approval to disseminate de-identified data was obtained from the University of San Diego Institutional Review Board.

Setting

This project was conducted at one of the oldest and largest nonprofit hospices in southern California. The organization provides hospice and palliative care services to San Diego and south Riverside counties. Each patient has a support team that includes hospice-trained physicians and nurse

practitioners, nurses trained in pain control and symptom management, hospice aides, social workers, spiritual counselors, and volunteers.

Practice Change

Several activities were involved in implementing the practice change. These included formation of a RMAD task force, creation of the RMAD device, identifying appropriate medications, developing a standard of practice, developing documentation forms, creating training materials, training staff, and implementing use of the device. Each of these activities is discussed below.

Task Force Formation

An interdisciplinary task force representing all stakeholders was appointed to coordinate the RMAD project. The project was chaired by a doctorally prepared nurse practitioner that acted as the project coordinator, clinical mentor, and guide. Other members of the task force included registered nurses, licensed vocational nurses, social workers, and chaplains. Task force members met monthly to keep up to date with the progress of the

project and provided feedback for project development. Each task force member was given a task to help expedite the project. Examples of tasks included creating a RMAD, identifying possible pain medications to be used with the device, narrowing participant criteria, and determining possible barriers to use of a rectal device.

Creating the Device

The rectal route was determined to be a suitable alternate route and a device was put together to help deliver the pain medication. Using the company-approved supply vendor, several possible devices were tested and a final device approved by the task force. Cost, ease of use, accessibility, and reproducibility were all factors in the selection of the final RMAD. The RMAD was created with a 16 French Foley catheter, a Luer tip catheter adapter, and a 3-way stopcock. The port for the urine collection device was removed from the Foley catheter and a Luer tip catheter adapter inserted. The 3-way stopcock was then attached to the Luer tip end of the adapter. Instructions for creating the device are shown in Figure 1, and the final RMAD is depicted in Figure 2.

Identifying RMAD medications

The RMAD pain medication formulary is based on the current emergency kit at the setting. The goal was to be able to use medications that were already available in a patient's home. Each of the medications available in the emergency kit, as well as commonly used opioids and other pain medications, were thoroughly researched for efficacy and safety of use for the rectal route. The head pharmacist at the company-approved pharmacy was consulted throughout this process about rectal use and efficacy of each medication.

Developing an RMAD standard of practice

The existing protocol for medication administration via subcutaneous button was used as a guideline for developing a standard of practice for the RMAD. The standard of practice was reviewed during task force meetings and corrections were made and finalized. The RMAD standard of practice is the guide for all staff and family members for use of a RMAD. The standard of practice describes the purpose of the device and how to contact the appropriate staff member for the provider's order to change the medication

route. It also lists what is included in each RMAD kit and provides step-by-step instructions on how to create the final device from the contents of the kit. Detailed instructions for RMAD insertion and removal, medication preparation, and medication administration are also included in the standard of practice. A list of RMAD medications is also included.

Creating Documentation Forms

A variety of documentation forms and teaching materials were needed to implement the project. RMAD forms were created based on the need to monitor pain levels. Forms created included a caregiver profile, medication form, and the RMAD evaluation form. The caregiver profile elicits background information about caregivers that is useful in determining the appropriateness of RMAD, such as education level, familiarity with route of medication administration, physical limitations and ability to use the RMAD, comfort with medication administration, and so on. The medication form was developed to monitor types of medication used, amount of water used for each administration, and FLACC pain scale before and after medication administration using the RMAD. The RMAD evaluation form provides feedback on how well managed the patient's pain is using the

RMAD and any questions, concerns, or complications that may arise during therapy. All RMAD forms were presented to the site's clinical operations quality team for approval and adoption. Copies of the final version of all RMAD forms were branded for site use.

Developing Training Materials

The RMAD training handbook is a one page, front and back, guide that provides easy step-by-step instructions at a third grade level for RMAD insertion, medication preparation, and medication administration. The training handbook was intended to be a quick reference for patients' caregivers and for staff with pertinent RMAD information, such as what a RMAD is, RMAD insertion, medication preparation, and medication administration via RMAD. The front section provided information about the device and what is in each RMAD kit. The second section included how to insert the device, how to prepare medications to be used, and how to give the prepared medications using the RMAD. Each caregiver was trained using this handbook and demonstrated verbal and written understanding of how to prepare and give medications using the RMAD.

Training RMAD Champions and Triage Staff

Registered nurse case managers (RNCMs) volunteered to participate in the RMAD pilot project. Two nurses from each geographic area served by the agency were chosen to be project champions and were trained on the RMAD and all forms. Triage staff members, including overnight triage staff, were also trained on the RMAD in case they needed to replace the device after hours or a patient was admitted that was eligible for RMAD use.

Implementing Use of the RMAD

Eligibility criteria for patients' use of an RMAD included admission to the hospice's care, being actively engaged in the dying process (in the last hours to days of life), and with an inability to swallow, uncontrolled nausea or vomiting, or pain uncontrolled by other routes except the subcutaneous route. These patients and their family members were educated about the RMAD by a RMAD champion, and, if they agreed to participate, a RMAD was inserted. The patient was changed to crisis care status for the first 24 hours after RMAD placement to monitor pain levels and assure that patients and caregivers had adequate support, if needed. Caregivers who were

comfortable with management of medications through the RMAD were trained to prepare and administer medications and did not need a bedside nurse. Caregivers were not trained to insert the device; only the hospice staff was allowed to insert the RMAD. Patients were monitored on the RMAD on days 1, 2, 3, and 6 after insertion or earlier if complications occurred.

Evaluating Project Results

The main purpose of this project was to improve pain management using a RMAD. The overall goal was a decrease in pain levels for patients using RMAD. Specific objectives for this project included: (a) a decrease in pain level in 80% of patients, (b) participation of 60% of RMAD eligible patients in the program, and (c) participation of 50% of providers in the program.

Evaluation of the effectiveness of this program included whether the RMAD was a device that would be accepted by patients, caregivers, and staff and the cost-benefit of using a RMAD versus a subcutaneous button. Evaluation of the RMAD included review of RMAD packets to evaluate pain levels and speaking with caregivers and staff about their opinions of the

device and rectal route. The RMAD packets were a folder that included all the RMAD forms – caregiver profile, RMAD standard of practice, RMAD training handbook, RMAD medication sheet, and RMAD evaluation form. Cost analysis for the RMAD compared to the subcutaneous button was based on the cost of the kits and the medications involved.

Evaluation Findings

Objectives a and c were both met. All participating patients experienced a decrease in pain levels using a RMAD (see Figure 3) and 100% of the providers participated in the program. Unfortunately, only 11% of RMAD-eligible patients participated in the project (see Figure 4). Some reasons for not participating in the program included staff members that were not familiar with the device and did not want to use it. Staff members unfamiliar with the rectal route also raised doubts in caregivers and often talked them out of using the rectal route once they had agreed. Some caregivers were adamantly against the rectal route for their loved one, and some patients passed before a RMAD champion could get them enrolled in the program.

A cost comparison for the RMAD versus the subcutaneous button showed a savings of \$14.34 for the kit and \$149.09 for medications. Further savings derive from the fact that the subcutaneous button needs to be changed every three days and usually there are two buttons placed because some medications are caustic and cannot be run through the same device. The RMAD does not need to be replaced unless it becomes clogged or is removed and even then, the only part that needs to be replaced is the catheter itself, at a cost of \$0.86. The bulk price for the subcutaneous button kit was \$17 and the individual pricing for all the components of a RMAD kit totaled \$2.66. If the RMAD were to be packaged as a self-contained kit, as are the subcutaneous button kits, instead of piece-meal ordering, the estimated cost per kit at bulk prices would be less than \$1. The average cost of medications for the subcutaneous button is \$180 for methadone, morphine, Ativan, and haloperidol. The RMAD only uses medications from the emergency kit at a cost of \$30.

Discussion

Continuation of RMAD use would provide an alternate route of medication administration that is easy to use, efficient, and cost effective.

Every patient experienced a decrease in pain levels, which means that pain management was successful using a RMAD. The device is simple to put together and also much more portable for RN case managers (RNCMs). Using the available emergency medication kit that patients already have in their house eliminates the need to wait for medications.

Some limitations of the project included time constraints, patient participation, and general attitude towards the rectal route on the part of both staff and caregivers. The project was started during first week of December 2014 and ended in Feb 2015. Patient participation could have been affected by RMAD eligibility criteria. In general, staff did not feel that eligibility criteria for patient participation in the program were too strict. However, there were some concerns about whether the patient needed to meet all criteria or a few of the criteria. For this program the main criteria were that the patient was actively dying and had pain that could not be managed through other methods.

The biggest obstacle to program implementation was overcoming negative caregiver and staff attitudes toward using the rectal route. Staff attitude was an unexpected barrier. LVNs who were uncomfortable with the

device essentially talked the caregivers out of using the rectal device because the LVNs would be the ones maintaining the RMAD if the caregivers were not comfortable with medication administration via RMAD. Other staff simply refused to use a RMAD and were not even open to education about the device. Additional champions were needed and trained about halfway through the project. A few patients were eligible but because their RNCM was not RMAD trained, they needed to contact a RMAD champion, and the patients expired by the time a champion could get to the site.

Several lessons were learned as a result of this project, the biggest lesson being the need to be adaptable. Many factors came up during the time from project initiation to the end. A good environment and site support was crucial to implementation of this project. Initiating this project as a pilot program was both good and bad. Starting as a pilot meant that the availability of the device to the entire site was limited, this was a problem because not enough staff was exposed to the device; greater exposure might have eliminated the uncertainties some staff had about the device. On the other hand, keeping the project small meant that not everyone was trying to use the device on every patient, which helped to keep variables low. The most useful comment from a RMAD champion was to start talking about the

device earlier in the patient's care so this new and often stigmatized route is not introduced to the caregiver when they are overwhelmed with their loved one dying.

CONCLUSIONS/IMPLICATIONS

Having an additional route for medication administration is vital. Although many people are averse to using the rectal route, more education needs to be done for medical professionals and caregivers about the ease and effectiveness of rectal administration using a RMAD. Using a RMAD eliminates the need for caregivers to keep turning their loved ones and to constantly be giving rectal suppositories. This creates an increase in patient and caregiver satisfaction. Future research can be done using different types of medications and/or different populations of patients. More effective modes of educating caregivers and staff regarding RMAD use can also be studied.

More education of the general population is also needed. The rectal route is important not only in end-of-life care, but has the potential to be used in other situations, such as a patient with uncontrolled nausea and vomiting. This route has the potential to serve many patients.

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Figure 1. How to Create the RMAD. 1. Unwrap foley catheter. 2. Remove plug from urine collection port of the catheter. 3. Insert Luer tip adapter in urine collection port of catheter. 4. Make sure Luer tip adapter fits snugly into catheter. 5. Attach stopcock to Luer tip adapter. 6. Screw stopcock tightly to adapter.

Figure 2. Final RMAD.

Figure 3. Pain levels during RMAD intervention.

Figure 4. Number of patients using specific administration routes before and during intervention.

Poster Abstract

Purpose: The purpose of this project was to improve end-of-life pain management among hospice patients using a rectal medication administration device (RMAD).

Background: Approximately 1.5 to 1.6 million patients received hospice services in 2013 (National Hospice and Palliative Care Organization, 2013), and almost 75% of terminally ill patients experience pain during the dying process (Fink & Gates, 2010). Patients are often unable to tolerate oral pain medications at the end of life. Rectal administration of medication is an appropriate alternative for these patients. The rectal route has several benefits including low cost, consistent and predictable absorption of medications, ease of use, and good symptom management (Davis, Walsh, LeGrand, & Naughton, 2002).

Approach: End-of-life patients unable to tolerate oral pain medications are currently switched to a subcutaneous button route. These patients will be offered the RMAD as an alternative before the subcutaneous button is used. After consent is obtained for use, patients will have a trained licensed nurse place the device and sit bedside to administer the medications until the

patient's status changes. Pain levels will be monitored before and after medication administration using the FLACC scale.

Outcomes: A total of four patients over 3 months, 100% of the patients experienced a decrease in pain scores.

Conclusion: This program showed that a RMAD device is useful for pain medication administration and resulted in a decrease in pain levels in all four participants. Continuation of RMAD use would provide an alternate route of medication administration that is easy to use, efficient, and cost effective when oral medication administration is not appropriate.

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Poster Presentation

Managing End-of-Life Pain using a Rectal Medication Administration Device

Yen Tse, BSN, RN, DNP Student

Mary Jo Clark, PhD, RN

Jacqueline Copeland, DNP, MSN, APRN, FNP

BACKGROUND

- In 2013, approximately 1.5-1.6 million patients received hospice services (NHPCHO, 2013).
- Almost 75% of terminally ill patients experienced pain during the dying process (Fink & Gates, 2010).
- Pain is a common symptom during the end of life and management of pain is a key element in end-of-life care.
- Unrelieved pain can be a source of distress for the patient, the patient's family, and other caregivers.
- End-of-life patients are often unable to tolerate oral medications due to a change in mental status, a nonresponsive or comatose state, difficulty or inability swallowing, the risk of aspiration, and so on.

AIM/PURPOSE

- To improve end-of-life pain management using a rectal medication administration device (RMAD) in hospice patients.

EVIDENCE

- Rectal administration of medications is an appropriate alternative for patients that are unable to tolerate oral medications at the end of life.
- The efficacy and safety of the rectal route is comparable to the oral route (Radbruch et al., 2010).
- Pain relief can be up to six times faster for rectal versus oral routes (Bacon et al., 1995).
- Rectal route includes low cost, consistent and predictable absorption of medications, ease of use, and good symptom management (Davis, Walsh, LeGrand, & Naughton, 2002).
- Complications of the rectal route are usually localized and are uncommon (Davis, Walsh, LeGrand, & Naughton, 2002).
- The rectal route of administration is applicable to almost the entire population of patients and almost any pill can be given rectally (Samala & Davis, 2012).
- The only absolute contraindications for rectal administration are diarrhea, anorectal disease, previous abdominoperineal resection, neutropenia, and thrombocytopenia (Davis, Walsh, LeGrand, & Naughton, 2002).

EVALUATION METHOD

- Compared pain levels before, during, and after therapy using FLACC scores.
- Pain levels measured 30 minutes after pain medications administered via RMAD.

PRACTICE INNOVATION

- Identified the need for an alternative route of pain medication administration before the subcutaneous route.
- Identified the most common types of pain medication used.
- Identified the number of patients placed on crisis care (CC) for pain management.
- Created an alternative route that is currently not being used.
- Wrote a standard of practice for RMAD.
- Educated pilot team of providers and nurses – RMAD champions.
- With the help of the pilot team, identified patients with uncontrolled pain eligible for RMAD.
- Created a standard of practice for pain medication according to hospice administration for RMAD.
- Licensed registered nurses from project site placed RMAD and monitored pain levels during therapy.
- Caregivers were taught to administer medication if they felt comfortable with the process and received training from a RMAD champion.

LIMITATIONS AND LESSONS LEARNED

- Small number of participants
- Limited amount of time for pilot program
- Limited number of RMAD champions for a large patient population – needed to train more champions halfway into the program
- Difficulty explaining device
- Rectal route stigma
- Staff not on RMAD pilot team not educated well enough to provide information to caregivers
- Some staff uncomfortable with device and rectal route
- Introduce RMAD earlier in care instead of at the end when family/caregivers might be overwhelmed

Rectal medication administration device (RMAD)

RESULTS

- Total of 4 patients participated in RMAD pilot
- 100% of patients with decreased pain scores (see graph below)
- Pain medication used: Morphine 15mg, although all emergency kit medications and any previous pain medications were available for use
- No side effects noted
- Patient/provider/caregiver comments
 - Device easy to use and convenient
 - Loose cap on stopcock
 - Rectal route preferred over sublingual by 2/3 caregivers
 - Patient dignity intact; patient could be covered with diaper
 - "It worked really well"
 - BNs preferred rectal route to sublingual route
 - FAMILY immediately accepted rectal route and very please with ease of administration

TABLES and GRAPHS

CONCLUSIONS/IMPLICATIONS FOR CLINICAL PRACTICE

- Continuation of RMAD use would provide an alternative route of medication administration that is easy to use, efficient, and cost effective.
- Increase in patient satisfaction due to decreased cost of system and medications, appropriate pain management, rapid response to pain, and decreased risk of aspiration.
- Ability to use RMAD for other types of medications, patients, and settings.
- Apply for patent for device.
- Alternate route of medication administration before more invasive routes such as subcutaneous or intravenous.
- Small sample size could be a result of lack of education of staff, this provides a teaching and learning opportunity for staff as well as caregivers.

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Stakeholder Presentation

Managing End-of-Life Pain using a Rectal Medication Administration Device

Yen Tse, BSN, RN, DNP Student

Mary Jo Clark, PhD, RN (Faculty Chair)
Jacqueline Copeland, DNP, MSN, APRN, FNP (Clinical Mentor)

BACKGROUND

- Almost 75% of terminally ill patients experience pain during the dying process
- End-of-life patients are often unable to tolerate oral medications due to a change in mental status, a nonresponsive or comatose state, difficulty swallowing or inability to swallow, increased risk for aspiration, etc
- Rectal administration of medications is an appropriate alternative for patients that are unable to tolerate oral medications at the end of life
- Efficacy & safety of the rectal route is comparable to the oral route
- Complications of the rectal route are usually localized & are uncommon
- Rectal route is applicable to almost the entire population of patients & almost any pill can be given rectally

AIM/PURPOSE

To improve end-of-life pain management using a rectal medication administration device (RMAD) in hospice patients.

PRACTICE INNOVATION

- Establish need for alternate route
- Create task force for RMAD
 - RMAD
 - Identify medications to be used
 - Forms
 - Target patient population
 - Standard of practice
- Train RMAD Champions
- Initiate pilot program

RMAD

RESULTS

- Total of 4 patients participated
- 100% of patients had decreased pain scores
- Medications used: emergency kit
- No side effects noted
- Caregiver/provider/staff comments
 - Device easy to use & convenient
 - Loose cap on stopcock
 - Rectal route preferred over sublingual by 2/3 caregivers
 - Patient dignity intact – patient could be covered with diaper
 - “it worked wonderfully” – caregiver
 - RN’s preferred rectal route to sublingual
 - Family immediately accepted rectal route & very pleased with ease of administration

COST COMPARISON: RMAD VS SQB

	RMAD	SQB
KIT	\$2.66	\$17
MEDICATIONS	\$30	\$149.09

LIMITATIONS & LESSONS LEARNED

- Small number of participants
- Limited amount of time for pilot program
- Limited number of RMAD champions for a large patient population – needed to train more champions halfway into the program
- Difficulty explaining device
- Rectal route stigma
- Staff uncomfortable with device & rectal route
- Introduce RMAD earlier in care instead of at the end when family/caregivers might be overwhelmed

CONCLUSIONS/IMPLICATIONS FOR CLINICAL PRACTICE

- RMAD would provide an alternate route of medication administration that is easy to use, efficient, & cost effective
- Increase in patient satisfaction
- Ability to use RMAD for other types of medications, patients, & settings
- Patent for RMAD

**QUESTIONS?
COMMENTS?**