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Referrals to Integrative Medicine in a Tertiary Hospital: Findings from Electronic Health Record Data and Qualitative Interviews

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SUPPLEMENTARY FILES

The study protocol and a methods appendix are provided as supplementary materials. No additional data are available.

ABSTRACT

Objective: To examine patterns of and decision-making processes informing referrals for inpatient access to integrative medicine (IM) services at a large, acute care hospital.

Design: Retrospective electronic health record review and structured qualitative interviews.

Setting: A 630-bed tertiary care hospital with an IM service available to inpatients.

Participants: IM referrals of all inpatients aged ≥18 years between July, 2012 and December, 2014 were identified using the hospital's electronic health record. Fifteen physicians, fifteen nurses, and seven administrators were interviewed in order to better understand roles and perspectives in referring patients for IM services.

Results: In the study hospital, there was a higher frequency of referrals for general IM consults compared with acupuncture consults. Primary sources of referrals were the orthopedic and neuroscience/spine service lines. While the largest number of referrals was made for patients with lengths of stay of three days or fewer, a disproportionate number of referrals for IM was made for patients with long lengths of stay (≥10 days). Physicians and nurses were more likely to refer patients who displayed strong symptoms (e.g., pain, anxiety) and/or did not respond to conventional therapies. IM referrals were predominantly nurse-initiated. A built-in delay in the time from referral initiation to service delivery discouraged referrals of some patients.

Conclusions: Conventional providers refer patients for IM services when these services are available in a tertiary hospital. Referral patterns are influenced by patient characteristics, operational features, and provider perspectives. Nurses play a key role in the referral process. Overcoming cultural and knowledge differences between conventional and complementary medicine providers is likely to be a continuing challenge to providing IM in inpatient settings.

Strengths and limitations of this study

- We accessed two and a half years of electronic health record data to understand the flow of referrals for integrative medicine (IM) in the hospital, a process that has not been reported on previously despite the growing presence of IM services in inpatient settings.
- Qualitative interviews with physicians, nurses, and administrators from across the hospital provided insight into how decisions are made surrounding referrals and help to explain or substantiate some of the patterns seen in the EHR data.
- This is a case study from one hospital with a unique and well-established IM program, and as such, it may have limited generalizability.
- In the course of conducting interviews with physicians and nurses, we learned that mid-level providers (e.g., physician assistants, nurse practitioners) have an important role in placing referrals for IM; however, we did not interview any staff in these roles.

INTRODUCTION

In this paper, we examine referrals for integrative medicine (IM) services in a large tertiary care hospital, where "referrals" denotes orders placed within the hospital's electronic health record for IM therapies. The integration of complementary medicine modalities (e.g., massage, acupuncture, mind-body therapies) with conventional medicine is becoming more common in US healthcare [1-3], but occurs infrequently in inpatient settings, where little is known regarding how patients access these therapies. In outpatient settings, IM usage is largely a function of consumer decisions. However, for hospitalized patients, the process by which patients access IM is more complex, with conventional healthcare providers playing an important role in the decision to refer for these services. Without an effective referral process, integration of complementary medicine with conventional medicine cannot occur in inpatient settings.

Patterns of referrals for IM have been studied previously in health network and primary care settings, but not in a single hospital [4, 5]. Other studies have examined interprofessional dynamics among conventional and complementary medicine providers in IM clinics and hospitals [6, 7], and have described models of IM primary care, with some broad overview of how various referral networks operate [8]. In this study, we examined referrals for IM within a large, acute care hospital.

METHODS

Study Setting

Abbott Northwestern Hospital (ANW), a 630-bed teaching and specialty hospital in Minneapolis, MN, has a well-established IM program available to all inpatients without cost. In this program, physicians, nurses, and other hospital providers order IM as they would any other

service in the hospital (e.g., a CT scan, physical therapy) using an electronic health record (EHR) system. The creation of the IM program in 2003 is described in detail elsewhere [9]. Initially the inpatient IM program was structured around specific clinical areas; however, currently the IM practitioners can serve patients in any area of the hospital as requested. IM services generally are available Monday through Friday, from 9am to 5pm.

The IM team, comprised of 16 credentialed practitioners, currently includes six acupuncturists, eight massage therapists, a holistic nurse, and a music therapist. All practitioners are trained in a core curriculum of IM modalities such as relaxation techniques, acupressure, and aromatherapy, as well as in approaches to delivering IM therapies in a hospital setting. Only licensed acupuncturists are able to provide acupuncture in the hospital.

At the outset of the program, referrals were made through direct calls from hospital clinicians to the IM team's office. Paper orders originating from the EHR then were sent to the IM office and printed out for the team to review and assign. This system subsequently was revised, so that referrals now are placed and viewed using the electronic health record (EHR) (Epic; Verona, WI). Providers on a patient's care team make referrals for IM, and the practitioners triage these referrals, because demand for services often exceeds capacity for service delivery.

Data

In describing the flow of inpatient referrals, we tracked all inpatients age 18 years or older at ANW, who were admitted between July 16, 2012 and December 15, 2014. We excluded patients who were seen as outpatients, in the emergency room, or who were in the hospital solely for observation. EHR data were obtained on all eligible inpatients. All patients whose EHR data

were obtained gave written permission upon or prior to admission to the hospital to use their records for general research purposes. As such, the retrospective data collection portion of this study was approved by the Quorum Institutional Review Board with a waiver of informed consent.

We collected interview data to understand the influence on referrals of physicians', nurses', and administrators' own attitudes and beliefs towards integrative care and their professional experience ordering IM for their patients at ANW. We interviewed physicians, nurses, and administrators across five clinical service lines at ANW: oncology, maternity care ("Mother Baby"), cardiovascular, neuroscience and spine, orthopedics (administrators and physicians only), and the hospitalist service (administrators and physicians only). Physicians and nurses were divided, based on referral records, into "high-referring" and "low-referring" designations before recruitment began, in order to ensure that providers in the study represented both frequent and occasional referrers for IM services.

Our goal was to recruit two high-referring and two low-referring physicians and nurses in each service line, resulting in a total of 24 physicians and 16 nurses. There were no nurses associated with the hospitalist group. Orthopedic nurses were not recruited for the study because of the presence of standing orders on the joint replacement area of the orthopedic unit, a topic discussed in the Results section of this paper. The lists of high and low referring physicians and nurses were placed in random order before recruitment began. Additionally, we planned to recruit physician administrators for each of the six service lines, in order to obtain their insights into how IM is perceived, used, and supported in each service line. All administrators were practicing currently as physicians in their service lines, in addition to their administrative roles.

Prospective participants received emailed or mailed invitations from the study PI (JD) and follow-up contacts by the study coordinator (KG) if they did not respond to the initial invitation.

Structured interview protocols were developed by the study team and approved by the institutional review board. All protocols addressed professional background and personal experience with IM. Administrators were asked to assess the knowledge and support of IM services by providers in their service lines, as well as their own personal and professional perspectives on IM. Physicians and nurses were asked about their use of the IM referral system and interactions with patients and patients' family members regarding IM services. In total, 37 hospital staff and affiliates were recruited (See Table 1).

Table 1. Occupations and clinical service lines of qualitative interview participants

	Clinical Service Line						Total
Provider type	Oncology	Cardiology	Mother Baby	Neuroscience and Spine	Orthopedics	Hospitalist Service	
Administrator	1	1	1	2	1	1	7
Physician	4	2	3	2	2	2	15
Nurse	4	3	4	4	N/A	N/A	15

Interviews were audio recorded using a handheld digital recorder and then were transcribed by an independent transcriptionist. Transcripts were organized and coded using Atlas.ti version 7.5.4 software. Data saturation, the point at which no new codes emerged during analysis, was reached in all groups. Methods are described further in the Appendix.

RESULTS

Referral Flow

During the study period, there were approximately 14,000 referrals for IM services at ANW hospital, out of approximately 84,000 unique admissions. (Tables 2 and 3). The bulk of the referrals were for general IM consults (Table 2). Patients referred for IM services were more

likely to be middle aged and female. Referrals were tracked across several different service lines. A disproportionate number of referrals came from the orthopedic, oncology, and neuroscience/spine service lines (Table 3), with the greatest actual number of referrals also coming from orthopedics and neuroscience/spine (Table 4). In the case of orthopedics, this reflects the presence of standing orders for IM referrals in the hospital's joint replacement program, as discussed in the interview findings. A quality improvement project with spine patients that took place during the study period may partially account for the high number of referrals in that service line. Referrals from all service lines were fairly consistent across the two and a half years that referrals were tracked (Table 4). Patients with lengths of stay of three or fewer days constituted the bulk of first referrals (defined as the first referral placed for IM during a hospital admission), but a relatively small portion of these patients were referred. In contrast, a larger proportion of long-stay patients were referred for IM services, while the absolute number of these patient referrals was smaller. (Table 3). The median time from first referral until contact with an IM practitioner was approximately 23 hours, ranging from 21.5 hours for neuroscience/spine referrals to 48 hours for rehabilitation referrals, with response times for most service lines falling between 22 and 25 hours (Table 5). Longer median patient stays generally were associated with longer referral to response times across service lines.

Table 2. Integrative medicine referrals over time

	Total (N=13,991)	Acupuncture (N=2,550)	General IM Consult (N=11,441)
2012	**2,782 (19.9%)**	**702 (27.5%)**	**2,080 (18.2%)**
Jul-Dec	*2,782 (19.9%)*	*702 (27.5%)*	*2,080 (18.2%)*
2013	**5,457 (39.0%)**	**1,289 (50.5%)**	**4,168 (36.4%)**
Jan-Jun	*2,653 (19.0%)*	*652 (25.6%)*	*2,001 (17.5%)*
Jul-Dec	*2,804 (20.0%)*	*637 (25.0%)*	*2,167 (18.9%)*
2014	**5,752 (41.1%)**	**559 (21.9%)**	**5,193 (45.4%)**
Jan-Jun	*2,919 (20.9%)*	*274 (10.7%)*	*2,645 (23.1%)*
Jul-Dec	*2,833 (20.2%)*	*285 (11.2%)*	*2,548 (22.3%)*

Table 3. Demographics of inpatients at Abbott Northwestern Hospital
July 16, 2012 – December 15, 2014

	Total (N=83,677)	No IM Referral (N=69,686)	Referral for IM Services (N=13,991)	p-value
Age				<0.0001
Age<=39	20,899 (25.0%)	18,449 (26.5%)	2,450 (17.5%)	
39<Age<=59	21,481 (25.7%)	17,053 (24.5%)	4,428 (31.6%)	
59<Age<=79	28,077 (33.6%)	22,371 (32.1%)	5,706 (40.8%)	
Age>79	13,220 (15.8%)	11,813 (17.0%)	1,407 (10.1%)	
Gender				<0.0001
Female	49,994 (59.7%)	40,766 (58.5%)	9,228 (66.0%)	
Male	33,683 (40.3%)	28,920 (41.5%)	4,763 (34.0%)	
Primary Race				<0.0001
American Indian or Alaska Native	1,567 (1.9%)	1,349 (1.9%)	218 (1.6%)	
Asian	1,619 (1.9%)	1,452 (2.1%)	167 (1.2%)	
Black or African American	7,991 (9.5%)	7,143 (10.3%)	848 (6.1%)	
Native Hawaiian or Other Pacific Islander	151 (0.2%)	134 (0.2%)	17 (0.1%)	
Unknown	1,158 (1.4%)	1,027 (1.5%)	131 (0.9%)	
White	71,191 (85.1%)	58,581 (84.1%)	12,610 (90.1%)	
Ethnicity				<0.0001
Patient Declined	790 (0.9%)	687 (1.0%)	103 (0.7%)	
Caucasian, Not Hispanic/Not Latino	81,226 (97.1%)	67,532 (96.9%)	13,694 (97.9%)	
Hispanic or Latino	1,661 (2.0%)	1,467 (2.1%)	194 (1.4%)	
Marital Status				<0.0001
Life Partner, Married, Significant Other	45,604 (54.5%)	37,686 (54.1%)	7,918 (56.6%)	
Separated, Divorced	7,587 (9.1%)	6,062 (8.7%)	1,525 (10.9%)	
Widowed	9,562 (11.4%)	8,230 (11.8%)	1,332 (9.5%)	
Single	20,812 (24.9%)	17,608 (25.3%)	3,204 (22.9%)	
Unknown, Other	112 (0.1%)	100 (0.1%)	12 (0.1%)	
Length of Stay				<0.0001
1=<LOS<=3	50,782 (60.7%)	44,981 (64.5%)	5,801 (41.5%)	
4<=LOS<=6	18,794 (22.5%)	15,236 (21.9%)	3,558 (25.4%)	
7<=LOS<=9	6,635 (7.9%)	4,945 (7.1%)	1,690 (12.1%)	
LOS>=10	7,466 (8.9%)	4,524 (6.5%)	2,942 (21.0%)	
Clinical Service Line				<0.0001
All Other	25,599 (30.6%)	22,501 (32.3%)	3,098 (22.1%)	
Cardiovascular	13,703 (16.4%)	12,271 (17.6%)	1,432 (10.2%)	
Mental Health	6,272 (7.5%)	5,799 (8.3%)	473 (3.4%)	
Mother & Baby	12,503 (14.9%)	11,414 (16.4%)	1,089 (7.8%)	
Neuroscience & Spine	12,249 (14.6%)	9,624 (13.8%)	2,625 (18.8%)	
Oncology	5,813 (6.9%)	4,533 (6.5%)	1,280 (9.1%)	
Orthopedic	6,151 (7.4%)	2,839 (4.1%)	3,312 (23.7%)	
Rehabilitation	1,387 (1.7%)	705 (1.0%)	682 (4.9%)	

Table 4. Frequency of integrative medicine referrals by clinical population

	All Other (N=3,098)	Cardiovascular (N=1,432)	Mental Health (N=473)	Mother & Baby (N=1,089)	Neuroscience & Spine (N=2,625)	Oncology (N=1,280)	Orthopedic (N=3,312)	Rehabilitation (N=682)	Total (N=13,991)
2012	**592 (19.1%)**	**317 (22.1%)**	**102 (21.6%)**	**234 (21.5%)**	**483 (18.4%)**	**247 (19.3%)**	**642 (19.4%)**	**165 (24.2%)**	**2,782 (19.9%)**
Jul-Dec	*592 (19.1%)*	*317 (22.1%)*	*102 (21.6%)*	*234 (21.5%)*	*483 (18.4%)*	*247 (19.3%)*	*642 (19.4%)*	*165 (24.2%)*	*2,782 (19.9%)*
2013	**1,297 (41.9%)**	**553 (38.6%)**	**156 (33.0%)**	**444 (40.8%)**	**904 (34.4%)**	**534 (41.7%)**	**1307 (39.5%)**	**262 (38.4%)**	**5,457 (39.0%)**
Jan-Jun	*638 (20.6%)*	*274 (19.1%)*	*83 (17.5%)*	*237 (21.8%)*	*424 (16.2%)*	*232 (18.1%)*	*618 (18.7%)*	*147 (21.6%)*	*2,653 (19.0%)*
Jul-Dec	*659 (21.3%)*	*279 (19.5%)*	*73 (15.4%)*	*207 (19.0%)*	*480 (18.3%)*	*302 (23.6%)*	*689 (20.8%)*	*115 (16.9%)*	*2,804 (20.0%)*
2014	**1,209 (39.0%)**	**562 (39.2%)**	**215 (45.5%)**	**411 (37.7%)**	**1,238 (47.2%)**	**499 (39.0%)**	**1,363 (41.2%)**	**255 (37.4%)**	**5,752 (41.1%)**
Jan-Jun	*598 (19.3%)*	*280 (19.6%)*	*90 (19.0%)*	*235 (21.6%)*	*648 (24.7%)*	*271 (21.2%)*	*676 (20.4%)*	*121 (17.7%)*	*2,919 (20.9%)*
Jul-Dec	*611 (19.7%)*	*282 (19.7%)*	*125 (26.4%)*	*176 (16.2%)*	*590 (22.5%)*	*228 (17.8%)*	*687 (20.7%)*	*134 (19.6%)*	*2,833 (20.2%)*

Table 5. Median time from first referral until contact with an IM practitioner

	All Other (N=3098)	Cardiovascular (N=1432)	Mental Health (N=473)	Mother & Baby (N=1089)	Neuroscience & Spine (N=2625)	Oncology (N=1280)	Orthopedic (N=3312)	Rehabilitation (N=682)	Total (N=13991)
Length of stay									
Median overnights (Q1, Q3)	6 (4,11)	7 (4,13)	8 (4,14)	4 (3,9)	4 (3,6)	4 (2,8)	3 (3,3)	14 (8,23)	4 (3,8)
Time until first referral									
Median hours : minutes (Q1, Q3)	41:58 (17:47, 96:50)	55:30 (25:57, 121:00)	27:12 (3:27, 78:50)	26:12 (13:45, 51:03)	11:50 (7:27, 57:37)	22:40 (7:42, 57:37)	7:27 (6:01, 8:58)	3:31 (0:29, 67:33)	17:55 (7:01, 53:52)
Time from first referral until fulfillment	**2,925**	**1363**	**434**	**1,024**	**2,481**	**1,230**	**3,074**	**659**	**13,190**

Table 5. Median time from first referral until contact with an IM practitioner

	All Other (N=3098)	Cardiovascular (N=1432)	Mental Health (N=473)	Mother & Baby (N=1089)	Neuroscience & Spine (N=2625)	Oncology (N=1280)	Orthopedic (N=3312)	Rehabilitation (N=682)	Total (N=13991)
Median hours : minutes (Q1, Q3)	23:08 (17:16, 29:27)	24:36 (19:17, 46:00)	30:37 (20:27, 73:38)	22:26 (7:09, 28:38)	21:50 (16:43, 29:51)	22:56 (10:27, 28:25)	22:37 (19:47, 25:18)	48:47 (38:05, 91:27)	23:11 (18:14, 29:50)
Time until first acupuncture referral (N)	**245**	**47**	**233**	**33**	**253**	**73**	**1,597**	**69**	**2550**
Median hours : minutes (Q1, Q3)	15:18 (3:30, 51:27)	26:50 (3:52, 91:08)	47:18 (22:19, 102:00)	20:18 (8:33, 39:03)	9:08 (6:16, 24:55)	4:49 (0:19, 25:48)	7:17 (5:55, 8:36)	48:31 (1:31, 90:55)	7:49 (5:52, 11:57)
Time until first general IM consult referral (N)	**2,853**	**1,385**	**240**	**1,056**	**2,372**	**1,207**	**1,715**	**613**	**11441**
Median hours : minutes (Q1, Q3)	44:31 (19:17, 100:00)	57:08 (26:27, 121:00)	6:24 (1:12, 54:30)	26:21 (14:00, 51:33)	12:25 (7:36, 35:15)	23:24 (9:38, 62:07)	7:37 (6:07, 9:26)	2:38 (0:26, 55:23)	23:05 (7:41, 64:53)

Interview Findings

We organized themes that emerged from the interviews into three general categories: criteria used by clinicians to make referrals; factors influencing the referral process; and concerns and challenges related to having an IM program available in the hospital.

Criteria for IM Referrals

In response to a broadly stated question about what circumstances or characteristics would lead someone to refer a patient to IM, respondents mentioned the following four criteria: patients' actual or expected length of stay, symptoms, using IM as a "last resort," and patients specifically requesting IM.

Length of stay and chronic conditions. Nurses, physicians, and administrators frequently mentioned that patients who were in the hospital longer (or were expected to be in the hospital longer) than average were common candidates for receiving an IM referral. Typically, these were individuals with chronic conditions. One physician suggested that "our chronic, long-term players" would be a promising group to receive more IM in the hospital than they do at present. An administrator and several physicians described IM as not being relevant for young, otherwise healthy surgical patients who recover quickly from surgery and have short lengths of stay. Conversely, this administrator said, "there are patients with chronic conditions who've had chronic pain for a long time, and I think those are the patients that I would look to helping [with IM], and where you could reduce pain medication." Similarly, Mother Baby nurses and physicians reinforced the idea that longer term—typically antenatal—patients in their service

line were more commonly referred for IM, versus labor and delivery patients whose hospital stays were too short for IM to be helpful or feasible.

> *I would be much more inclined to use it for the people who are chronically hospitalized. Or, if somebody's had a very complicated course, and we know – either we're pretty sure they're going to be here much longer than a routine person, or it just turns out they have been here longer and that's part of the problem, you know, they're having trouble dealing with that discouragement and putting up with that. Yeah, but it's almost always chronic, chronic people that I would call for. (Physician)*

A large proportion of longer-stay patients in the Mother Baby service line was confirmed by the referral data, where among Mother Baby patients with lengths of stay longer than ten days, 82% were referred for IM. In contrast, among Mother Baby patients with lengths of stay from one to three days, only 4% were referred for IM. Providers who were hesitant to refer shorter length of stay patients expressed concern that services are not typically available until the day after the referral is made, a topic discussed further below (under "Factors Influencing the Referral Process"). It is also is possible that chronically ill patients with longer stays may be referred commonly for IM simply because providers work with these patients longer and have more time to consider what combination of conventional and IM approaches may help them.

Importance of patient symptoms. IM referrals were cited by all physicians, nurses, and administrators as being driven by patient symptoms, primarily pain, anxiety, and stress or difficulty coping. Nausea was mentioned as well, particularly in the case of oncology patients. Often, providers viewed IM therapies as a method to reduce the use of medications, especially those that may have adverse side effects. A patient's health condition or reason for

hospitalization was not the principal driver of the decision to make a referral; rather, the common element was almost always related to symptoms.

A lot of times…the people who have the most expressed amount of pain [are referred]. And especially the people who are having a difficult time with trying to cope with the hospitalization and the difficulties that come with it. (Nurse)

Use as last resort. Frequently, physicians, nurses, and administrators saw IM services as an option to use in caring for patients when the providers had exhausted all other strategies. There were references to "difficult patients" who did not seem to respond to any other treatment, or whose anxiety was very persistent. Participants felt that it "cannot hurt" to try IM, and at best it might provide some sense of relief, comfort, or improvement for challenging patients.

It's for people that don't have heart disease but are desperate for some kind of way to feel better. And so, I've ruled everything out that's deadly, and then it's like, "oh, there's not really [something] else, I can't really do anything else, try this." (Physician)

I just see that is something else they will benefit from. I'm like, "Have you tried this? OK, we have this and…you can also benefit from that," especially if we've tried everything else and they seem not to be comfortable. (Nurse)

Respondents generally did not describe criteria for referrals as being "either-or"; rather, their reasons for considering patients as good IM candidates often were influenced by nuanced combinations of criteria:

I deal with very sick patients, with essentially end-stage heart failure. A frequent accompaniment of the comorbidities is anxiety and pain. And also they tend to be elderly,

and they've had arthritic conditions. And these patients are usually already heavily medicated on polypharmacy. So any other therapeutic interventions I can make which don't involve pills, and which may actually be more effective, I would rather go down that road. (Physician)

Patient request. Some physicians and nurses mentioned ordering IM when patients requested it. This view was most frequently mentioned in response to an interview question about whether or not patients ever initiated a request for services, although a few participants raised it without being prompted. According to participants, occasionally patients and/or family members do directly request IM services. Typically, these patients have experienced IM services previously (either at ANW or elsewhere in outpatient settings), or friends or family members have recommended the services.

Some of them…they ask for it. They start asking for, "Oh, can I get integrative medicine to come see me?" Or, "I need acupuncture." Or they want massage. And most of them will ask for it already, then I put the referral in…I think the ones that ask for it…they've been to alternative medicine or had integrative medicine before. (Nurse)

Factors Influencing the Referral Process

Beyond the criteria used to make decisions about who is referred for or receives services, a number of factors influence how and why providers make referrals, e.g., conditions in the workflow that are perceived as facilitating or limiting engagement with or usefulness of IM. Three primary factors emerged in the interviews: the presence of standing orders on a unit (where all or nearly all patients receive an IM referral), the role of nurses and/or mid-level

practitioners in driving most referrals (mid-level practitioners, e.g., nurse practitioners and physician assistants, were not interviewed in this study), and the overall operational characteristics of the referral process.

Standing orders. On several inpatient units in the hospital, standing orders or quality improvement projects existed for specific medical conditions or procedures (e.g., hip/knee replacements, spinal fusion). One oncologist also described having IM referrals ordered for all her patients. This approach increased the number of referrals for IM but then left the decision to accept IM services with the patient (who typically did not know about the referral) when the IM practitioner arrived to provide services. Physician attitudes on standing orders ranged from enthusiastically supportive to somewhat detached (a version of the "it can't hurt" approach). A repeated idea related to standing orders is that patients always have the option to decline IM services.

> *[W]e found it was so beneficial for the ones that were electing to do it within the first year that we felt we should standardize it for everybody, and then the patients still have the option to opt out and surgeons still have the option to opt out, but most of the surgeons don't. (Administrator)*

> *So they're on our order sets as augments for breast cancer and our colon cancers. And so we, I order them on everybody. But whether or not the patients want to do it, how much they do, I don't really know…So the consult gets ordered, and then they will come and evaluate the patient. Then the patient ultimately gets to decide what they want or don't want. (Physician)*

Nursing-driven service. Physicians and administrators consistently described the IM referral process as being driven primarily by nurses (except in the case of standing orders). Nurses had the authority to refer for a general IM consult, although a physician was required to authorize an acupuncture order. In addition, the nurse-driven nature of the IM referral process was attributed both by nurses and physicians to the fact that nurses spend the most time interacting with patients and thus have a better sense of whether patients may be receptive to or helped by IM. Many physicians also emphasized the central role of physician assistants and nurse practitioners in determining patients who should receive IM and in placing IM referrals, due to the greater amount of time these mid-level providers spent interacting with patients.

When asked whether there were ever differences of opinion between nurses and physicians on whether a patient should receive IM, nurses consistently said that physicians were supportive of the nurses' judgment regarding whether IM could benefit the patient. The situations identified where a physician might not support an IM referral related to patients with conditions (e.g., bleeding disorders, sutures) that might preclude the use of a modality like acupuncture or massage.

> *Well, I think, I mean the nurses are better about thinking about this, and I think having them able. I don't know. I think having them ask for integrative medicine consults has probably accomplished more than depending on the doctors to think about it themselves…We're just sort of trying to get through the day, and they're there with the patient all day, and so they're more likely to think about it. (Physician)*

> *The nurses, the RNs, are usually the ones who identify patients who may benefit and they make a suggestion. I could tell you, neither myself or, for that matter, probably any*

physician within my group would say, would turn down an RN request for integrative medicine . . . So it's usually an RN-driven, an RN-driven consult for the most, a lot of times. (Administrator)

A physician who stated that she actually was more likely than her nurses to place an IM referral for her patients emphasized that she and the nurses generally agreed about whether a patient should receive IM, and that she would support placing a referral on a nurse's suggestion.

Issues regarding how the referral process functioned. Most nurses and physicians remarked that the referral process generally worked well for them, with some mentioning that it was quick and easy to use, and others commenting positively on their interactions with the IM practitioners who regularly visited their units. Caveats such as wishing for IM weekend services ("pain doesn't stop on the weekends," one nurse said) or more IM practitioner availability were generally qualified by comments that the system works well given its size and scope.

The primary factor found to negatively influence referrals, from the perspective of all groups interviewed, was the timing of IM service delivery relative to when a referral was made. Typically, referrals placed were not seen the same day, reducing the usefulness of services in acute episodes of care. Referring providers expected a lag time of a day or more between the referral and service delivery, which may be one reason that referrals were placed for a relatively high percentage of patients who had longer lengths of stay. One of the physician administrators said, "I think there's a lot of people that I would otherwise use it for if it was more readily available quickly." Other providers felt the delay was not a problem both because of the non-critical nature of using IM and due to the fact that chronic, longer-term patients were generally—in their experiences—the best fits for receiving IM anyway.

IM services are only offered Monday through Friday during the day shift, contributing to the gap between referral and service delivery as well as occasionally prompting providers not to place referrals on Fridays (due to the lack of IM services on weekends). Several participants discussed concerns about shorter stay patients potentially wanting to stay in the hospital until they had received their IM session. This issue of patient expectation or desire to receive the service occasionally influenced provider decisions regarding referring for IM.

> *I think sometimes [patients] wish it was more often. Or like, you know, when you talk about the referral, sometimes they don't get it till the next day or even the following day. So I think sometimes they would probably want it, like, more quickly, right after it's put in…If I have patients going home the next day, then I won't put it in. Because I know that it would probably be useless. (Nurse)*

Generally, however, referring providers found the service to be useful despite its limitations related to timing.

Clinician Concerns and Challenges Related to the Presence of IM in the Hospital

Although clinicians generally felt that the IM service was beneficial for their patients, they did raise concerns, and made suggestions, related to the presence of the IM service in general. These included a desire for more information about IM and the recognition of inherent differences between the pace and philosophy of complementary healing approaches and conventional western medicine.

Desire for better education and information about IM. A commonly raised concern, on the part of physicians more than nurses, was a desire for more information and education about

IM offerings and evidence of their effectiveness. For some participants, this reflected a lack of familiarity with the IM modalities actually available to patients. This was true even among physicians who had personal experience using IM modalities in outpatient settings. Some felt that they could better discuss IM as a possibility with patients if they were more familiar with the "menu" of services at the hospital. Others wanted more information regarding which modalities might be most useful for specific patient symptoms. One physician, in discussing a wish to see more collaboration between IM providers and his patients' care teams, said, "maybe I'm sending inappropriate referrals…Is this the right patient to refer for this consult, and is this the right thing to ask for?" This comment was consistent with a sentiment expressed by other physicians that they were not always confident in how best to use the IM service, and that they would appreciate more clarity from the IM team in this regard.

Nurses, on the other hand, generally had more familiarity with the IM program offerings. While neither nurses nor physicians said they had received formal training from the IM program, many nurses had completed education modules at some point in their careers on nurse-delivered aromatherapy or other nurse-delivered services. They also were more likely to see and interact with IM practitioners. Thus, they were more familiar with the IM program, and they expressed less interest than physicians in receiving additional information on the program. This finding fits into the theme, described previously, of a high degree of nurse involvement with the referral process.

Another concern related to information/education focused on the evidence base for IM. Physicians and administrators, in particular, expressed a desire for more information about the efficacy and safety of IM modalities, both from IM research conducted at ANW, and in the medical literature at-large.

Well, I think it's a good thing, but again, I don't know efficacious it is. Meaning that I think there's literature to support it…and I think that it draws some patients. But again, I don't know how we're evaluating it. Is there something that should be more cookbook, that patients that have bowel surgery should have lavender post-op to help with their nausea? It doesn't seem like it's very well-prescribed. (Physician)

Balancing two different approaches to medicine. Finally, clinicians often noted that supporting and engaging with IM in the hospital can be simultaneously challenging and valuable, because it represents the meeting of two different paradigms: conventional/western medicine and complementary and alternative medicine. Some clinicians pointed to this as a motivating factor for placing a referral; in particular, more experienced nurses commented on how they previously had the time to provide some of the comfort now given by IM providers, but that their pace of work no longer allowed for that level of care. Hence, they viewed IM as filling an important role in the rushed modern medicine model. One physician described this role as "develop[ing] a little stillness and peace in the hospital." Several physicians perceived the IM service to be underutilized.

A physician administrator commented on the two different paces of IM and conventional medicine:

[W]e get very busy, so, we rush through and we, we're focusing on sort of absolute vital parameters regarding the patient. We're focusing on getting the patient out of the hospital quickly, and I think that a lot of the increased pressure to move patients out quickly is perhaps taking away a little bit of the, you know, integrative medicine is a, I think it's a really good system, and I think for chronic pain patients, it can be extremely

helpful. But we have to fit it in, a kind of a slower-paced concept, into this fast-paced, get your physical therapy, get your x-ray, get walking, and get out of here. And patients need a little bit more than that. Sometimes there are times when patients need to be a little quieter, if their bodies need time to heal…And so, and I think this, this pressure we're feeling to move patients out of the hospital quickly is detracting a little bit from the opportunities. And I think that it would be worthwhile for us to explore the use of integrative medicine, not only while they're in the hospital, but to teach them techniques that they can continue after they leave. (Administrator)

Connecting Inpatient and Outpatient Settings. Lastly, several physicians were concerned that, while IM is especially suitable for long-term treatment of chronic issues and for recovery after discharge, there currently is not an obvious mechanism for linking patients to continued IM services once they are discharged. This applied both to physicians who used the service for their patients regularly and recognized its limits, as well as to those who referred infrequently but recognized the potential of IM to help patients under more ideal circumstances.

And so it's about how you describe it in a way that gets insurance to cover it and things like that. That's more the obstacle, will they cover this or not. While you're here in the hospital, it's fine. But my patients, I see longitudinally over years and years and years…And so, after the acute phase, there's this other phase where it [IM service] is particularly necessary and ***that's*** *where it becomes a resistance, is that you can offer something in the hospital, but then, because of financial issues, the patients can't keep it up, so if that strategy is your strategy, and then you can't use it, it becomes a little hard*

to, to offer it in one place and then not be able to sustain it.(Physician) (emphasis speaker's)

DISCUSSION

As IM programs become more prevalent in hospitals, it will be important to draw on the successes and challenges of existing models such as the ANW IM service. We found that the IM referral process is very rooted in nursing, suggesting the importance of ongoing interaction between IM providers and hospital nurses for the success of inpatient IM programs. Given the concern articulated by physicians about a need for more thorough education regarding the merits of and best uses for IM, information on research findings related to IM should be made available to interested physicians, as well as information on program offerings and recommendations regarding which patients may benefit most from receiving IM. The finding that projected or actual length of stay has a bearing on whether a patient is referred for IM may not be useful for a facility with a greater ratio of IM practitioners to patients, but it is likely to be a common challenge in programs similar to this one. That the provision of integrative therapies is distinct in nature from other hospital care, and that it is optional, was cited as a motivating factor for why providers might place an order: to improve the patient's inpatient experience in ways that might not otherwise be met by conventional medical approaches.

As in all case studies, an inherent limitation of this study is that our findings may not be generalizable to all inpatient settings where similar programs now exist or are being considered. However, the structure and operations of ANW are fairly typical of a large, tertiary care hospital. Another potential limitation is that the 30 physicians and nurses who agreed to be interviewed (30% of those invited) may have been different than those who declined or did not respond,

despite the use of randomized lists of prospective participants in recruitment. The designation of "high" and "low" referring providers, which was intended to capture a representative range of engagement with the IM services, was not as meaningful as expected. Some high-referring physicians, according to clinical records, were in units with standing orders for IM; therefore they did not engage in regular decision-making regarding IM referrals. Alternately, some low-referring providers did not place many referrals directly, but regularly supported staff who did. In general, however, high-referring providers had more regular contact and engagement with IM services than low-referring providers. Uncovering the exceptions to this pattern revealed a nuance in the referral system. Finally, several nurses and physicians mentioned the important role of mid-level providers such as physician assistants and nurse practitioners in referring for IM, but we did not include any of these providers in our recruitment for interviews. However, the referral role of these mid-level providers was itself a useful finding of the study that could inform future research into the flow of referrals in inpatient settings. Mid-level providers play an increasingly important role in hospitals, as use of these providers is incentivized and supported at policy and administrative levels. Further research on referrals for IM services within hospitals should include mid-level providers in the study design.

In addition to study limitations, the current research highlighted operational elements of the IM program at ANW that merit review. Primarily, the delay between referral and service delivery emerged as a common reason why providers might not consider using the service with some patients. Although providers generally accepted this delay as part of how the program functions, same-day delivery of IM services potentially could allow the system to reach more patients who currently do not have the opportunity to receive IM.

Our study addresses several gaps in the literature with regard to the provision of IM in the hospital, as referrals within an inpatient setting have not been studied previously. IM referral patterns have been explored within a health network [4] and in a primary care setting [5], but not within a single inpatient facility offering IM as ANW does. Research on healthcare providers' perspectives on IM has been used primarily to examine provider awareness of IM and opinions on its general usefulness or perceived legitimacy in an ambulatory setting [10-12]. Qualitative interviews by Grant and Bensoussan [13], which included a respondent from the ANW IM program, focused on the "process of care" in integrative healthcare programs at a broad level, addressing topics such as organizational structure and the use of practice guidelines; however, all but one other of the nine programs described in that study were outpatient settings. One interview-based study of physician and IM practitioner views on a short term, integrative collaboration for treating hospitalized multiple sclerosis patients reflected a much more specific and limited setting than our hospital-wide study; it also revealed themes related to the importance and challenges of collaboration and organizational support in integrating conventional and alternative therapeutic approaches [14].

To date, studies about IM that have included nurse perspectives have focused primarily on assessing the knowledge and attitudes of nurses toward complementary therapies [11, 15-19]. Generally, attitudes are positive, although reported knowledge about complementary therapies is highly variable from study to study. A qualitative study that included nurses reported interviewee attitudes toward integration of conventional and complementary medical approaches and found nurses to be supportive and interested [20]. One study conducted among oncology patients in inpatient and outpatient settings found that patients perceived nurses to be important figures in decision-making processes around IM use [21], but nurses were not interviewed.

There is evidence in the US of poor to moderate physician-patient communication about outside complementary medicine use [22-27] or resistance by physicians to their patients using complementary or alternative therapies [28, 29]. Generally, however, this resistance or disengagement has been reported with regard to patient use of these therapies outside the context of conventional medical care, in other words, in situations where use of therapies is driven by patients as health care consumers. Because IM programs embedded in hospitals are relatively new, evidence of provider attitudes about complementary therapies in the inpatient setting has not been addressed in the literature prior to this study. Furthermore, resistance by conventional providers to integrative therapies for patients may be diminishing. Several surveys have found supportive attitudes by physicians for the use of complementary and integrative therapies [10, 30, 31]. A recent qualitative study with physicians, nurses, and administrators at a large veterans' medical center cited respondents as recognizing the role of complementary medicine in making care more patient-centered [20]. And physicians at an academic medical center where complementary therapies were offered showed a marked increase in their willingness to refer patients to those therapies over the course of an eight-year period [32]. We generally found acceptance among providers interviewed for this study; even those who referred for IM infrequently tended to feel the service was beneficial with regard to patient satisfaction and expressed the view that it "cannot hurt."

In addition to seeking perspectives from mid-level providers, as suggested above, future research should address patient perspectives, as patients (and/or their family members) also play a role in the referral process. Beyond qualitative research, some investigation into how a system might respond to the concerns or suggestions articulated here by nurses, physicians, and administrators may be warranted. For example, a number of physicians expressed a desire to see

more of a transitional process established for patients between IM services received in the hospital and outpatient services after discharge, implying a recognition of the potential long-term value of integrative care. As other hospital IM programs develop, questions should continue to be asked about referral processes, use of resources, and cultural integration in order to design better programs and streamline existing ones. Same-day referrals or approaches based around clinical service lines rather than hospital-wide programs would be worth consideration.

CONCLUSIONS

Conventional providers refer patients for IM services when these services are available in a tertiary hospital. Referrals are driven primarily by symptoms such as pain and anxiety, and patients with longer hospital stays are viewed as appropriate and feasible referral candidates. Nurses are a major source of IM referrals and have a great deal of support from physicians in their decision-making processes surrounding IM. Overcoming cultural and knowledge differences between providers of conventional versus complementary medicine is likely to be a continuing challenge to the provision of integrative medicine in inpatient settings.

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COMPETING INTERESTS

We have read and understood BMJ policy on declaration of interests and declare that we have no competing interests.

AUTHOR CONTRIBUTIONS

KHG collected, coded, and analyzed qualitative data, interpreted findings, and drafted the manuscript. KCN coded and analyzed qualitative data, interpreted findings, and contributed to drafting. RLR managed and analyzed electronic health record data, interpreted findings, and contributed to drafting. JC conceptualized the study, collected data, and contributed to drafting. JAD conceptualized the study and contributed to drafting. All authors gave final approval of the current version.

DATA SHARING

The study protocol and a methods appendix are provided as supplementary materials. No additional data are available.

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Referrals to Integrative Medicine in a Tertiary Hospital: Methods Appendix

Selection of Interview Participants

We set out to recruit 46 participants, comprised of physicians, nurses, and administrators at Abbott Northwestern Hospital (ANW). Our goal was to interview individuals representing various clinical service lines in the hospital: Cardiovascular, Mother Baby (maternity care), Neuroscience and Spine, Orthopedics, and Oncology, as well as physicians and an administrator in the Hospitalist Service. Physician and nurse participants had to have made at least one patient referral for integrative medicine services in the year before we created our list of prospective participants. Additionally, for nurses and physicians, we were interested in speaking with both "high referring" and "low referring" providers, that is, those who had a recent history of placing either many or very few orders for integrative medicine. The prospective study sample was as follows:

- 24 physicians: two high and two low IM referring physicians employed by or affiliated with Abbott Northwestern Hospital from the Cardiovascular, Mother Baby, Neuroscience and Spine, Orthopedics, and Oncology clinical service lines and the Abbott Northwestern Hospitalist Service.
- 16 nurses: two high and two low IM referring nurses from the Abbott Northwestern Hospital Cardiovascular, Mother Baby, Neuroscience and Spine, and Oncology clinical service lines. (It was decided the orthopedics nurses would not be included because their department generally relies on standing orders for IM, a process in which they do not have a role in decision making or placing orders.)
- 6 administrators (i.e., the acting physician lead) of the Cardiovascular, Mother Baby, Neuroscience and Spine, Orthopedics, and Oncology clinical service lines and the Hospitalist service.

Administrators were identified based on the study PI's (JD) knowledge of who the acting physician leads were for each service line. To identify prospective physician and nurse participants based on referrals, data were obtained from the hospital's Electronic Data Warehouse (EDW). To minimize the effects of employment length on referral rate, we only counted referrals from nurses and physicians who had continuously worked at Abbott Northwestern Hospital and had had referral privileges for the previous year. Nurses were required to be FTE>.6 at the time of the study to be considered eligible. Physician and nurse staff rosters were used to identify years/dates of employment and FTE. Using the 'Orders' file from the EHR, three order codes were retrieved: 207179-Acupuncture Evaluation and Treatment, 207180-IP Consult to Integrative Medicine, and 207853-Nursing Consult to Integrative Medicine. "Authorized provider" and "order writer" names were extracted from the file. A list of eligible nurses was generated by comparing a roster of nurses with a list of orders placed for IM services. The same process was used for physicians. Physicians and nurses were categorized according to specialty/location: hospitalist (physicians only) or clinical service line (Oncology,

Cardiovascular, Mother Baby, Orthopedics [physicians only], and Neuroscience and Spine). Specialty/location designation was determined by physician and hospitalist rosters obtained from the Medical Staff department and nursing rosters obtained from the Nursing department at Abbott Northwestern. Within each of the clinical service line/hospitalist and nurse groups, frequencies were obtained using SAS to determine high, moderate, and low referring provider status for physicians and nurses. High and low referring providers were identified (again, using SAS) by way of randomly ordering each list and isolating the top 10 percent most frequent referrers (high) and anyone with two or one referrals (low: two or fewer referrals constituted the bottom 50 percent of the population).

Random selection of physician and nurse participants was intended to occur until two interviews were completed from both the high and the low referring groups for each clinical service line. However, because interview transcripts were coded and analyzed as they became available (see Processing, Coding, and Analyzing Data below), data saturation was reached before completing all 24 physician and 16 nurse interviews.

Recruitment and Scheduling

JD initially proposed the study to all potential participants via an emailed letter. A "Common Questions" document and a consent information document accompanied the email letter and provided additional details on the study. Following low initial response rates in all groups, follow-up contacts were made in the following ways:

- Administrators: Follow-up phone calls or emails from JD to administrators and/or their administrative assistants.
- Physicians: A hard copy packet sent by FedEx or internal mail, depending on office location. Packets contained a signed copy of the invitation letter from JD, a signed copy of a generic support letter for the study (addressed "Dear Colleague") from the clinical service line administrator to any physician in that administrator's service line, the common questions sheet, and the verbal consent information. These packets were followed by a phone call and/or email from study coordinator KG asking for confirmation of receipt and inquiring as to interest in participation.
- Nurses: A hard copy packet sent by internal mail. Packets included a signed copy of the invitation letter from JD, a signed copy of a generic support letter for the study from the head of nursing at ANW, the common questions sheet, and the verbal consent information. These packets were followed by an email from KG inquiring as to interest in participation.

If a potential participant was interested in learning more about the study and/or scheduling an interview, they were asked to contact KG. KG scheduled all interviews and tracked recruitment status in a private Excel spreadsheet. Those who declined to participate communicated to KG that they were not interested (no reason given); had family/scheduling commitments or were too busy; or had recently retired. Other individuals provided no response after the initial invitation

and a series of follow-up communications, and were considered not interested in participation. Seventy invited individuals either did not respond or declined to participate (36 physicians and 34 nurses). Decisions to participate were communicated either to JD or KG via email or telephone. A total of 37 individuals participated:

- 15 physicians
- 15 nurses
- 7 administrators. This group included two administrators associated with the Neuroscience and Spine service line, because this service line was undergoing a leadership transition during the study period. One of the two neuroscience and spine interviews was not used when it was determined that that administrator's duties were primarily outpatient-focused.

Eight of the physicians, two of the administrators, and all of the nurses interviewed were women.

Recruitment began on March 19, 2014 and was completed on April 7, 2015. As mentioned above, data saturation was reached before completing all 24 physician and 16 nurse interviews. These two groups were also more challenging and time-intensive to recruit and schedule. Recruitment was completed for administrators.

Interviews and Consent Process

Interviewers

KG began the study as a Research Coordinator and her title changed to Associate Scientific Advisor during the course of the study. KG was trained in qualitative research methods and analysis and participated in qualitative data collection, management, and analysis on a range of projects for several years before this study. JC was an experienced qualitative researcher. As a consultant on the study, he designed the protocol and interview questions. Before data collection, the interviewers participated in a practice interview session to establish similar approaches to using the interview protocol with prospective participants. Neither interviewer had any interaction before the study with the participants interviewed.

Interviews

KG conducted 35 interviews among the administrators, physicians, and nurses. JC was in attendance for one of the nurse interviews. JC conducted two administrator interviews (with KG in attendance). Interviews were conducted between May 1, 2014 and April 16, 2015. Nurse interviews were conducted either in a private room at the study team office or in a quiet and unoccupied seating area near the hospital's main lobby. Nurse interviews were generally scheduled for a window of time before or after the nurse's shift. Physician interviews were conducted either at the physician's office or in a quiet and unoccupied seating area near the hospital's main lobby or another lobby area in the hospital (e.g. lobby of the Mother Baby Center). One physician interview was conducted in an unoccupied examination room near where the physician was working that day. Physician interviews were frequently conducted on same-

day short notice, when the physician had a window of availability during a shift. Administrator interviews were held either at the administrator's office or in a private meeting room elsewhere in the hospital.

Separate interview protocols were used for each type of participant, having been created by the research team and approved by the IRB. Questions went through several rounds of revisions by the team, and were tested in practice interview sessions among the interviewers. As data collection was underway, some commonly-used prompts were added after receiving approval from the IRB. Administrator questions addressed professional background, personal experience with IM, their assessment of the knowledge and support of IM services by providers in their service line, and personal perspectives on IM. Nurses were asked about professional background/role, personal and professional experience with IM, use of the IM referral system, and interactions with patients and patients' family members regarding IM services.

Interviews ranged from six to 28 minutes. Interviews were shorter than the estimated 30 to 45 minutes, due to time constraints of the participants (e.g., most physicians fit the interviews into the midst of a clinic day or on-call shift at the hospital). Each participant was interviewed only once. All interviews were recorded on a handheld Olympus DM-620 digital voice recorder, and immediately following the interview the digital files were saved to a private folder on the server only accessible to interviewers, and erased from the recording device. Notes were made by the interviewer during and/or after each interview. Immediately following each interview, these notes were scanned and saved to a private folder on the server only accessible to interviewers, and hard copies were securely destroyed.

Consent Process

The verbal informed consent process took place at the beginning of each interview, before recording was begun. Participants were asked if they had read and understood the consent information (provided during recruitment) and were given the option to take another hard copy of the information with them. For participants who had not read the information or wished to be reminded of its contents, the interviewer reviewed key points of the document. Participants were asked if they agreed to be audio-recorded. All said yes without hesitation. Once recording began, each participant was asked again to confirm that she or he agreed to be recorded. At the conclusion of each interview, the interviewer confirmed that she was stopping the recording device. Only individuals able to consent of their own volition were recruited and interviewed.

Processing, Coding, and Analyzing Data

Interview audio files were transcribed in batches by two experienced transcriptionists hired through a local temporary employment agency. Either Olympus Sonority or Olympus DSS Transcription Module software was used for audio file playback, with files removed by KG from the playback software immediately after each transcriptionist's workday concluded. Only one

transcriptionist worked at a time; the second was hired when the first moved away and was no longer available. A transcription protocol[1] was used to ensure consistency, and all transcripts were checked against the corresponding audio file by KG, with corrections made as necessary. Completed transcripts were saved in a secure and private folder on the server only accessible to the interviewers. Transcripts were not returned to participants for review.

KG and KCN used Atlas.ti version 7 to organize and code transcripts. This process was ongoing, as transcripts became available. The interview protocol questions were used to establish a basic coding structure, to which inductive analysis[2] and grounded theory[3] principles were then applied. The inductive analysis process involves open coding to develop codes, categories, patterns, and themes. These elements are then refined, finally using deductive processes to form analytical hypotheses about the data. Different code catalogues were created for each participant group (i.e., physicians, nurses, and administrators). KG and KCN met regularly (weekly, in most cases) to discuss the coding process and the emerging catalogue of codes. Intercoder reliability was established early in the coding process by way of KG and KCN coding several of the same transcripts and comparing findings, which were overwhelmingly similar. JC and another consultant, Dr. Michael Finch, also met once with KG to review a sample of transcripts and review the accompanying codes that were associated with each interview question. KCN completed the majority of the coding and then created documents for each participant type in which he summarized primary findings by question, in addition to any other notable themes that had emerged in each participant group.

1. McLellan E, MacQueen KM, Neidig JL. Beyond the qualitative interview: data preparation and transcription. Field Methods. 2003;15(1):63.
2. Patton M. *Qualitative Research and Evaluation Methods*. 3rd ed. ed. Thousand Oaks, CA: Sage; 2002.
3. Glaser B, Strauss, A. . *Discovery of Grounded Theory: Strategies for Qualitative Research*. Chicago: Aldine; 1967.

Effect of Complementary and Alternative Medicine on Pain Among Inpatients

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1. Background, Rationale, and Purpose

Our *long-term objective* is to develop a comprehensive understanding of the cost effectiveness of offering Complementary and Alternative (CAM) therapies to hospital inpatients and the impact of CAM therapies on a broad array of patient outcomes. As part of this long-term effort, the ***goal of the proposed research*** is to study a model for the delivery of CAM therapies and to evaluate the effectiveness of CAM therapies for pain management among inpatients in a large acute care hospital.

While current pain management guidelines emphasize pharmaceutical interventions, these interventions increase the incidence of adverse events, potential for addiction, and adverse impact on recovery if used excessively.[1,2] Nowhere is this more evident than in the post-operative period where roughly 80% of patients report moderate to severe pain after surgery even after receiving pharmaceutical interventions.[3] In a 2009 New England Journal of Medicine article, Dr. Jean Woodcock (former head of FDA) writes that despite promising non-pharmacologic approaches to managing pain, pain is still most often treated with analgesics, even though risk and safety issues are associated with their use.[4] The issues with traditional pain approaches are "undertreatment" and "overtreatment" with the former leading to residual pain and the latter resulting in the potential for adverse events. An integrated approach, utilizing both CAM and traditional pain management strategies, could address residual pain and result in a wider therapeutic margin for providers.

A. Previous research: CAM for pain management

Several systematic reviews report the efficacy of (non-pharmacologic) CAM approaches to pain management in hospitalized, surgical patients.[5-7] As shown in Table 1, 10 studies demonstrate short-term effects of CAM on pre- and post-therapy patient-reported pain scores,[8-17] whereas one study found no short-term change in pain.[18] Four studies have examined long-term effects of CAM on pain reduction several hours after CAM therapy.[12,13,16,19]

Table 1: Studies of efficacy of CAM for pain management in hospitalized patients.

Author (year)	Type of Study	IM Therapy	Control	Short Term	Short term % Pain Reduction	Long Term (Hours)	Long Term % Pain Reduction	Time points	Patient Type (n=)
Mitchinson (2007)[8]	RCT	Massage	Routine care or individual attention	X	19%*				Surgical: thoracic, abdominal (n=605)
Albert (2009)[18]	RCT	Massage	Usual care	X	0%#				Surgical: cardiac (n=252)
Cutshall (2010)[9]	RCT	Massage	Standard care/20 min. quiet time	X	72%*				Surgical: cardiac (n=53)
Grealish (2000)[10]	NRT	Massage	Complete quiet activity in bed	X	39%				Oncology (n=87)
Smith (2002)[11]	NRT	Massage	Nurse interaction	X	23%				Oncology (n=41)
Weinrich (1990)[12]	RCT	Massage	10 min visitation	X	30%*	X	1 hr: 27.7%*; 2 hr: 43.2%*	1,2 hrs	Male Oncology (n=28)
Wang (2000)[13]	RCT	AQ	Placebo AQ	X	31%*	X	0.5 hr: 40.7%*, 1hr: 48.2%*, 2 hr: 54.6%*, 6 hr: 63.4%*	0.5, 1, 2, 6 hrs	Surgical: spine (n=132)
Mehling (2007)[19]	RCT	Massage + AQ	Usual care			X	32.4%*	~3 hrs	Surgical: cancer (n=138)
Wang (2004)[14]	PP	AQ	No control	X	50%				Surgical (n=17)
Currin (2008)[15]	PP	Massage	No control	X	43%				Oncology (n=251)
Jane (2009)[16]	PP	Massage	No control	X	43%	X	0.5 hr: 48.1%*, 1 hr: 42.6%*, 1.5 hr: 44.4%*, 2 hr: 40.7%*	0.5, 1, 1.5, 2 hrs	Oncology: metastatic bone pain (n=36)
Adams (2010)[17]	PP	Massage	No control	X	55%				Surgical/Medical and OB (n=53)

Legend: RCT= randomized controlled trial, NRT= non-randomized trial, PP= Pre-post study, RO= Retrospective Observational study. AQ= acupuncture. # =Not significantly different than control. * =Significantly different than control group.

Although the efficacy of non-pharmacologic CAM therapies to reduce pain has been demonstrated, there is limited understanding of the effectiveness of CAM therapies in applied settings. While randomized controlled trials are the gold standard for clinical efficacy research, careful observational studies are required to understand the effectiveness of interventions without artificial constraints.[20-22] Observational studies provide an opportunity to assess which CAM therapies are acceptable to patients and clinical care providers as actually implemented in conventional treatment settings[23,24] and in large collaborative non-research settings.[25,26]

Despite the need for effectiveness studies to inform the practical employment of CAM therapies for pain management, there are only two published studies which assessed the effectiveness of CAM on inpatient pain management.[27,28] Cassileth and Vickers[27] conducted a retrospective observational study to investigate whether massage therapy affected self-reported pain scores in hospitalized cancer patients. Patients were referred by a medical professional for the massage intervention. Before and again after the massage, patients provided a written pain score. The initial massage visit yielded a 40% decrease in immediate pain. Within 2 to 5 hours after completion of the massage, pain was re-assessed in a sub-sample of patients. While pain rebounded above the post-intervention level, it remained below the pre-intervention pain level.

Our research team recently published the second study, which examined the effectiveness of CAM on inpatient pain management.[28] Similar to the previous study,[27] patients were referred by medical personnel for treatment and patients provided a self-reported pain score prior to and immediately after the CAM therapy. Extending the work of Cassileth and Vickers, however, our research included a broader array of CAM therapies, including mind/body, acupuncture, massage or combinations of these therapies. Further, we examined data from multiple clinical populations (cardiac, orthopedics, spine, rehabilitation, medical and surgical, and women's health). We found that the initial CAM visit yielded an average immediate pain reduction of 56% and that 33% of these patients reported complete pain relief after receiving the CAM therapy.

We recognize important inadequacies of these two retrospective studies that limit both our knowledge of how CAM therapies are implemented in hospitals and the effect of various CAM therapies on pain management. These include incomplete information about: (1) which patients are referred for CAM pain management; (2) which patients benefit most from receiving CAM therapies; (3) whether there are differential effects of pain reduction for specific CAM interventions; (4) the dose of CAM therapies required for short-term pain reduction; and 5) the duration of pain relief for these CAM interventions. **The proposed research is aimed at addressing these important limitations.**

B. Implications for knowledge and clinical practice changes: Improved integration of CAM therapy and usual care to improve pain management

The percent of hospitals providing CAM to inpatients nearly doubled from 2004 to 2007 (8% to 15%), with continued rapid growth expected.[29,30] While CAM therapies can be used to address many symptoms, the most common in the inpatient setting is residual pain experienced after treatment with usual care (e.g., opioids and other analgesics).

Answers to the above questions will inform the clinical practice of both CAM providers and physicians. Specifically, we will examine the differential effect on pain of different CAM therapies, which patients respond to which therapies, and evidence of the dose and duration of pain relief. In addition, our results will provide hospitals with a clear model of how CAM can be delivered in acute care settings. **Taken together, this information will address many of the traditional barriers in hospitals to the integration of usual care and CAM therapy for pain management.**

2. Investigator Qualifications

Jeff Dusek, PhD, is the lead investigator. Dr. Dusek currently serves as the Research Director of the Penny George Institute for Health and Healing and as Research Director of the Integrative Health Research Center for Allina's Center for Healthcare Innovation (CHI). For over a decade, Dr. Dusek has demonstrated a record of successful and productive projects of high relevance for the field of CAM. His role in this study will include oversight of data collection and management as well as assisting with data analyses and dissemination.

Pamela Jo Johnson, MPH, PhD, Co-Investigator, is a Research Investigator, Senior Research Consultant for the Healthcare Equity Research program at Allina Health, Adjunct Assistant Professor of Epidemiology & Community Health in the University of Minnesota School of Public Health with graduate faculty appointments in Health Services Research and in Population Studies and Assistant Professor in the Center for Spirituality & Healing, University of Minnesota. Her research interests are focused on healthcare disparities,

complementary and alternative medicine/integrative healthcare, and women's health. Dr. Johnson has extensive experience with health services research, medical statistics, analytic techniques for complex survey data, and methods for non-experimental, observational studies. Dr. Johnson will assist with data analyses and dissemination for this study.

Dr. Jon Christianson, a health economist, is the James A. Hamilton Chair in Health Policy and Management at the University of Minnesota. He is an expert in the use of quantitative and qualitative data to evaluate large-scale organizational redesign efforts and has written extensively on the implementation of evidence-based treatment processes in healthcare organizations. Dr. Christianson has a well-established relationship with Allina, as he is currently Co-Investigator of a large randomized trial examining care coordination in clinics conducted by the Center for Healthcare Innovation. Dr. Christianson will assist with data collection, data analyses, and dissemination for this study.

Michael Finch, PhD, is a methodologist and currently an independent research consultant and an Adjunct Associate Professor at the University of Minnesota with appointments in the Division of Health Services Research and the Carlson School of Management's Department of Finance. Dr. Finch recently co-authored a book with Dr. Christianson exploring the experience of different hospitals across the United States in use of CAM. He also has an established relationship with Allina's George Institute and recently co-authored the paper on CAM and pain change with Dr. Dusek. For this study, Dr. Finch will assist with data analyses.

Jill Johnson, PhD, MPH, is a Senior Scientific Advisor at the Penny George Institute for Health and Healing and the Integrative Health Research Center for Allina's Center for Healthcare Innovation (CHI). Dr. Johnson is an epidemiologist with an extensive and broad background analyzing, interpreting, and publishing basic, epidemiologic, and clinical studies. Dr. Johnson will assist Dr. Dusek with oversight of data collection and management and will contribute to data analysis and dissemination.

3. Study Hypothesis and Objectives/Specific Aims

Our proposed research is an **observational study of a model for the delivery of CAM therapies and an evaluation of the effectiveness of CAM therapies for pain management** in an acute care inpatient hospital. Specifically, we plan to study the use of CAM therapies as a complement to usual pain control regimens in an acute care setting where CAM modalities are in routine use. Additionally, we would like to explore the interaction between pain and anxiety. To accomplish this, we will address the following *specific aims*:

Aim 1a: Quantitatively describe a model for delivering CAM therapies to understand selection of patients and CAM therapies for pain management. We will use a series of binomial and multinomial logit models to describe the process by which patients are referred, triaged, assessed, and finally treated with CAM for pain management. Controlling for patient demographics, clinical group characteristics, and time from admission, these models will allow us to predict: 1a) which patients are referred for CAM, 1b) of those referred, which patients are seen by a CAM provider, 1c) of those seen by a CAM provider, which patients are in pain, and 1d) of those patients in pain, which CAM therapy is provided to address their pain.

Aim 1b: Qualitatively describe the referral and data collection processes. Through interviews of administrators, physicians, nurses, IM practitioners, and research assistants dedicated to this study, we will qualitatively describe the process by which patients are referred, triaged, assessed, and finally treated with CAM for pain management to:

1) More thoroughly understand the effectiveness and acceptance of our data collection methodology, and
2) Understand the influence of physicians, nurses, and administrators' own attitudes and beliefs towards integrative care, their personal experience with integrative care, and the experience of their patients on making referrals for integrative care.

Aim 2a: Examine the effects of selected CAM therapies on immediate change in pain. We will examine the effectiveness of Mind Body (MB), Massage (MA), and Acupuncture (AQ) therapies alone, or in combination, on self-reported pain measured just before and immediately after service delivery. Analyses will include an assessment of the effects of type(s) of CAM therapy and CAM therapy dose (i.e., minutes of service) on self-reported immediate pain change accounting for differences in demographic (including street address), clinical, and CAM visit characteristics among patients. Differential effects of CAM on immediate pain

change will also be examined for selected subgroups (e.g., clinical group, initial pain status). Specifically, we will: 2a) estimate the effect of CAM type(s) on amount of immediate pain change, and 2b) estimate the effect of CAM dose (in minutes) on amount of immediate pain change.

Aim 2b: Comparison of the effects of CAM therapies vs other pain management strategies (i.e., pain medications) on self-reported pain. Analyses will include a comparison of the immediate pain score changes in the patients receiving CAM vs patients who do not receive CAM. Since the cost effectiveness of CAM interventions for symptom relief is important for the Allina Health system, this aim will also compare the cost effectiveness of pain management interventions across these two groups.

Aim 3: Examine the effects of selected CAM therapies on duration of pain change. We will examine the effectiveness of MB, MA, AQ alone, or in combination, on repeated measures of self-reported pain and anxiety over several hours after therapy to assess the distribution and decay of the pain change effect. Assessment of the effects of type(s) of CAM therapy and CAM therapy dose on duration of pain change will be explored using techniques for repeated measures and accounting for differences in patient characteristics as above. Growth curve models will be used to estimate the shape of the pain change curve overall and for selected subgroups. We will: 3a) estimate the duration of pain change and the shape of the pain curve by CAM therapy type(s), and 3b) estimate the duration of pain change and the shape of the pain curve by CAM therapy dose.

3. Study Procedures

Aim 1a The George Institute receives referrals from physicians, nurses and allied health professionals on a daily basis. A patient, family or friend may also request a referral, but a nurse or physician must approve and submit the referral through the hospital's electronic health record (EHR). Acupuncture referrals require a specific physician order and patients are required to sign a consent form to receive acupuncture.

The George Institute maintains 50-60 ongoing patients and obtains 25-35 new referrals daily. An average daily staffing of 10-13 practitioners provide CAM services to 60-65 patients each weekday. Each weekday morning the providers meet as a group to triage cases. During the triage meeting, providers review current patient load and new referrals are assigned to an appropriate CAM provider, who serves as the care coordinator for the duration of the hospital stay or until a patient is discharged from the CAM service. Whether a specific patient is seen by the provider depends on the number of referrals the CAM provider is assigned, the number of hours the provider works, and the availability of the patient when the provider arrives at the patient's room. After the triage meeting, providers review the priority in which their assigned patients will be seen. Priority depends on the urgency of the request, patient condition, the proximity of patients and patient availability.

Prior to providing a CAM therapy to the patient, practitioners complete an assessment which involves: (1) reviewing the patient's record; (2) communicating with the patient's traditional care provider; and (3) completing a formal face-to-face assessment with the patient.

The target population for Aim 1 (describing CAM referral and service delivery decision making) is all Abbott Northwestern Hospital inpatients during the data collection period. Subsets of those patients will be selected for analysis for the sub-aims based on their referral status for CAM and whether they received services from a CAM provider. Because the data used to examine Aim 1 are collected for clinical purposes and available in the EHR for all patients admitted to the hospital, referred for CAM, and seen by a CAM provider, the sample for this portion of the study will be accessed through electronic health record extraction based on dates of admission and discharge within the study time period.

Aim 1b We will conduct an interview-based qualitative study among Abbott Northwestern employees/consultants in the same clinical service lines used for the other aims of the study: Cardiovascular, Mother Baby, Neuroscience & Spine, Orthopedics, and Oncology.

Research Director, Dr. Jeff Dusek, will initially propose the study to potential participants via an email letter. In the case of low response rates, a second contact may be made via hard copy letter or telephone call. A 'Common Questions' document and a consent information document will accompany the email letter and the hard copy letter (when applicable) and will provide additional details on the study. If a potential participant is interested in learning more about the study and/or scheduling an interview, they are asked to contact study staff.

In each of these service lines, we will interview the following: physicians and nurses who have the opportunity to refer patients for integrative medicine services; hospitalists who have the opportunity to refer patients for integrative medicine services; and administrators of the aforementioned service lines. In addition, we will interview Integrative Medicine practitioners who provide integrative services and research assistants (RAs) from the Integrative Health Research Center who are collecting the quantitative data for Aim 3.

One 30-45 minute visit will be required of each participant and it will take place at a scheduled appointment time convenient to the participant. For physicians and administrators, research staff will consent and conduct interviews in the physician/administrator's office. For nurses and IM practitioners, participants will be asked to come to the Integrative Health Research Center (IHRC) for consenting and interviews. IHRC has two private rooms available for patient consent and study procedures. For RAs, research staff will consent and conduct interviews in a private conference room located outside of the IHRC.

Aims 2a, and 2b In deciding which CAM therapy to provide to a patient, practitioners discuss the proposed treatment options with the patient prior to delivery of the therapy. Practitioners use their clinical judgment to provide whichever CAM therapies, within their scope of practice, they deem necessary and therapeutic to reduce pain in a given patient. CAM visits average 25 minutes in duration and are provided in patients' rooms at no expense to patients. Before beginning a treatment, CAM providers ask patients to rate, on a scale of 0 to 10, their current level of pain. After the treatment, CAM providers again ask patients to rate their pain on a scale of 0 to 10. Providers then discuss treatment and/or discharge goals and, before leaving a patient's room, set expectations for follow up treatment visits.

Aim 3 Aim 3 requires the collection of repeated follow up measures for the same group of patients as Aim 2a and 2b, but will require active consent. Once a patient is identified by the CAM provider as part of the target population for Aims 2 and 3, and a pre pain score of >0 is obtained, they will call and refer a patient to a research assistant (RA). The RA will then check the patient's EHR to see whether or not the patient has consented to release his/her EHR information for research purposes. The RA will also check other eligibility requirements at that time. Once a patient has been identified as eligible, the RA will enter the patient's room and go through a verbal consent process with the patient for collection of additional pain and anxiety scores in six scheduled visits over five hours. Within those scheduled time windows for visits, if a patient is awake and available, the RA will collect the pain and anxiety scores. If a patient is not available, the RA will record the reason scores were not collected (out of room, sleeping, with physician, etc.)

4. Participants

Aim 1a The target population for Aim 1 (describing CAM referral and service delivery decision making) is all Abbott Northwestern Hospital inpatients during the data collection period.

A. Inclusion Criteria

- Admission to Abbott Northwestern Hospital
- Consent to release of electronic health record for research purposes
- 18 years of age or older Length of stay greater than 24 hours

B. Exclusion Criteria

- None

Aim 1b The study population for Aim 1b is comprised of the following individuals:

- 24 physicians: two high and two low CAM referring physicians from Cardiovascular, Mother Baby, Neuroscience & Spine, Orthopedics, and Oncology Clinical Service Lines and the Hospitalist service.
- 20 nurses: two high and two low CAM referring nurses from Cardiovascular, Mother Baby, Neuroscience & Spine, Orthopedics, and Oncology Clinical Service Lines.
- 7 administrators of the Cardiovascular, Mother Baby, Neuroscience & Spine, Orthopedics, and Oncology Clinical Service Lines and the Hospitalist service.
- Integrative medicine practitioners who provide services to Cardiovascular, Mother Baby, Neuroscience & Spine, Orthopedics, and Oncology Clinical Service Lines inpatients.
- Research Assistants from the Integrative Health Research Center who enroll patients and collect data.

All Integrative Medicine practitioners and Integrative Health Research Center research assistants will be identified from the AKN or staff rosters provided by department management.

To identify prospective physician and nurse participants based on referrals, data will be obtained from the Electronic Data Warehouse (EDW). Using the 'Orders' file from EMR, three order codes will be retrieved: 207179-Acupuncture Evaluation and Treatment, 207180-IP Consult to Integrative Medicine, and 207853-Nursing Consult to Integrative Medicine. Authorized provider and order writer names will be extracted from the file, and the physicians and nurses will be categorized according to specialty/location: hospitalist (MDs only) or clinical service line (Oncology, Cardiovascular, Mother Baby, Orthopedics and Neuroscience & Spine). Specialty/location designation will be determined by physician and hospitalist rosters obtained from the Medical Staff department and nursing rosters obtained from the Nursing department at Abbott Northwestern. Within each of the clinical service line/hospitalist and nurse groups, frequencies will be obtained to determine high, moderate, and low authorized providers for physicians and nurses. Within the high and low distribution groups, people will be randomly selected by a computer program for participation in the study. Random selection of participants will occur until two interviews are completed from both the high and the low referring groups. Dependent on accrual rates, a convenience sampling approach may be adopted.

To minimize the effects of employment length on referral rate, we will only count referrals from nurses and physicians who have continuously worked at Abbott Northwestern Hospital and had referral privileges for the previous year. Physician and nurse staff rosters will be used to identify years/dates of employment.

A. Inclusion Criteria:

- Abbott Northwestern Hospital administrator of one of the following Clinical Service Lines: Cardiovascular, Mother Baby, Neuroscience & Spine, Orthopedics and Oncology.
- Abbott Northwestern Hospital hospitalist, physician or physician with consulting privileges for one of the following Clinical Service Lines: Cardiovascular, Mother Baby, Neuroscience & Spine, Orthopedics, and Oncology.
- Abbott Northwestern Hospital nurse for one of the following Clinical Service Lines: Cardiovascular, Mother Baby, Neuroscience & Spine, Orthopedics, and Oncology.
- Abbott Northwestern Hospital Integrative Medicine practitioner who currently delivers services to patients or who delivered services to patients during a portion of quantitative data collection.
- Research Assistant at the Integrative Health Research Center, Penny George Institute for Health and Healing, Abbott Northwestern Hospital who enrolls patients and collects data on study AT006518-01 Phase II Abbott Northwestern Hospital Pain Study.
  And:
- For physician and nurse participants: Must have made at least one patient referral for integrative medicine services.

B. Exclusion Criteria:

- None

Aims 2a and 2b The target sample for Aim 2 is all Abbott Northwestern Hospital inpatients within the data collection period including both patients who did and did not receive CAM services.

A. Inclusion Criteria

- Admission to Abbott Northwestern Hospital
- Consent to release of electronic health record for research purposes
- 18 years of age or older
- Length of stay greater than 24 hours

B. Exclusion Criteria

- None

AIM 3 The target sample for Aim 3 is all Abbott Northwestern Hospital inpatients within the data collection period who received CAM services. It is anticipated that we will need to consent 7,000 participants in order to obtain enough data on approximately 3,575 participants.

A. Inclusion Criteria

- Admitted to Abbott Northwestern Hospital

- Length of stay greater than 24 hours
- Consent to release of electronic health record for research purposes
- 18 years of age or older
- Received CAM therapy in current hospitalization
- Pain level of 1 or greater at the pre-treatment assessment by practitioner
- English-speaking
- Integrative medicine therapy ended between 9:00 am and 4:00 pm

B. Exclusion Criteria

- Refuses consent
- Unable to provide consent due to competency concerns
- Has declined study participation 3 times during current hospitalization
- Has hard declined during current hospitalization
- Has been approached 6 times during current hospitalization
- Has been approached to consent earlier that day

5. Consent Process

Aims 1a, 2a, and 2b Since all the data required for Aims 1 and 2 are in the EHR, we will follow Allina Health system-wide policies for EHR data use for research. Under this policy, all patients are asked for permission to use their electronic health data for research purposes. Traditionally, the IRB approves a waiver of consent for these data. This means that data from any patient who has indicated they are unwilling to share their medical record data for research purposes (historically 4%) will be excluded from the sample. For patients who have provided general research consent, we will extract data from the EHR which includes such data as patients' demographics (including street address), clinical diagnosis, age, pre-therapy and immediate post-therapy pain and anxiety scores as well as cost data (i.e., billing records).

Aim 1b The informed consent process will take place at the beginning of the scheduled interview appointment time. Staff will verbally consent the study participants for collection of interview data and separately for the recording of responses.

Research staff conducting the informed consent process will introduce the study as an investigation to describe the referral, triage, assessment, and therapy decision process for the delivery of CAM in a large hospital. Consent will be obtained for participants in a private area – either the administrator or physician's office, the Integrative Health Research Center participant rooms, or a private conference room. The consenting information sheet will be reviewed with participants by the research staff, and participants will be encouraged to ask questions throughout the process. Staff will stress that this is a voluntary study and that a participant is able to withdraw from the study at any time and their employment/consulting privileges at Abbott Northwestern/Allina Health will not be affected. Only individuals able to consent of their own volition will be recruited.

Aim 3 If a patient has consented to release his/her EHR information for research purposes and meet all other eligibility criteria, they will be approached by a RA from the study. The RA will go through a verbal consent process with the patient and offer a study information sheet. The consent process will take place within the privacy of the patient's hospital room and time will be provided for the patient to ask any questions they may have. Only individuals able to consent of their own volitions will be enrolled in Aim 3. RAs will stress that this is a voluntary study and that a participant is able to withdraw from the study at any time without affecting the care they receive.

6. Data Quality and Safety Review Plan and Monitoring

A. Confidentiality

- Protection of Subject Privacy / Data – When information collected during the visit becomes part of the EHR, these data will become subject to all the privacy, confidentiality, and protection offered by Allina's EHR system, which is bound and protected by HIPAA. Although stored in an internal database separate from the EHR, the repeated pain scores (Aim 3) and interviews (Aim 1b) will be under the same level of protection. All Allina EHR data are strictly protected by password-only access, secure data archival practices, and data encryption. EHR data will only be extracted for

patients who have a signed HIPAA data release form in the medical record indicating they have explicitly authorized use of their EHR data for purposes of research. Patient data that resides in the EHR will be accessed only by physicians and clinic staff and project investigators will not require access to data on an individually identifiable basis. Data security will be monitored through monthly scheduled audits, ensuring only staff from the research team are able to get to and use study data.

The majority of data used for this study is part of standard clinical practice data collection, and thus part of the patient's EHR. All EHR data will be subject to the same stringent access and security as currently applied to the EHR according to HIPAA standards. Additional measures, primarily follow-up pain scores for sub-study in Aim 3 will not become part of the patient's EHR, but will be stored in a secure database using an internal Allina application that is linked to the EHR via each patient's unique medical record number and hospital stay number. Data from these two sources (internal database and EHR) will be extracted and linked together for analyses. Data to be analyzed by the investigators of this project will have been stripped of personal identifiers and all results will be presented in aggregate.

Disruption of patients participating in the sub-study for Aim 3 will be minimized by not waking patients or interrupting care by medical providers. Additionally patients have the option of refusing any single measurement or dropping out of the study entirely.

Patients under the age of 18 will not be included in the study so there are no issues related to participation and protection of minors.

B. Confidentiality During AE Reporting

AE reports and annual summaries will not include subject-identifiable material. Each will include the identification code only.

C. Adverse Event Information

Definition – An adverse event (AE) is any untoward medical occurrence in a subject temporally associated with participation in the clinical study or with use of the experimental agent being studied. An adverse finding can include a sign, symptom, abnormal assessment (laboratory test value, vital signs, electrocardiogram finding, etc.) or any combination of these.

A Serious Adverse Event (SAE) is any adverse event that results in one or more of the following outcomes:

- Death
- A life-threatening event
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant disability/incapacity
- A congenital anomaly or birth defect
- Important medical event based upon appropriate medical judgment

Classification of AE Severity – The investigators will monitor participants, and document and report any undesirable experiences and/or events that occur during the course of the study. Severity will be determined by the PI using the following categories:

Mild: Does not adversely impact (in any way) the subject's course of wellness or illness.
Moderate: Impacts the subject's course of illness but is not life-threatening or incapacitating.
Severe: Fatal, life threatening, permanently disabling; severely incapacitating; requires/prolongs hospitalization.

AE Attribution Scale – AEs will be categorized according to the likelihood that they are related to the study intervention.

Not related: The event is clearly related to factors such as the subject's clinical state, not with therapeutic interventions associated with the study protocol.
Remote: The event was most likely related to factors such as the subject's clinical state, not with therapeutic interventions associated with the study protocol.

Possible: The event follows a reasonable temporal sequence from initiating the intervention, but is possibly related to factors such as the subject's clinical state.
Probable: The event follows a reasonable temporal sequence from initiating the intervention and cannot be reasonably explained by factors such as the subject's clinical state.
Highly Probable: The event follows a reasonable temporal sequence from initiating the intervention and cannot be reasonably explained by factors such as the subject's clinical state. In addition, the event occurs immediately following intervention or as a direct result of intervention-initiated procedures.

Expected Risks – Due to the nature of this project, adverse events are expected to be minimal. Providing pain scores is extremely low risk for adverse events. There is potential risk for invasion of privacy, including use of personal information or the improper disclosure of information. Patients participating in the sub-study for Aim 3 with repeated follow-up pain measures may experience some disruption of their schedule. The risk and inconveniences are addressed in the protocol and consent form. Staff will be trained to keep all written and electronic data secure and confidential.

SAE Reporting – SAEs that are unanticipated, serious, and possibly related to the study intervention will be reported to the IRB and NCCAM in accordance with requirements.

Safety Review Plan – Study progress and safety will be reviewed yearly. AEs will be provided to the Independent Monitors yearly. An annual report will be compiled and will include a list and summary of AEs. In addition, the annual report will address (1) whether adverse event rates are consistent with pre-study assumptions; (2) reason for dropouts from the study; and (3) whether all participants met entry criteria. The annual report will be signed by the Independent Monitors and will be forwarded to the IRB and NCCAM. The IRB and other applicable recipients will review progress of this study on an annual basis.

D. Monitoring

Per NIH requirements, Dr. Dusek will submit the Data and Safety Monitor's annual report to NCCAM.

Data Quality and Management and Subject Accrual

Description of Plan – Data security will be monitored through monthly audits, ensuring only staff from the research team are able to get to and use study data.

Data integrity for Aim 3 relates primarily to the repeated measures collected by the RAs as well as study consent materials. After training, RAs will be shadowed by the PI, Co-Investigator, or Research Coordinator for a select number of patients to ensure that RAs are appropriately following the protocol for eligibility screening, study consent, and data collection. Repeated measures data quality monitoring will be examined by a senior research staff member to examine differences in the data collection protocol by RA. Any differences identified will be addressed through re-training, and more intense supervision of RAs.

Frequency of Data Review for this Study – Dr. Mary Jo Kreitzer and Dr. Patricia Herman will be the independent health care professionals serving as the Data and Safety Monitors. Dr. Kreitzer is the Director of Center for Spirituality and Healing at the University of Minnesota and Dr. Herman is a Research Scientist in the Health Outcomes and PharmacoEconomics Center at the University of Arizona. As shown in the table below, Drs. Kreitzer and Herman will monitor the quality of the collected data, summaries of study progress to ensure that the consent process documentation is properly obtained and stored on a quarterly basis. The monitors will also review subject accrual, enrollment and adverse events on a quarterly basis. The monitors will issue a report annually to the PI and the IRB, which will be forwarded to NCCAM.

Data type	Frequency of review	Reviewer
Subject accrual (adherence to protocol regarding demographics, inclusion/exclusion)	Quarterly	Principal Investigator, Independent Monitors
Adverse event rates (injuries)	Quarterly	Principal Investigator, Independent Monitors
Report	Yearly	Independent Monitors

7. Quantitative Statistical Analysis – Aims 1a, 2a, 2b, and 3

A. Data sources

Two sources of data will yield the information required to generate measures for analysis: **EHR data** generated by providers and **ancillary database records** generated by research assistants. Abbott Northwestern Hospital's electronic health record, an Epic product (Excellian®), contains patient demographic information, clinical information, CAM referral information, CAM provider triage outcomes, and CAM service delivery information (including detailed therapy information about each visit), and pre- and post-therapy pain and anxiety scores. ANW has had a fully-implemented EHR in place since July 2005.

In addition to data extracted from the EHR, research assistants will obtain verbal consent from patients who meet all eligibility criteria as noted above. If subjects consent, then the research assistants will collect six additional pain scores. The first pain score will be obtained from consented patients about 30 minutes after the immediate post-therapy pain score. The second pain score will be obtained 30 minutes after that, and then every hour after that up to five hours post-therapy. Anxiety scores will be collected similarly. The five hour follow-up time period was selected based on a synthesis of previous research.[12,13,16,19] Data for the pre and immediate post-service measures will be directly entered into the EHR. Subsequent pain and anxiety scores and information collected from the patient's EHR will be entered and stored into a password protected custom Microsoft Access research database along with a unique identifier to link to the EHR.

B. Data management & quality control

We will extract and create an analytic data set combining data from the EHR and the ancillary database, which will be imported into STATA (version 11), SPSS (version 18), or SAS (version 9.2) for analysis. In addition to the safeguards implicit in the electronic data collection we employ, we will conduct weekly quality checks to identify obviously erroneous and/or missing data. Validation rules will be imposed to detect invalid or out-of-range entries. Error reports will be generated and a research assistant will be charged with verification of proper values. Both missing and invalid data will be tracked to the original source of the data for verification. In cases where missing or invalid values cannot be corrected, we will use statistical methods to handle missing data (see end of analysis section).

C. Data elements

Dependent variables: For Aim 1a, we have four separate outcome variables: *CAMorder* is a classification of whether or not the patient had a CAM referral order entered into the EHR; *triage* is a three-category variable indicating the result of the triage process (i.e., patient seen; triaged to be seen, but not seen; and patient not seen); *pain* is a dichotomous variable indicating whether the patient was documented to have pain at the visit; and *CAM type*, which is an 8-category variable representing our seven CAM type(s) of interest (MB, MA, AQ, MB/MA, MB/AQ, MA/AQ, MB/MA/AQ) and a residual other.

For Aims 2a and 2b, our primary outcome variable is change in self-reported pain. *Pain change* will be modeled as the difference in self-reported pain from just before the CAM treatment and just after the CAM treatment (i.e. postpain-prepain). The pre and post pain scores will be collected by the CAM therapist. Nursing staff collect pain scores before and after all pain management interventions and these scores will be used in analyses comparing CAM and other pain management interventions on change in pain. For Aim 3, *duration of pain relief* is defined as the elapsed time from CAM therapy to sustained increases in self-reported pain. *Pain and anxiety scores* will be collected by the RAs as noted above. The corresponding curves will be modeled as a series of repeated measures up to five hours post therapy.

Independent variables and covariates: The primary independent variable and covariates for each analysis are shown in Table 2 below, where "DV" indicates dependent variable, "IV" indicates primary independent variable and "x" indicates covariate. For aims 2a, 2b and 3, the independent variables are *CAM*

type, a set of indicator variables for CAM therapy type (MB, MA, AQ, MB/MA, MB/AQ, MA/AQ, MB/MA/AQ) and *CAM dose*, which represents the amount of time (in minutes) the CAM therapy was delivered. Relevant covariates include: *demos* is a set of variables for patient demographic characteristics (e.g., sex, age, street address); *MDC* is a set of indicator variables representing aggregated medical diagnosis code groups; *M/S* is an indicator variable distinguishing medical and surgical patients; and *admtime* and *proctime* represent the time from admission and last major procedure, respectively, to CAM service; *referring unit* (refunit) is a set of indicator variables for the nursing unit that initiated the CAM referral; *camtime* is the time of day the CAM therapy was provided; *camprov* is an indicator for which CAM provider delivered the therapy; *camvis* represents the visit number (e.g., 1st, 2nd). *Opioid* and *NonOpioid* are two time-varying variables that represent the dose of either non-opioid or opioid analgesics translated into equivalent units of pain medication.[31]

Table 2. Summary of analytic variables by specific aim

			Specific Aims							
Variable	**Variable Description**	**Source**	**1.a**	**1.b**	**1.c**	**1.d**	**2.a**	**2.b**	**3.a**	**3.b**
camorder	CAM referral order (y/n)	EHR	**DV**							
triage	CAM triage outcome	EHR		**DV**						
pain	Pain as reason for visit (y/n)	EHR			**DV**					
camtype	CAM therapy type provided	EHR				**DV**	**IV**		**IV**	
camdose	Duration of CAM service	EHR						**IV**		**IV**
prepain	Pre-therapy pain score	EHR					**DV**	**DV**	**DV**	**DV**
postpain	Immediate post-therapy pain score	EHR					**DV**	**DV**	**DV**	**DV**
post30	Post pain 30 minutes	RA							**DV**	**DV**
post60	Post pain 1 hr	RA							**DV**	**DV**
post120	Post pain 2 hrs	RA							**DV**	**DV**
post180	Post pain 3 hrs	RA							**DV**	**DV**
post240	Post pain 4 hrs	RA							**DV**	**DV**
post300	Post pain 5 hrs	RA							**DV**	**DV**
DEMOS	Demographics (age, gender, etc.)	EHR	x	x	x	x	x	x	x	x
mdc	Major Diagnostic Category (MDC)	EHR	x	x	x	x	x	x	x	x
ms	Medical/Surgical indicator	EHR	x	x	x	x	x	x	x	x
admtime	Time from admission	EHR	x	x	x	x	x	x	x	x
proctime	Time from major procedure	EHR	x	x	x	x	x	x	x	x
refunit	Referring unit	EHR	x	x	x	x	x	x	x	x
camtime	Time of CAM assessment/service	EHR			x	x	x	x	x	x
camprov	CAM provider	EHR				x	x	x	x	x
camvis	CAM visit number	EHR					x	x	x	x
opioid	Time & dose of opioid analgesics	EHR							x	x
nonopioid	Time & dose of non-opioid analgesics	EHR							x	x

EHR = Electronic Health Record; RA = Research Assistant; DV = Dependent variable; IV = Indepndent variable; x = covariates

D. Analysis and interpretation of results

In this section, we briefly describe the analytic techniques to be used for Aims 1a, 2a, 2b and 3, followed by an overview of our statistical methods for handling missing data and our sample size estimates.

Aim 1a: Quantitatively describe a model for delivering CAM therapies so as to understand the selection of patients, and therapies, for pain management.

We will use a series of binomial and multinomial logit models to describe the process by which patients are referred, triaged, assessed, and finally treated with CAM for pain management. These models will allow us to predict: 1a) which patients are referred for CAM, 1b) of those referred, which patients are seen by a CAM provider, 1c) of those seen by a CAM provider, which patients are in pain, 1d) of those patients in pain, which CAM therapy is provided to address their pain. Below we outline the relevant patient population, dependents, and independent variables for each of these questions.

1a.a Logistic regression model to predict who gets a CAM referral order

Population = all inpatients
Outcome = CAM referral order entered in EHR: yes or no
CAM order = demos + referring unit + MDC + M/S + admit time

1a.b Multinomial logistic regression model to predict who is seen by a CAM provider
Population = inpatients with EHR documented CAM order
Outcome = Triage status: 1-patient seen, 2-triaged to be seen but not seen, 3-patient not seen
Triage status = demos + referring unit + MDC + M/S + admit time

1a.c Logistic regression model to predict who is assessed with pain at CAM visit
Population = inpatients triaged for CAM service & assessed by CAM provider
Outcome = Practitioner assessed pain: yes or no
Pain status = demos + referring unit + MDC + M/S + admit time + camtime
(Note: We have added time of day (camtime) to control for the effects of circadian rhythm on pain)

1a.d Multinomial logistic regression model to predict what CAM therapy is provided
Population = inpatients assessed with pain as CAM visit focus
Outcome = CAM type: 1-MB, 2-MA, 3-AQ, 4-MB/MA, 5-MB/AQ, 6-MA/AQ, 7-MB/MA/AQ
CAM type = demos + referring unit + MDC + M/S + admit time + camtime + provider

For Aim 1a, all of our analyses are either binomial or multinomial logit. We will present for each model both the regression coefficients and the odds ratios for each category. We will use z-tests from the logistic regression output to assess the significance of the coefficients. Our discussion of these results will lie primarily with the odds ratios, because of their ease of interpretation. However, one disadvantage of odds ratios is that, because they are non-linear, they only reflect changes at the mean of the distribution. In our interpretation, we will also develop prototypic cases to illuminate effects at different points on the distribution.[32,33] In other words, we will calculate predicted probabilities for "ideal types" of patients, as defined by specific clinical and demographic characteristics.

Aim 1b: See Section 8 (Qualitative Data Analysis) below

Aim 2a: Examine the effects of selected CAM therapies on immediate change in pain.

We will examine the effects of MB, MA, and AQ therapies alone or in combination on self-reported pain change measured just before and immediately after service delivery. Analyses will include an assessment of the effects of type(s) of CAM therapy and amount of CAM therapy dose (i.e., minutes of service) on self-reported immediate pain change accounting for differences in demographic, clinical, and CAM visit characteristics among patients. Differential effects of CAM on immediate pain change will also be examined for selected subgroups (e.g., clinical community, initial pain status).

2a.a OLS model to estimate effect of CAM therapy type on amount of immediate pain change
Population = inpatients receiving MA, MB, AQ or any combination for pain
Outcome = amount of pain change (prepain - postpain)
Pain change = **CAM type(s)** + visit + demos + clinical

2a.b OLS model to estimate effect of CAM dose (in minutes) on amount of immediate pain change
Population = inpatients receiving MA, MB, AQ or any combination for pain
Outcome = amount of pain change (prepain - postpain)
Pain change = **CAM minutes** + visit + demos + clinical

Where: VISIT is a set of CAM visit characteristics (e.g., CAM provider, visit number [1st, 2nd, 3rd], time of day)
DEMOS is a set of patient demographic characteristics (e.g., age, sex)
CLINICAL is a set of clinical characteristics (e.g., referring unit, MDC, med/surg, admit time)

In addition to modeling results for the stated population, each model will be stratified by selected clinical communities and by initial pain score where sample size permits.

For aims 2a.a and 2a.b we will examine the data for violations of normality of the dependent variable using the Box-Cox procedure to determine the appropriate transformation as needed. For ease of interpretation, all results will be discussed in appropriately retransformed form.[34] We will estimate all standard errors using Stata's robust variance estimation option (Huber/White/sandwich estimator) to correct for

violations of the homoscedasticity assumption. We will also examine the possibility of non-linear relationships between the independent and dependent variables by introducing and testing various polynomial forms.

Interpretation of the effects of our analyses for Aim 2a is straightforward because the OLS estimators are linear. We will examine unstandardized effects (when comparing across populations) and both unstandardized and standardized effects when comparing within equations. This allows us to examine the effect of differing metrics of the independent variables.

Aim 2b: Comparison of the effects of CAM therapies vs other pain management strategies (i.e., pain medications) on self-reported pain.

2b.a OLS model to estimate effect of CAM therapies versus other pain management on amount of immediate pain change.
Population = all Abbott Northwestern Hospital inpatients
Outcome = Amount of pain change (pre-pain – post pain)
Pain change = **CAM type(s)** + demographics + clinical + opioid + nonopioid

Aim 3: Examine the effects of selected CAM therapies on duration of pain change.

We will examine the effectiveness of MB, MA, AQ alone or in combination on repeated measures of self-reported pain status over five hours after therapy to assess the distribution and decay of the pain change effect. Assessment of the effects of type(s) of CAM therapy and CAM therapy dose (in minutes) on duration of pain change will be explored using techniques for repeated measures and accounting for differences in patient characteristics as above. Growth curve modeling techniques are the current method of choice for estimating change over time.[35-38]

We will employ growth curve techniques as they overcome the many problems posed by traditional approaches such as repeated measures ANOVA and MANOVA. They are flexible and accommodate a number of problems typically encountered in repeated measures data collection, such as missing data and unbalanced designs. In addition, they are statistically more efficient than their predecessors and allow for both linear and non-linear estimation.

3.a Bayesian growth curve analysis to estimate the duration of pain change and the shape of the pain curve by CAM therapy type
Population = inpatients receiving MA, MB, AQ or any combination for pain
Outcome = repeated measures of pain change over time
Pain change = **CAM type(s)** + visit + demos + clinical + pain meds

3.b Bayesian growth curve analysis to estimate the duration of pain change and the shape of the pain curve by CAM therapy dose
Population = inpatients receiving MA, MB, AQ or any combination for pain
Outcome = repeated measures of pain change over time
Pain change = **CAM dose** + visit + demos + clinical + pain meds

Where: VISIT is a set of CAM visit characteristics (e.g., CAM provider, visit number [1st, 2nd, 3rd], time of day)
DEMOS is a set of patient demographic characteristics (e.g., age, sex, etc.)
CLINICAL is a set of clinical characteristics (e.g., referring unit, MDC, med/surg, admit time)
PAIN MEDS is two time-varying covariates that represent non-opioid and opioid analgesics

Similar to Aims 2a and 2b, in addition to overall models for Aim 3, we will stratify each by selected clinical communities and by initial pain score as sample size permits.

The interpretation of results for aim 3 will be presented in graphical form. Using the estimated parameters from the growth curve we will draw the curve for each population of interest. This provides a more intuitive view of the results than simply reporting the coefficients and very clearly illustrates both the amount and duration of pain reduction for each analysis. Duration of pain reduction will be defined as the inflection point of the growth curve after smoothing.

E. Treatment of missing data

As noted previously, during the data collection and quality control process, research assistants will attempt to verify any missing data through chart review or follow-up. Missing values will be flagged, documented, and manually corrected in the analytic database. When no additional information can be used to manually correct missing information, a statistical approach will be used.

Analytic datasets will be assessed to understand patterns of missing data (i.e., MCAR, MAR). Even in cases where data are missing completely at random (MCAR), we prefer not to case-wise delete because of the impact on sample size and standard errors. Rather, we will use accepted "hot deck" methods to impute missing data for the independent variables and covariates.[39] Specifically, we will use the *hotdeck* procedure for Stata to impute missing values.[40,41] Following standard practice, we will not impute missing dependent variables.

In the case of missing repeated pain measures for Aim 3, the approach to growth curves that we propose to use accommodates unbalanced designs and thus reasonable amounts of missing data pose no problem to the estimation of effects. As long as each subject has 2 or more repeated pain measures, they can be included in these models without biasing estimates of the models' coefficients.

F. Sample size estimation

Given our 5+ years of providing CAM at Abbott Northwestern Hospital, we have a reasonably good estimate of the number of patients who will receive each of the three CAM therapies to relieve their pain. We anticipate that, based on our current workflow, we will see approximately over 200 patients per month who receive a CAM therapy for pain management. We are planning for a 30 month data collection period, which will yield approximately 6,000 patients in our target population. There will of course be attrition at several steps of the process. The first is a patient's refusal to sign the general research consent for use of medical records for research purposes, which all patients are asked to sign at admission. At Abbott Northwestern Hospital, roughly 96% of all patients sign this consent. Data from individuals who do not provide this consent will neither be approached for study participation (Aim 3), nor will their medical records be used (Aims 1a, 2a, 2b). The second point of attrition will be missed opportunities, which result from the inability of an RA to respond to a therapist's request to recruit and consent a patient. We estimate this, from our experience shadowing therapists as they provide the CAM intervention, to be not more than 20% lost. Our last point of attrition is the patient's refusal to consent to the collection of additional pain scores (Aim 3). We estimate this to be no more than 25% as the additional data collection is both nominal and non-intrusive. Note that the second and third points of attrition do not affect the sample size for Aims 1a, 2a and 2b. **This approach yields an anticipated sample size of approximately 5,900 subjects for Aim 2 and 3,575 for Aim 3.**

We performed a traditional power analysis for our anticipated Aim 3 sample size, a more conservative approach than powering for Aim 2, using the historical number of patients by CAM therapy type. This yields an anticipated sample of 793 patients receiving mind/body, 627 patients receiving acupuncture, and 2,157 patients receiving massage. Using the smallest of these, acupuncture, and assuming a type I error rate (alpha) of 0.05 and a power of 80%, we can estimate average immediate pain reduction within plus/minus 4%. Because of the Bayesian repeated measures techniques that we will employ to analyze the duration of pain data, we are confident that these sample sizes will provide estimates that are at least as precise as the plus/minus 4% obtained for the immediate pain change analysis.

Aim 1a is a purely descriptive analysis, which serves to provide context for Aims 2 and 3. As such, we did not perform a power analysis. However, with an estimated sample size of more than 83,000 patients over 30 months, we feel confident these equations are adequately powered to address substantive differences.

In our research experience, it is sometimes the case that our attrition assumptions are not accurate. We have powered this study for 30 months of data collection, but our timeline allows for up to 36 months of data collection. We did this to assure that at the end of our data collection period, we can reasonably expect to have met our sample size goals.

8. Qualitative Data Analysis – Aim 1b

Our analytical methods will adhere to common practices in the field of qualitative analysis; as such, statistical tests are not applicable.

Investigators and study staff will read the transcripts from all interviews conducted, identifying themes that emerge from the transcripts relating to the research questions. Atlas.ti version 7 software will be used to organize and code transcripts and visually represent relationships between codes and themes as they emerge. This process will occur sequentially, as typed interview transcripts become available, so that we can use

insights from earlier interviews to inform later interviews. Interview questions will be used to establish a basic coding structure, which will be combined with inductive analysis, as described by Patton[42] and drawing from Glaser and Strauss's "grounded theory."[43] The inductive analysis process involves open coding to develop codes, categories, patterns, and themes. These elements are then refined, finally using deductive processes to form analytical hypotheses about the data. Within each of the five types of interviewees, the themes identified in the first few interviews will be tested against evidence gathered in subsequent interviews and against the data gathered in interviews with respondents in the other three respondent categories. Themes will be refined and modified as data accumulate throughout the interviewing process. The evolving coding scheme will be discussed during periodic team meetings.

All transcripts will be verified to assure accuracy by comparing the transcript to the audio file. Should we find significant quality problems in the early transcripts, we will address these problems by working with the transcriptionist or hiring a new transcriptionist.

Intercoder reliability (i.e., consistency in the application of codes to the text) will be measured on a subset of data (15%) by computing the ratio of the total number of disagreements in code applied to the total number of items coded by the two coders. If necessary, discrepancies will be resolved with the assistance of a third investigator, and a second round of intercoder reliability testing will be conducted until we reach a reliability level of .90, before the two primary coders code the remaining transcripts.

9. Anticipated Results and Potential Pitfalls

This research, if positive, will help focus attention on leveraging integrative medicine, which adds CAM as an adjunct to traditional care, as a mechanism to address pain management. In addition, the methodological approaches employed in this research can be transferred to other outcomes, many of which are related to pain, including anxiety, stress and nausea. This research will also enable a long-term focus on the cost-effectiveness of an integrative model.

The results of the proposed study will provide critical guidance to both physicians and CAM practitioners on how best to balance the use of pharmaceutical interventions and CAM to manage patients' pain. In addition, managing patients' pain remains one of the highest priorities in hospitals. If we demonstrate CAM is an effective adjunct to traditional pain management, hospitals will have a new tool, and the beginnings of an evidence base to use that tool, in meeting the pain management goals of the Joint Commission[44,45] and ultimately, of patients.

We have carefully considered several challenges in the design of this study. First, since we propose collecting additional pain scores on a large number of patients, it is possible that the attrition rate will exceed our anticipated 25% and require a longer data collection period. While this might be a concern for applicants proposing to implement a new CAM service, our estimates are based on 5+ years of providing CAM at Abbott Northwestern Hospital. Regardless, should it be necessary, we could recruit the required patients in 36 months rather than the 30 months proposed and still meet our enrollment goals.

Second, since we will be studying the effectiveness of CAM therapies on pain management in a non-controlled research setting, patients will receive opioids and other pain analgesics as part of their standard clinical care. The issue is whether the provision of pharmacologic pain interventions will interfere with our ability to examine the effects of CAM therapies on duration of pain change. Anticipating this possibility, we can reliably access the EHR to document the time/day of all pain medications provided during patients' hospital stay. We have included in our analytic plan accepted procedures for comparing differences in type and dose of these opioid and non-opioid analgesic medications.

Third, it is possible that collecting repeated pain scores for up to five hours may not capture the complete pain reduction curve. However, the decision to use a five hour duration was based on 3 factors: (1) we used comparable timepoints as previous studies;[12,13,16,19] (2) five hours is approximately the same duration of typical dosing of narcotic pain medications;[46-48] and (3) there are logistical barriers to longer data collection (e.g., patients sleeping), which would lead to an unacceptable amount of missing data.

Finally, our proposed study will result in data based on the experience of patients in one hospital, which raises the concern of generalizability. While this may be a concern for a hospitals serving one type of patient population (e.g., cancer or pediatrics), our study would take place in a typical tertiary hospital suggesting that its experience will be generalizable to a considerable degree to other tertiary hospitals across the US.

10. Risk/Benefits and Reporting

This study involves no physical or psychological risks. There are minimal risks to the confidentiality and privacy of participants. Risk is limited to the possible breach of confidentiality of the pain and anxiety scores and interview data. The probability and magnitude of risk is small. Risks are minimized by using a limited access, password protected database as well as using the smallest number of identifiers necessary. The Data Safety Monitoring Plan outlines the procedures for identifying and reporting any adverse events. There are no direct benefits to participants. We hope that information learned from this study will help us better understand CAM therapies for pain and anxiety management.

11. Regulatory and Ethical Considerations

This study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with the Belmont Report, Good Clinical Practice and applicable regulatory requirements. The study will be conducted in accordance with the regulations of the United States Food and Drug Administration (FDA) as described in 21 CFR 50 and, applicable laws and the IRB requirements. The study's data will be made available for monitoring, auditing, IRB review, and regulatory inspection by providing direct access to study-related source data.

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Referrals to Integrative Medicine in a Tertiary Hospital: Findings from Electronic Health Record Data and Qualitative Interviews

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SUPPLEMENTARY FILES

The study protocol, a methods appendix, and the interview guides used for data collection are provided as supplementary materials.

DATA SHARING STATEMENT

No additional data are available.

ABSTRACT

Objective: To examine patterns of and decision-making processes informing referrals for inpatient access to integrative medicine (IM) services at a large, acute care hospital.

Design: Retrospective electronic health record review and structured qualitative interviews.

Setting: A 630-bed tertiary care hospital with an IM service available to inpatients.

Participants: IM referrals of all inpatients aged ≥18 years between July, 2012 and December, 2014 were identified using the hospital's electronic health record. Fifteen physicians, fifteen nurses, and seven administrators were interviewed in order to better understand roles and perspectives in referring patients for IM services.

Results: In the study hospital, primary sources of referrals for IM services were the orthopedic and neuroscience/spine service lines. While the largest absolute number of IM referrals was made for patients with lengths of stay of three days or fewer, a disproportionate number of total IM referrals was made for patients with long lengths of stay (≥10 days), compared with a smaller percentage of patients in the hospital with lengths of stay ≥10 days. Physicians and nurses were more likely to refer patients who displayed strong symptoms (e.g., pain, anxiety) and/or did not respond to conventional therapies. IM referrals were predominantly nurse-initiated. A built-in delay in the time from referral initiation to service delivery discouraged referrals of some patients.

Conclusions: Conventional providers refer patients for IM services when these services are available in a tertiary hospital. Referral patterns are influenced by patient characteristics, operational features, and provider perspectives. Nurses play a key role in the referral process. Overcoming cultural and knowledge differences between conventional and integrative medicine providers is likely to be a continuing challenge to providing IM in inpatient settings.

Strengths and limitations of this study

- We accessed two and a half years of electronic health record data to understand the flow of referrals for integrative medicine (IM) therapies in the hospital, a process that has not been reported on previously despite the growing presence of IM services in inpatient settings.
- Qualitative interviews with physicians, nurses, and administrators from across the hospital provided insight into how decisions are made surrounding referrals and help to explain or substantiate some of the patterns seen in the EHR data.
- This article reports results of a case study from one hospital with a unique and well-established IM program, and as such, it may have limited generalizability.
- In the course of conducting interviews with physicians and nurses, we learned that mid-level providers (e.g., physician assistants, nurse practitioners) have an important role in placing referrals for IM; however, we did not interview any staff in these roles.

INTRODUCTION

In this paper, we examine referrals for integrative medicine (IM) services in a large tertiary care hospital, where "referrals" denotes orders placed within the hospital's electronic health record for IM therapies. The integration of complementary medicine modalities (e.g., massage, acupuncture, mind-body therapies) with conventional medicine is becoming more common in U.S. healthcare,[1-4] but occurs infrequently in inpatient settings, where little is known regarding how patients or providers access these therapies. In outpatient settings, IM usage is largely a function of consumer decisions. However, for hospitalized patients, the process by which patients access IM is more complex, with conventional healthcare providers playing an important role in the decision to refer for these services. Without an effective referral process, integration of complementary medicine with conventional medicine cannot occur in inpatient settings.

Patterns of referrals for IM have been studied previously in health network and primary care settings, but not in a single hospital setting.[5, 6] Other studies have examined interprofessional dynamics among conventional and complementary medicine providers in IM clinics and hospitals,[7, 8] and have described models of IM primary care, with some broad overview of how various referral networks operate.[9] In this study, we examined referrals for IM within a large, acute care hospital.

METHODS

Study Setting

Abbott Northwestern Hospital (ANW), a 630-bed teaching and specialty hospital in Minneapolis, MN, has a well-established IM program available to all inpatients without cost. In

this program, physicians, nurses, and other hospital providers order IM as they would any other service in the hospital (e.g., a CT scan, physical therapy) using a referral in the electronic health record (EHR) system (Epic; Verona, WI). The creation of the IM program in 2003 has been described in detail elsewhere.[10] Initially the inpatient IM program was structured around specific clinical areas; however, currently the IM practitioners can serve patients in any area of the hospital as requested via referrals. IM services, which encompass visits to patients from practitioners offering a range of IM modalities and/or education, generally are available Monday through Friday, from 9am to 5pm.

During the study period, the IM team was comprised of 16 credentialed practitioners, including six acupuncturists, eight massage therapists, a holistic nurse, and a music therapist. (Several staffing changes notwithstanding, the IM team currently has a similar composition, with 16 practitioners and 10.6 FTE). All practitioners are trained in a core curriculum of IM modalities such as relaxation techniques, acupressure, and aromatherapy, as well as in approaches to delivering IM therapies in a hospital setting. All acupuncturists on the IM team are licensed and practice under the Minnesota Board of Medical Practice.

The process of placing referrals has evolved since the start of the program. At the outset in 2003, referrals were made through direct calls from hospital clinicians to the IM team's office. Calls were replaced thereafter by paper orders originating from the EHR, then sent to the IM office and printed out for the team to review and assign. This system subsequently was revised to the process currently in place, in which referrals are placed and viewed using the EHR. Providers on a patient's care team make EHR referrals for IM, and the practitioners triage these referrals, because demand for services often exceeds capacity for service delivery. The triage process happens daily at a morning staff meeting before patient visits begin and is based on a system of

flags from the patient's EHR for symptoms such as pain, anxiety, nausea, or bowel dysfunction. Notes from referring providers also are considered in decisions about which patients will be seen, and by which practitioners. The triage process and decision-making factors affecting it are described in more detail elsewhere from the perspective of IM practitioners at ANW.[11]

There are two major categories of referrals for IM: acupuncture and general IM consults; the latter can encompass any of the IM services available. Acupuncture orders also can result in an acupuncturist delivering a service other than acupuncture (e.g., acupressure, aromatherapy, mind-body therapy). Acupuncture referrals require authorization in the EHR by a physician or mid-level provider, while general IM referrals can be placed by nurses and other providers. General IM referrals can be fulfilled by acupuncturists as well as other IM practitioners, but only acupuncturists can respond to acupuncture referrals.

Data

In describing the flow of inpatient referrals, we tracked all inpatients age 18 years or older at ANW, who were admitted between July 16, 2012 and December 15, 2014. We excluded patients who were seen as outpatients, in the emergency room, or who were in the hospital solely for observation. EHR data were obtained on all eligible inpatients. All patients whose EHR data were obtained gave written permission upon or prior to admission to the hospital to use their records for general research purposes. As such, the retrospective data collection portion of this study was approved by the Quorum Institutional Review Board with a waiver of informed consent. We amended the study protocol (available as a supplementary file) to include qualitative interviews with providers.

We collected interview data to understand the influence on referrals of physicians', nurses', and administrators' own attitudes and beliefs towards integrative care and their professional experience ordering IM for their patients at ANW. We interviewed physicians, nurses, and administrators across five clinical service lines at ANW: oncology, maternity care ("Mother Baby"), cardiovascular, neuroscience and spine, orthopedics (administrators and physicians only), and the hospitalist service (administrators and physicians only). Physicians and nurses were divided, based on referral records, into "high-referring" and "low-referring" designations before recruitment began, in order to ensure that providers in the study represented both frequent and occasional referrers for IM services.

Our goal was to recruit two high-referring and two low-referring physicians and nurses in each service line, resulting in a total of 24 physicians and 16 nurses. There were no nurses associated with the hospitalist group. Orthopedic nurses were not recruited for the study because of the presence of standing orders on the joint replacement area of the orthopedic unit, a topic discussed in the Results section of this paper. The lists of high- and low-referring physicians and high- and low-referring nurses were placed in random order before recruitment began. Additionally, we planned to recruit physician administrators for each of the six service lines, in order to obtain their insights into how IM is perceived, used, and supported in each service line. All administrators were practicing currently as physicians in their service lines, in addition to their administrative roles. Prospective participants received emailed or mailed invitations from the study PI (JD) and follow-up contacts by the study coordinator (KG) if they did not respond to the initial invitation.

Structured interview protocols (available in a supplementary file) were developed by the study team and approved by the institutional review board. An interpretivist paradigm was used

in creating the interview guides and subsequently in analyzing the data. All protocols addressed professional background and personal experience with IM. Administrators were asked to assess the knowledge and support of IM services by providers in their service lines, as well as their own personal and professional perspectives on IM. Physicians and nurses were asked about their use of the IM referral system and interactions with patients and patients' family members regarding IM services.

Interviews were audio recorded using a handheld digital recorder and then were transcribed by an independent transcriptionist. Transcripts were organized and coded using Atlas.ti version 7.5.4 software. The analysis process was ongoing, as transcripts became available. The interview protocol questions were used to establish a basic coding structure, to which inductive analysis[12] principles then were applied. The inductive analysis process involves open coding to develop codes, categories, patterns, and themes. These elements then are refined, using deductive processes to form analytical hypotheses about the data. Different code catalogues were created for each participant group (i.e., physicians, nurses, and administrators).

Although random selection of physician and nurse participants was intended to occur until two interviews were completed from both the high- and the low-referring groups for each clinical service line, data saturation (the point at which no new themes emerged during analysis) was reached in all groups before initial recruitment numbers were achieved. Methods are described further in the Appendix (supplementary file). In total, 37 hospital staff and affiliates were recruited (See Table 1 and Figure 1).

Table 1. Occupations and clinical service lines of qualitative interview participants

	Clinical Service Line						Total
Provider type	Oncology	Cardiology	Mother Baby	Neuroscience and Spine	Orthopedics	Hospitalist Service	
Administrator	1	1	1	2	1	1	7

Physician	4	2	3	2	2	2	15
Nurse	4	3	4	4	N/A	N/A	15

Figure 1. Recruitment of interview participants

RESULTS

Referrals

During the study period, there were approximately 14,000 referrals for IM services at ANW hospital, out of approximately 84,000 unique admissions. (Table 2). A higher percentage of middle aged and female patients were referred for IM services. Referrals were tracked across several different service lines, and the greatest number of referrals came from the orthopedics and neuroscience/spine service lines (Table 3). In the case of orthopedics, this reflects the presence of standing orders for IM referrals in the hospital's joint replacement program, as discussed in the interview findings. A quality improvement project with spine patients that took place during the study period may partially account for the high number of referrals in that service line. Patients with lengths of stay of three or fewer days constituted the bulk of first referrals (defined as the first referral placed for IM during a hospital admission), but a relatively small portion of these patients were referred. In contrast, a larger proportion of long-stay patients were referred for IM services, while the absolute number of these patient referrals was smaller. (Table 2). The median time from first referral for any IM therapy until contact with an IM practitioner (i.e. fulfillment) was approximately 23 hours, ranging from just under 22 hours for neuroscience/spine referrals to over 48 hours for rehabilitation referrals, with response times for

most service lines falling between 22 and 25 hours (Table 3). Longer median patient stays generally were associated with longer referral to response times across service lines.

Table 2. Demographics of inpatients at Abbott Northwestern Hospital
July 16, 2012 – December 15, 2014

	Total (N=83,677)	No IM Referral (N=69,686)	Referral for IM Services* (N=13,991)
Age			
Age≤39	20,899 (25.0%)	18,449 (26.5%)	2,450 (17.5%)
39<Age≤59	21,481 (25.7%)	17,053 (24.5%)	4,428 (31.6%)
59<Age≤79	28,077 (33.6%)	22,371 (32.1%)	5,706 (40.8%)
Age>79	13,220 (15.8%)	11,813 (17.0%)	1,407 (10.1%)
Gender			
Female	49,994 (59.7%)	40,766 (58.5%)	9,228 (66.0%)
Male	33,683 (40.3%)	28,920 (41.5%)	4,763 (34.0%)
Primary Race			
American Indian or Alaska Native	1,567 (1.9%)	1,349 (1.9%)	218 (1.6%)
Asian	1,619 (1.9%)	1,452 (2.1%)	167 (1.2%)
Black or African American	7,991 (9.5%)	7,143 (10.3%)	848 (6.1%)
Native Hawaiian or Other Pacific Islander	151 (0.2%)	134 (0.2%)	17 (0.1%)
Unknown	1,158 (1.4%)	1,027 (1.5%)	131 (0.9%)
White	71,191 (85.1%)	58,581 (84.1%)	12,610 (90.1%)
Ethnicity			
Patient Declined	790 (0.9%)	687 (1.0%)	103 (0.7%)
Caucasian, Not Hispanic/Not Latino	81,226 (97.1%)	67,532 (96.9%)	13,694 (97.9%)
Hispanic or Latino	1,661 (2.0%)	1,467 (2.1%)	194 (1.4%)
Marital Status			
Life Partner, Married, Significant Other	45,604 (54.5%)	37,686 (54.1%)	7,918 (56.6%)
Separated, Divorced	7,587 (9.1%)	6,062 (8.7%)	1,525 (10.9%)
Widowed	9,562 (11.4%)	8,230 (11.8%)	1,332 (9.5%)
Single	20,812 (24.9%)	17,608 (25.3%)	3,204 (22.9%)
Unknown, Other	112 (0.1%)	100 (0.1%)	12 (0.1%)
Length of Stay			
1≤LOS≤3	50,782 (60.7%)	44,981 (64.5%)	5,801 (41.5%)
4≤LOS≤6	18,794 (22.5%)	15,236 (21.9%)	3,558 (25.4%)
7≤LOS≤9	6,635 (7.9%)	4,945 (7.1%)	1,690 (12.1%)
LOS≥10	7,466 (8.9%)	4,524 (6.5%)	2,942 (21.0%)
Clinical Service Line			
All Other	25,599 (30.6%)	22,501 (32.3%)	3,098 (22.1%)
Cardiovascular	13,703 (16.4%)	12,271 (17.6%)	1,432 (10.2%)
Mental Health	6,272 (7.5%)	5,799 (8.3%)	473 (3.4%)
Mother & Baby	12,503 (14.9%)	11,414 (16.4%)	1,089 (7.8%)
Neuroscience & Spine	12,249 (14.6%)	9,624 (13.8%)	2,625 (18.8%)
Oncology	5,813 (6.9%)	4,533 (6.5%)	1,280 (9.1%)

Table 2. Demographics of inpatients at Abbott Northwestern Hospital
July 16, 2012 – December 15, 2014

	Total (N=83,677)	No IM Referral (N=69,686)	Referral for IM Services* (N=13,991)
Orthopedic	6,151 (7.4%)	2,839 (4.1%)	3,312 (23.7%)
Rehabilitation	1,387 (1.7%)	705 (1.0%)	682 (4.9%)

*"Referral for IM Services" includes all IM referrals, both for acupuncture and general IM consults

Table 3. Length of stay and median time outcomes for IM referrals and fulfillment, by clinical service line

	All Other (N=3,098)	Cardiovascular (N=1,432)	Mental Health (N=473)	Mother & Baby (N=1,089)	Neuroscience & Spine (N=2,625)	Oncology (N=1,280)	Orthopedic (N=3,312)	Rehabilitation (N=682)	Total (N=13,991)
Length of stay									
Median overnights (Q1, Q3)*	6 (4,11)	7 (4,13)	8 (4,14)	4 (3,9)	4 (3,6)	4 (2,8)	3 (3,3)	14 (8,23)	4 (3,8)
Time until any first IM referral (acupuncture or general IM)									
Median hours : minutes (Q1, Q3)	41:58 (17:47, 96:50)	55:30 (25:57, 121:00)	27:12 (3:27, 78:50)	26:12 (13:45, 51:03)	11:50 (7:27, 57:37)	22:40 (7:42, 57:37)	7:27 (6:01, 8:58)	3:31 (0:29, 67:33)	17:55 (7:01, 53:52)
Time until placement of first acupuncture referral (N)	**245**	**47**	**233**	**33**	**253**	**73**	**1,597**	**69**	**2,550**
Median hours : minutes (Q1, Q3)	15:18 (3:30, 51:27)	26:50 (3:52, 91:08)	47:18 (22:19, 102:00)	20:18 (8:33, 39:03)	9:08 (6:16, 24:55)	4:49 (0:19, 25:48)	7:17 (5:55, 8:36)	48:31 (1:31, 90:55)	7:49 (5:52, 11:57)
Time until placement of first general IM consult referral (N)	**2,853**	**1,385**	**240**	**1,056**	**2,372**	**1,207**	**1,715**	**613**	**11,441**
Median hours : minutes (Q1, Q3)	44:31 (19:17, 100:00)	57:08 (26:27, 121:00)	6:24 (1:12, 54:30)	26:21 (14:00, 51:33)	12:25 (7:36, 35:15)	23:24 (9:38, 62:07)	7:37 (6:07, 9:26)	2:38 (0:26, 55:23)	23:05 (7:41, 64:53)
Time from placement of first referral (any IM) until fulfillment	**2,925**	**1363**	**434**	**1,024**	**2,481**	**1,230**	**3,074**	**659**	**13,190**

Table 3. Length of stay and median time outcomes for IM referrals and fulfillment, by clinical service line

	All Other (N=3,098)	Cardiovascular (N=1,432)	Mental Health (N=473)	Mother & Baby (N=1,089)	Neuroscience & Spine (N=2,625)	Oncology (N=1,280)	Orthopedic (N=3,312)	Rehabilitation (N=682)	Total (N=13,991)
Median hours : minutes (Q1, Q3)	23:08 (17:16, 29:27)	24:36 (19:17, 46:00)	30:37 (20:27, 73:38)	22:26 (7:09, 28:38)	21:50 (16:43, 29:51)	22:56 (10:27, 28:25)	22:37 (19:47, 25:18)	48:47 (38:05, 91:27)	23:11 (18:14, 29:50)

*Q1 and Q3 indicate first and third quartiles

Interview Findings

We organized themes that emerged from the interviews into three general categories: criteria used by clinicians to make referrals; factors influencing the referral process; and concerns and challenges related to having an IM program available in the hospital.

Criteria for IM Referrals

In response to a broadly stated question about what circumstances or characteristics would lead someone to refer a patient to IM, respondents mentioned the following four criteria: patients' actual or expected length of stay, symptoms, using IM as a "last resort," and patients specifically requesting IM.

Length of stay and chronic conditions. Nurses, physicians, and administrators frequently mentioned that patients who were in the hospital longer (or were expected to be in the hospital longer) than average were common candidates for receiving an IM referral. Typically, these were individuals with chronic conditions. One physician suggested that "our chronic, long-term players" would be a promising group to receive more IM in the hospital than they do at present. An administrator and several physicians described IM as not being relevant for young, otherwise healthy surgical patients who recover quickly from surgery and have short lengths of stay. Conversely, this administrator said, "there are patients with chronic conditions who've had chronic pain for a long time, and I think those are the patients that I would look to helping [with IM], and where you could reduce pain medication." Similarly, Mother Baby nurses and physicians reinforced the idea that longer term—typically antenatal—patients in their service

line were more commonly referred for IM, versus labor and delivery patients whose hospital stays were too short for IM to be helpful or feasible.

> *I would be much more inclined to use it for the people who are chronically hospitalized. Or, if somebody's had a very complicated course, and we know – either we're pretty sure they're going to be here much longer than a routine person, or it just turns out they have been here longer and that's part of the problem, you know, they're having trouble dealing with that discouragement and putting up with that. Yeah, but it's almost always chronic, chronic people that I would call for. (Physician)*

A large proportion of longer-stay patients in the Mother Baby service line was confirmed by the referral data, where among Mother Baby patients with lengths of stay longer than ten days, 82% were referred for IM. In contrast, among Mother Baby patients with lengths of stay from one to three days, only 4% were referred for IM. Providers who were hesitant to refer shorter length of stay patients expressed concern that services are not typically available until the day after the referral is made, a topic discussed further below (under "Factors Influencing the Referral Process").

Importance of patient symptoms. IM referrals were cited by all physicians, nurses, and administrators as being driven by patient symptoms, primarily pain, anxiety, and stress or difficulty coping. Nausea was mentioned as well, particularly in the case of oncology patients. Often, providers viewed IM therapies as a method to reduce the use of medications, especially those that may have adverse side effects. A patient's health condition or reason for hospitalization was not the principal driver of the decision to make a referral; rather, the common element was almost always related to symptoms.

A lot of times…the people who have the most expressed amount of pain [are referred]. And especially the people who are having a difficult time with trying to cope with the hospitalization and the difficulties that come with it. (Nurse)

Use as last resort. Frequently, physicians, nurses, and administrators saw IM services as an option to use in caring for patients when the providers had exhausted all other strategies. There were references to "difficult patients" who did not seem to respond to any other treatment, or whose anxiety was very persistent. Participants felt that it "cannot hurt" to try IM, and at best it might provide some sense of relief, comfort, or improvement for challenging patients.

It's for people that don't have heart disease but are desperate for some kind of way to feel better. And so, I've ruled everything out that's deadly, and then it's like, "oh, there's not really [something] else, I can't really do anything else, try this." (Physician)

I just see that is something else they will benefit from. I'm like, "Have you tried this? OK, we have this and…you can also benefit from that," especially if we've tried everything else and they seem not to be comfortable. (Nurse)

Patients with complex sets of circumstances and conditions were mentioned frequently as those whom providers might refer. For example, one physician described working with complex patients who are being treated with multiple medications, and the hope that non-pharmacologic IM treatment might provide additional relief without drugs:

I deal with very sick patients, with essentially end-stage heart failure. A frequent accompaniment of the comorbidities is anxiety and pain. And also they tend to be elderly, and they've had arthritic conditions. And these patients are usually already heavily

medicated on polypharmacy. So any other therapeutic interventions I can make which don't involve pills, and which may actually be more effective, I would rather go down that road. (Physician)

Several respondents from each of the three provider groups mentioned the value of IM as an alternative to medications, whether because a patient was already on the maximum amount of medication he or she could be given, or because the patient expressed an interest in trying a nonpharmacological approach to manage his or her symptoms.

Patient request. Some physicians and nurses mentioned ordering IM when patients requested it. This view was most frequently mentioned in response to an interview question about whether or not patients ever initiated a request for services, although a few participants raised it without being prompted. According to participants, occasionally patients and/or family members do directly request IM services. Typically, these patients have experienced IM services previously (either at ANW or elsewhere in outpatient settings), or friends or family members have recommended the services.

Some of them…they ask for it. They start asking for, "Oh, can I get integrative medicine to come see me?" Or, "I need acupuncture." Or they want massage. And most of them will ask for it already, then I put the referral in…I think the ones that ask for it…they've been to alternative medicine or had integrative medicine before. (Nurse)

Factors Influencing the Referral Process

Beyond the criteria used to make decisions about who is referred for or receives services, a number of factors influence how and why providers make referrals, e.g., conditions in the

workflow that are perceived as facilitating or limiting engagement with or usefulness of IM. Three primary factors emerged in the interviews: the presence of standing orders on a unit (where all or nearly all patients receive an IM referral), the role of nurses and/or mid-level practitioners in driving most referrals (mid-level practitioners, e.g., nurse practitioners and physician assistants, were not interviewed in this study), and the overall operational characteristics of the referral process.

*Standing orders***.** On several inpatient units in the hospital, standing orders or quality improvement projects existed for specific medical conditions or procedures (e.g., hip/knee replacements, spinal fusion). One oncologist also described having IM referrals ordered for all her patients. This approach increased the number of referrals for IM but then left the decision to accept IM services with the patient (who, according to the physician, typically did not know about the referral) when the IM practitioner arrived to provide services. Physician attitudes on standing orders ranged from enthusiastically supportive to somewhat detached (a version of the "it can't hurt" approach). A repeated idea related to standing orders is that patients always have the option to decline IM services.

> *[W]e found it was so beneficial for the ones that were electing to do it within the first year that we felt we should standardize it for everybody, and then the patients still have the option to opt out and surgeons still have the option to opt out, but most of the surgeons don't. (Administrator)*

> *So they're on our order sets as augments for breast cancer and our colon cancers. And so we, I order them on everybody. But whether or not the patients want to do it, how much they do, I don't really know…So the consult gets ordered, and then they will come*

and evaluate the patient. Then the patient ultimately gets to decide what they want or don't want. (Physician)

Nursing-driven service. Physicians and administrators consistently described the IM referral process as being driven primarily by nurses (except in the case of standing orders). Nurses had the authority to refer for a general IM consult, although a physician was required to authorize an acupuncture order. In addition, the nurse-driven nature of the IM referral process was attributed both by nurses and physicians to the fact that nurses spend the most time interacting with patients and thus have a better sense of whether patients may be receptive to or helped by IM. Many physicians also emphasized the central role of physician assistants and nurse practitioners in determining patients who should receive IM and in placing IM referrals, due to the greater amount of time these mid-level providers spent interacting with patients.

When asked whether there were ever differences of opinion between nurses and physicians on whether a patient should receive IM, nurses consistently said that physicians were supportive of the nurses' judgment regarding whether IM could benefit the patient. The situations identified where a physician might not support an IM referral related to patients with conditions (e.g., bleeding disorders, sutures) that might preclude the use of a modality like acupuncture or massage, although these exceptions were mentioned infrequently by interviewees.

Well, I think, I mean the nurses are better about thinking about this, and I think having them able. I don't know. I think having them ask for integrative medicine consults has probably accomplished more than depending on the doctors to think about it

themselves…We're just sort of trying to get through the day, and they're there with the patient all day, and so they're more likely to think about it. (Physician)

The nurses, the RNs, are usually the ones who identify patients who may benefit and they make a suggestion. I could tell you, neither myself or, for that matter, probably any physician within my group would say, would turn down an RN request for integrative medicine . . . So it's usually an RN-driven, an RN-driven consult for the most, a lot of times. (Administrator)

A physician who stated that she actually was more likely than her nurses to place an IM referral for her patients emphasized that she and the nurses generally agreed about whether a patient should receive IM, and that she would support placing a referral on a nurse's suggestion.

Issues regarding how the referral process functioned. Most nurses and physicians remarked that the referral process generally worked well for them, with some mentioning that it was quick and easy to use, and others commenting positively on their interactions with the IM practitioners who regularly visited their units. Caveats such as wishing for IM weekend services ("pain doesn't stop on the weekends," one nurse said) or more IM practitioner availability were generally qualified by comments that the system works well given its size and scope.

The primary factor found to negatively influence referrals, from the perspective of all groups interviewed, was the timing of IM service delivery relative to when a referral was made. Typically, referrals placed were not seen the same day, reducing the usefulness of services in acute episodes of care. Referring providers expected a lag time of a day or more between the referral and service delivery, which may be one reason that referrals were placed for a relatively

high percentage of patients who had longer lengths of stay. One of the physician administrators said, "I think there's a lot of people that I would otherwise use it for if it was more readily available quickly." Other providers felt the delay was not a problem both because of the non-critical nature of using IM and due to the fact that chronic, longer-term patients were generally—in their experiences—the best fits for receiving IM anyway.

IM services are only offered Monday through Friday during the day shift, contributing to the gap between referral and service delivery as well as occasionally prompting providers not to place referrals on Fridays (due to the lack of IM services on weekends). Several participants discussed concerns about shorter stay patients potentially wanting to stay in the hospital until they had received their IM session. This issue of patient expectation or desire to receive the service occasionally influenced provider decisions regarding referring for IM.

> *I think sometimes [patients] wish it was more often. Or like, you know, when you talk about the referral, sometimes they don't get it till the next day or even the following day. So I think sometimes they would probably want it, like, more quickly, right after it's put in…If I have patients going home the next day, then I won't put it in. Because I know that it would probably be useless. (Nurse)*

Generally, however, referring providers found the service to be useful despite its limitations related to timing.

Clinician Concerns and Challenges Related to the Presence of IM in the Hospital

Although clinicians generally felt that the IM service was beneficial for their patients, they did raise concerns, and made suggestions, related to the presence of the IM service in general. These included a desire for more information about IM and the recognition of inherent

differences between the pace and philosophy of complementary healing approaches and conventional western medicine.

Desire for better education and information about IM. A commonly raised concern, on the part of physicians more than nurses, was a desire for more information and education about IM offerings and evidence of their effectiveness. The physicians we interviewed did not recall receiving formal training or education on the hospital's IM services or the referral process. For some participants, their concerns regarded a lack of familiarity with the IM modalities actually available to patients. This was true even among physicians who had personal experience using IM modalities in outpatient settings. Some felt that they could better discuss IM as a possibility with patients if they were more familiar with the "menu" of services at the hospital. Others wanted more information regarding which modalities might be most useful for specific patient symptoms. One physician, in discussing a wish to see more collaboration between IM providers and his patients' care teams, said, "maybe I'm sending inappropriate referrals…Is this the right patient to refer for this consult, and is this the right thing to ask for?" This comment was consistent with a sentiment expressed by other physicians that they were not always confident in how best to use the IM service, and that they would appreciate more clarity from the IM team in this regard.

Nurses, on the other hand, generally had more familiarity with the IM program offerings. While neither nurses nor physicians said they had received formal training from the IM program, many nurses had completed education modules at some point in their careers on nurse-delivered aromatherapy or other nurse-delivered services. They also were more likely to see and interact with IM practitioners. Thus, even if their training had been informal, they were more familiar

with the IM program, and they expressed less interest than physicians in receiving additional information on the program. This finding fits with the theme, described previously, of a high degree of nurse involvement with the referral process.

Another concern related to information/education focused on the evidence base for IM. Physicians and administrators, in particular, expressed a desire for more information about the efficacy and safety of IM modalities, both from IM research conducted at ANW, and in the medical literature at-large.

> *Well, I think it's a good thing, but again, I don't know efficacious it is. Meaning that I think there's literature to support it…and I think that it draws some patients. But again, I don't know how we're evaluating it. Is there something that should be more cookbook, that patients that have bowel surgery should have lavender post-op to help with their nausea? It doesn't seem like it's very well-prescribed. (Physician)*

Balancing two different approaches to medicine. Finally, clinicians often noted that supporting and engaging with IM in the hospital can be simultaneously challenging and valuable, because it represents the meeting of two different paradigms: conventional/western medicine and complementary and alternative medicine. Some clinicians pointed to this as a motivating factor for placing a referral; in particular, more experienced nurses commented on how they previously had the time to provide some of the comfort now given by IM providers, but that their pace of work no longer allowed for that level of care. Hence, they viewed IM as filling an important role in the rushed modern medicine model. One physician described this role as "develop[ing] a little stillness and peace in the hospital." Several physicians perceived the IM service to be underutilized.

A physician administrator commented on the two different paces of IM and conventional medicine:

> *[W]e get very busy, so, we rush through and we, we're focusing on sort of absolute vital parameters regarding the patient. We're focusing on getting the patient out of the hospital quickly, and I think that a lot of the increased pressure to move patients out quickly is perhaps taking away a little bit of the, you know, integrative medicine is a, I think it's a really good system, and I think for chronic pain patients, it can be extremely helpful. But we have to fit it in, a kind of a slower-paced concept, into this fast-paced, get your physical therapy, get your x-ray, get walking, and get out of here. And patients need a little bit more than that. Sometimes there are times when patients need to be a little quieter, if their bodies need time to heal…And so, and I think this, this pressure we're feeling to move patients out of the hospital quickly is detracting a little bit from the opportunities. And I think that it would be worthwhile for us to explore the use of integrative medicine, not only while they're in the hospital, but to teach them techniques that they can continue after they leave. (Administrator)*

Connecting Inpatient and Outpatient Settings. Lastly, several physicians were concerned that, while IM is especially suitable for long-term treatment of chronic issues and for recovery after discharge, there currently is not an obvious mechanism for linking patients to continued IM services once they are discharged. This applied both to physicians who used the service for their patients regularly and recognized its limits, as well as to those who referred infrequently but recognized the potential of IM to help patients under more ideal circumstances.

And so it's about how you describe it in a way that gets insurance to cover it and things like that. That's more the obstacle, will they cover this or not. While you're here in the hospital, it's fine. But my patients, I see longitudinally over years and years and years…And so, after the acute phase, there's this other phase where it [IM service] is particularly necessary and ***that's*** *where it becomes a resistance, is that you can offer something in the hospital, but then, because of financial issues, the patients can't keep it up, so if that strategy is your strategy, and then you can't use it, it becomes a little hard to, to offer it in one place and then not be able to sustain it.(Physician) (emphasis speaker's)*

DISCUSSION

The present study provides a unique window into how patients access IM services at one U.S. tertiary care hospital. That the provision of integrative therapies is distinct in nature from other hospital care at ANW, and that it is optional, was cited as a motivating factor for why providers might place a referral: to improve the patient's inpatient experience in ways that might not otherwise be possible using conventional medical approaches. We found that the IM referral process is very rooted in nursing, suggesting the importance of ongoing interaction between IM providers and hospital nurses for the success of inpatient IM programs. Since a nurse was the key developer of the IM service,[10] the link to nursing is understandable. The presence of nurses on the IM team may be a factor in the acceptance by nurses of the service. In a separate set of interviews with the IM practitioners at ANW, those who had nursing backgrounds described their experiences of feeling accepted by nurses on the floor, due to being well-versed in the language, culture, and workflow of conventional medicine and nursing practice.[11]

Neither physicians nor nurses described training on the referral process that was systematic or driven by the IM program. Some respondents were better informed than others, but knowledge was uneven among staff in all service lines, depending on interest level, work hours, time in the position, and team dynamics. Given the concern articulated by physicians about a need for more thorough education regarding the merits of and best uses for IM, information on research findings related to IM should be made available to interested physicians, as well as information on program offerings and recommendations regarding which patients may benefit most from receiving IM.

We found that projected or actual length of stay can have a bearing on whether a patient is referred for IM; however, we must interpret this theme cautiously. While the tendency to refer longer-stay patients may be related to an operational delay in service delivery that would make short-stay patients less likely to be seen, it is also is possible that chronically ill patients with longer stays may be referred commonly for IM simply because providers work with these patients longer and have more time to consider what combination of conventional and IM approaches may help them.

As in all case studies, an inherent limitation of this study is that our findings may not be generalizable to all inpatient settings where similar programs now exist or are being considered. However, the structure and operations of ANW are fairly typical of a large, tertiary care hospital in the U.S. Another potential limitation is that the 30 physicians and nurses who agreed to be interviewed (30% of those invited) may have been different than those who declined or did not respond, despite the use of randomized lists of prospective participants in recruitment. The designation of "high" and "low" referring providers, which was intended to capture a representative range of engagement with the IM services, was not as meaningful as expected.

Some high-referring physicians, according to clinical records, were in units with standing orders for IM; therefore they did not engage in regular decision-making regarding IM referrals. Alternately, some low-referring providers did not place many referrals directly, but regularly supported staff who did. In general, high-referring providers had more regular contact and engagement with IM services than low-referring providers, but uncovering the exceptions to this pattern revealed a nuance in the referral system, whereby a provider's referral frequency was not necessarily indicative of his or her level of support for or interaction with the IM referral process.

Finally, several nurses and physicians mentioned the important role of mid-level providers such as physician assistants and nurse practitioners in referring for IM, but we did not include any of these providers in our recruitment for interviews. However, the referral role of these mid-level providers was itself a useful finding of the study that could inform future research into the flow of referrals in inpatient settings. In the U.S., mid-level providers play an increasingly important role in hospitals, as use of these providers is incentivized and supported at policy and administrative levels.[13] Further research on referrals for IM services within hospitals should include mid-level providers in the study design.

In addition to study limitations, the current research highlighted operational elements of the IM program at ANW that merit review. Primarily, the delay between referral and service delivery emerged as a common reason why providers might not consider using the service with some patients. Although providers generally accepted this delay as part of how the program functions, same-day delivery of IM services potentially could allow the system to reach more patients who currently do not have the opportunity to receive IM. Since the conclusion of the study period, several IM practitioners at ANW have been "embedded" on the Mother Baby and spine units, thus reducing the time from referral to fulfillment, so such a change has been

possible in this setting. The tendency for the demand for IM services to exceed supply likely contributes to the delay in service delivery, and the high demand may be related to the service being offered at no cost to patients. We previously addressed this challenge in an analysis of IM practitioner views of providing inpatient services.[11] However, we did not gather from our interviews that concerns about the service being free deterred providers from referring for the service in general.

Another operational feature potentially unique to ANW's IM service is the nature of how standing orders for IM services are implemented. At present, all instances of standing orders for IM are very specific (e.g., the order in joint replacement program is for group acupuncture, the order in the spine service line was related to a temporary and now-completed quality improvement project). It may be of interest in future analyses to examine the influence of standing orders more closely. As IM programs become more prevalent in U.S. hospitals, it will be important to draw on the successes and challenges of existing models such as the ANW IM service. Our study addresses several gaps in the literature with regard to the provision of IM in U.S. hospitals, as IM referral processes within an inpatient setting have not been studied previously. Although IM is increasingly being provided to U.S. inpatients in areas such as oncology[14, 15] and pediatrics,[16, 17] hospitals with well-established integrative medicine offerings for inpatients are more prevalent internationally (e.g., in Israel,[18, 19] Germany,[20, 21] and China[22]). However, operational processes and cultural contexts surrounding acceptance of IM are substantially different internationally in comparison with the U.S., where IM offerings are less widespread and assimilated.[4] Furthermore, international studies have examined feasibility and outcomes of inpatient IM, but inpatient IM referral patterns have not been described. IM referral

patterns have been explored within a U.S. health network[5] and in an Australian primary care setting,[6] but not, to our knowledge, within a single inpatient facility offering IM as ANW does.

The culture and challenges of providing inpatient IM have been described from the perspectives of the IM practitioners who provide services;[11, 23] however, it is also valuable to consider the views and decisions of the conventional medical providers who provide a crucial link to patients for receiving integrative therapies. Research on healthcare providers' perspectives on IM has been used primarily to examine provider awareness of IM and opinions on its general usefulness or perceived legitimacy in an ambulatory setting[24-26]. Qualitative interviews by Grant and Bensoussan[27], which included a respondent from the ANW IM program, focused on the "process of care" in integrative healthcare programs at a broad level, addressing topics such as organizational structure and the use of practice guidelines; however, all but one other of the nine programs described in that study were outpatient settings. One interview-based study of physician and IM practitioner views on a short term, integrative collaboration for treating hospitalized multiple sclerosis patients reflected a much more specific and limited setting than our hospital-wide study. It also revealed themes related to the importance and challenges of collaboration and organizational support in integrating conventional and alternative therapeutic approaches[28].

To date, studies about IM that have included nurse perspectives have focused primarily on assessing the knowledge and attitudes of nurses toward complementary therapies [25, 29-33]. Generally, attitudes are positive, although reported knowledge about complementary therapies is highly variable from study to study. A qualitative study that included nurses reported interviewee attitudes toward integration of conventional and complementary medical approaches and found nurses to be supportive and interested [34]. One study conducted among oncology patients in

inpatient and outpatient settings found that patients perceived nurses to be important figures in decision-making processes around IM use [35], but nurses were not interviewed.

There is evidence in the U.S. of poor to moderate physician-patient communication about outside complementary medicine use [36-41] or resistance by physicians to their patients using complementary or alternative therapies [42, 43]. Generally, however, this resistance or disengagement has been reported with regard to patient use of these therapies outside the context of conventional medical care, in other words, in situations where use of therapies is driven by patients as health care consumers. Because IM programs embedded in hospitals are relatively new, evidence of provider attitudes about complementary therapies in the inpatient setting has not been addressed in the literature prior to this study. Furthermore, resistance by conventional providers to integrative therapies for patients may be diminishing. Several surveys have found supportive attitudes by physicians for the use of complementary and integrative therapies [24, 44, 45]. A recent qualitative study with physicians, nurses, and administrators at a large veterans' medical center reported that respondents recognized the role of complementary medicine in making care more patient-centered [34]. And physicians at an academic medical center where complementary therapies were offered showed a marked increase in their willingness to refer patients to those therapies over the course of an eight-year period [46]. We generally found acceptance among providers interviewed for this study; even those who referred for IM infrequently tended to feel the service was beneficial with regard to patient satisfaction and expressed the view that it "cannot hurt."

In addition to seeking perspectives from mid-level providers, as suggested above, future research should address patient perspectives, as patients (and/or their family members) also play a role in the referral process. Beyond qualitative research, some investigation into how a system

might respond to the concerns or suggestions articulated here by nurses, physicians, and administrators may be warranted. For example, a number of physicians expressed a desire to see more of a transitional process established for patients between IM services received in the hospital and outpatient services after discharge, implying a recognition of the potential long-term value of integrative care. As other hospital IM programs develop, questions should continue to be asked about referral processes, use of resources, and cultural integration in order to design better programs and streamline existing ones. Same-day referrals or approaches based around clinical service lines rather than hospital-wide programs would be worth consideration.

CONCLUSIONS

Conventional providers refer patients for IM services when these services are available in a tertiary hospital. Referrals are driven primarily by patient symptoms such as pain and anxiety, and patients with longer hospital stays are viewed as appropriate and feasible referral candidates. Nurses are a major source of IM referrals and have a great deal of support from physicians in their decision-making processes surrounding IM. Overcoming cultural and knowledge differences between providers of conventional versus complementary medicine is likely to be a continuing challenge to the provision of integrative medicine in inpatient settings.

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COMPETING INTERESTS

We have read and understood BMJ policy on declaration of interests and declare that we have no competing interests.

AUTHOR CONTRIBUTIONS

KHG collected, coded, and analyzed qualitative data, interpreted findings, and drafted the manuscript. KCN coded and analyzed qualitative data, interpreted findings, and contributed to drafting. RLR managed and analyzed electronic health record data, interpreted findings, and contributed to drafting. JC conceptualized the study, collected data, and contributed to drafting. JAD conceptualized the study and contributed to drafting. All authors gave final approval of the current version.

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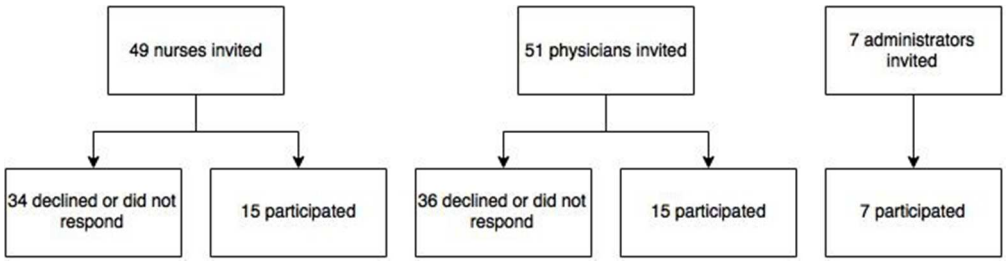

Figure 1. Recruitment of interview participants

57x14mm (300 x 300 DPI)

Effect of Complementary and Alternative Medicine on Pain Among Inpatients

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1. Background, Rationale, and Purpose

Our *long-term objective* is to develop a comprehensive understanding of the cost effectiveness of offering Complementary and Alternative (CAM) therapies to hospital inpatients and the impact of CAM therapies on a broad array of patient outcomes. As part of this long-term effort, the ***goal of the proposed research*** is to study a model for the delivery of CAM therapies and to evaluate the effectiveness of CAM therapies for pain management among inpatients in a large acute care hospital.

While current pain management guidelines emphasize pharmaceutical interventions, these interventions increase the incidence of adverse events, potential for addiction, and adverse impact on recovery if used excessively.[1,2] Nowhere is this more evident than in the post-operative period where roughly 80% of patients report moderate to severe pain after surgery even after receiving pharmaceutical interventions.[3] In a 2009 New England Journal of Medicine article, Dr. Jean Woodcock (former head of FDA) writes that despite promising non-pharmacologic approaches to managing pain, pain is still most often treated with analgesics even though risk and safety issues are associated with their use.[4] The issues with traditional pain approaches are "undertreatment" and "overtreatment" with the former leading to residual pain and the latter resulting in the potential for adverse events. An integrated approach, utilizing both CAM and traditional pain management strategies, could address residual pain and result in a wider therapeutic margin for providers.

A. Previous research: CAM for pain management

Several systematic reviews report the efficacy of (non-pharmacologic) CAM approaches to pain management in hospitalized, surgical patients.[5-7] As shown in Table 1, 10 studies demonstrate short-term effects of CAM on pre- and post-therapy patient-reported pain scores,[8-17] whereas one study found no short-term change in pain.[18] Four studies have examined long-term effects of CAM on pain reduction several hours after CAM therapy.[12,13,16,19]

Table 1: Studies of efficacy of CAM for pain management in hospitalized patients.

Author (year)	Type of Study	IM Therapy	Control	Short	Short term % Pain Reduction	Long Term (Hours)	Long Term % Pain Reduction	Time points	Patient Type (n=)
Mitchinson (2007)[8]	RCT	Massage	Routine care or individual attention	X	19%*				Surgical: thoracic, abdominal (n=605)
Albert (2009)[18]	RCT	Massage	Usual care	X	0%#				Surgical: cardiac (n=252)
Cutshall (2010)[9]	RCT	Massage	Standard care/20 min. quiet time	X	72%*				Surgical: cardiac (n=53)
Grealish (2000)[10]	NRT	Massage	Complete quiet activity in bed	X	39%				Oncology (n=87)
Smith (2002)[11]	NRT	Massage	Nurse interaction	X	23%				Oncology (n=41)
Weinrich (1990)[12]	RCT	Massage	10 min visitation	X	30%*	X	1 hr: 27.7%*, 2 hr: 43.2%*	1,2 hrs	Male Oncology (n=28)
Wang (2000)[13]	RCT	AQ	Placebo AQ	X	31%*	X	0.5 hr: 40.7%*, 1hr: 48.2%*, 2 hr: 54.6%*, 6 hr: 63.4%*	0.5, 1, 2, 6 hrs	Surgical: spine (n=132)
Mehling (2007)[19]	RCT	Massage + AQ	Usual care			X	32.4%*	~3 hrs	Surgical: cancer (n=138)
Wang (2004)[14]	PP	AQ	No control	X	50%				Surgical (n=17)
Currin (2008)[15]	PP	Massage	No control	X	43%				Oncology (n=251)
Jane (2009)[16]	PP	Massage	No control	X	43%	X	0.5 hr: 48.1%*, 1 hr: 42.6%*, 1.5 hr: 44.4%*, 2 hr: 40.7%*	0.5, 1, 1.5, 2 hrs	Oncology: metastatic bone pain (n=36)
Adams (2010)[17]	PP	Massage	No control	X	55%				Surgical/Medical and OB (n=53)

Legend: RCT= randomized controlled trial, NRT= non-randomized trial, PP= Pre-post study, RO= Retrospective Observational study. AQ= acupuncture. # =Not significantly different than control. * =Significantly different than control group.

Although the efficacy of non-pharmacologic CAM therapies to reduce pain has been demonstrated, there is limited understanding of the effectiveness of CAM therapies in applied settings. While randomized controlled trials are the gold standard for clinical efficacy research, careful observational studies are required to understand the effectiveness of interventions without artificial constraints.[20-22] Observational studies provide an opportunity to assess which CAM therapies are acceptable to patients and clinical care providers as actually implemented in conventional treatment settings[23,24] and in large collaborative non-research settings.[25,26]

Despite the need for effectiveness studies to inform the practical employment of CAM therapies for pain management, there are only two published studies which assessed the effectiveness of CAM on inpatient pain management.[27,28] Cassileth and Vickers[27] conducted a retrospective observational study to investigate whether massage therapy affected self-reported pain scores in hospitalized cancer patients. Patients were referred by a medical professional for the massage intervention. Before and again after the massage, patients provided a written pain score. The initial massage visit yielded a 40% decrease in immediate pain. Within 2 to 5 hours after completion of the massage, pain was re-assessed in a sub-sample of patients. While pain rebounded above the post-intervention level, it remained below the pre-intervention pain level.

Our research team recently published the second study, which examined the effectiveness of CAM on inpatient pain management.[28] Similar to the previous study,[27] patients were referred by medical personnel for treatment and patients provided a self-reported pain score prior to and immediately after the CAM therapy. Extending the work of Cassileth and Vickers, however, our research included a broader array of CAM therapies, including mind/body, acupuncture, massage or combinations of these therapies. Further, we examined data from multiple clinical populations (cardiac, orthopedics, spine, rehabilitation, medical and surgical, and women's health). We found that the initial CAM visit yielded an average immediate pain reduction of 56% and that 33% of these patients reported complete pain relief after receiving the CAM therapy.

We recognize important inadequacies of these two retrospective studies that limit both our knowledge of how CAM therapies are implemented in hospitals and the effect of various CAM therapies on pain management. These include incomplete information about: (1) which patients are referred for CAM pain management; (2) which patients benefit most from receiving CAM therapies; (3) whether there are differential effects of pain reduction for specific CAM interventions; (4) the dose of CAM therapies required for short-term pain reduction; and 5) the duration of pain relief for these CAM interventions. **The proposed research is aimed at addressing these important limitations.**

B. Implications for knowledge and clinical practice changes: Improved integration of CAM therapy and usual care to improve pain management

The percent of hospitals providing CAM to inpatients nearly doubled from 2004 to 2007 (8% to 15%), with continued rapid growth expected.[29,30] While CAM therapies can be used to address many symptoms, the most common in the inpatient setting is residual pain experienced after treatment with usual care (e.g., opioids and other analgesics).

Answers to the above questions will inform the clinical practice of both CAM providers and physicians. Specifically, we will examine the differential effect on pain of different CAM therapies, which patients respond to which therapies, and evidence of the dose and duration of pain relief. In addition, our results will provide hospitals with a clear model of how CAM can be delivered in acute care settings. **Taken together, this information will address many of the traditional barriers in hospitals to the integration of usual care and CAM therapy for pain management.**

2. Investigator Qualifications

Jeff Dusek, PhD, is the lead investigator. Dr. Dusek currently serves as the Research Director of the Penny George Institute for Health and Healing and as Research Director of the Integrative Health Research Center for Allina's Center for Healthcare Innovation (CHI). For over a decade, Dr. Dusek has demonstrated a record of successful and productive projects of high relevance for the field of CAM. His role in this study will include oversight of data collection and management as well as assisting with data analyses and dissemination.

Pamela Jo Johnson, MPH, PhD, Co-Investigator, is a Research Investigator, Senior Research Consultant for the Healthcare Equity Research program at Allina Health, Adjunct Assistant Professor of Epidemiology & Community Health in the University of Minnesota School of Public Health with graduate faculty appointments in Health Services Research and in Population Studies and Assistant Professor in the Center for Spirituality & Healing, University of Minnesota. Her research interests are focused on healthcare disparities, complementary and alternative medicine/integrative healthcare, and women's health. Dr. Johnson has extensive experience with

health services research, medical statistics, analytic techniques for complex survey data, and methods for non-experimental, observational studies. Dr. Johnson will assist with data analyses and dissemination for this study.

Dr. Jon Christianson, a health economist, is the James A. Hamilton Chair in Health Policy and Management at the University of Minnesota. He is an expert in the use of quantitative and qualitative data to evaluate large-scale organizational redesign efforts and has written extensively on the implementation of evidence-based treatment processes in healthcare organizations. Dr. Christianson has a well-established relationship with Allina, as he is currently Co-Investigator of a large randomized trial examining care coordination in clinics conducted by the Center for Healthcare Innovation. Dr. Christianson will assist with data collection, data analyses, and dissemination for this study.

Michael Finch, PhD, is a methodologist and currently an independent research consultant and an Adjunct Associate Professor at the University of Minnesota with appointments in the Division of Health Services Research and the Carlson School of Management's Department of Finance. Dr. Finch recently co-authored a book with Dr. Christianson exploring the experience of different hospitals across the United States in use of CAM. He also has an established relationship with Allina's George Institute and recently co-authored the paper on CAM and pain change with Dr. Dusek. For this study, Dr. Finch will assist with data analyses.

Jill Johnson, PhD, MPH, is a Senior Scientific Advisor at the Penny George Institute for Health and Healing and the Integrative Health Research Center for Allina's Center for Healthcare Innovation (CHI). Dr. Johnson is an epidemiologist with an extensive and broad background analyzing, interpreting, and publishing basic, epidemiologic, and clinical studies. Dr. Johnson will assist Dr. Dusek with oversight of data collection and management and will contribute to data analysis and dissemination.

3. Study Hypothesis and Objectives/Specific Aims

Our proposed research is an **observational study of a model for the delivery of CAM therapies and an evaluation of the effectiveness of CAM therapies for pain management** in an acute care inpatient hospital. Specifically, we plan to study the use of CAM therapies as a complement to usual pain control regimens in an acute care setting where CAM modalities are in routine use. Additionally, we would like to explore the interaction between pain and anxiety. To accomplish this, we will address the following *specific aims*:

Aim 1a: Quantitatively describe a model for delivering CAM therapies to understand selection of patients and CAM therapies for pain management. We will use a series of binomial and multinomial logit models to describe the process by which patients are referred, triaged, assessed, and finally treated with CAM for pain management. Controlling for patient demographics, clinical group characteristics, and time from admission, these models will allow us to predict: 1a) which patients are referred for CAM, 1b) of those referred, which patients are seen by a CAM provider, 1c) of those seen by a CAM provider, which patients are in pain, and 1d) of those patients in pain, which CAM therapy is provided to address their pain.

Aim 1b: Qualitatively describe the referral and data collection processes. Through interviews of administrators, physicians, nurses, IM practitioners, and research assistants dedicated to this study, we will qualitatively describe the process by which patients are referred, triaged, assessed, and finally treated with CAM for pain management to:

1) More thoroughly understand the effectiveness and acceptance of our data collection methodology, and
2) Understand the influence of physicians, nurses, and administrators' own attitudes and beliefs towards integrative care, their personal experience with integrative care, and the experience of their patients on making referrals for integrative care.

Aim 2a: Examine the effects of selected CAM therapies on immediate change in pain. We will examine the effectiveness of Mind Body (MB), Massage (MA), and Acupuncture (AQ) therapies alone, or in combination, on self-reported pain measured just before and immediately after service delivery. Analyses will include an assessment of the effects of type(s) of CAM therapy and CAM therapy dose (i.e., minutes of service) on self-reported immediate pain change accounting for differences in demographic (including street address), clinical, and CAM visit characteristics among patients. Differential effects of CAM on immediate pain change will also be examined for selected subgroups (e.g., clinical group, initial pain status). Specifically, we will: 2a) estimate the effect of CAM type(s) on amount of immediate pain change, and 2b) estimate the effect of CAM dose (in minutes) on amount of immediate pain change.

Aim 2b: Comparison of the effects of CAM therapies vs other pain management strategies (i.e., pain medications) on self-reported pain. Analyses will include a comparison of the immediate pain score changes in the patients receiving CAM vs patients who do not receive CAM. Since the cost effectiveness of CAM interventions for symptom relief is important for the Allina Health system, this aim will also compare the cost effectiveness of pain management interventions across these two groups.

Aim 3: Examine the effects of selected CAM therapies on duration of pain change. We will examine the effectiveness of MB, MA, AQ alone, or in combination, on repeated measures of self-reported pain and anxiety over several hours after therapy to assess the distribution and decay of the pain change effect. Assessment of the effects of type(s) of CAM therapy and CAM therapy dose on duration of pain change will be explored using techniques for repeated measures and accounting for differences in patient characteristics as above. Growth curve models will be used to estimate the shape of the pain change curve overall and for selected subgroups. We will: 3a) estimate the duration of pain change and the shape of the pain curve by CAM therapy type(s), and 3b) estimate the duration of pain change and the shape of the pain curve by CAM therapy dose.

3. Study Procedures

Aim 1a The George Institute receives referrals from physicians, nurses and allied health professionals on a daily basis. A patient, family or friend may also request a referral, but a nurse or physician must approve and submit the referral through the hospital's electronic health record (EHR). Acupuncture referrals require a specific physician order and patients are required to sign a consent form to receive acupuncture.

The George Institute maintains 50-60 ongoing patients and obtains 25-35 new referrals daily. An average daily staffing of 10-13 practitioners provide CAM services to 60-65 patients each weekday. Each weekday morning the providers meet as a group to triage cases. During the triage meeting, providers review current patient load and new referrals are assigned to an appropriate CAM provider, who serves as the care coordinator for the duration of the hospital stay or until a patient is discharged from the CAM service. Whether a specific patient is seen by the provider depends on the number of referrals the CAM provider is assigned, the number of hours the provider works, and the availability of the patient when the provider arrives at the patient's room. After the triage meeting, providers review the priority in which their assigned patients will be seen. Priority depends on the urgency of the request, patient condition, the proximity of patients and patient availability.

Prior to providing a CAM therapy to the patient, practitioners complete an assessment which involves: (1) reviewing the patient's record; (2) communicating with the patient's traditional care provider; and (3) completing a formal face-to-face assessment with the patient.

The target population for Aim 1 (describing CAM referral and service delivery decision making) is all Abbott Northwestern Hospital inpatients during the data collection period. Subsets of those patients will be selected for analysis for the sub-aims based on their referral status for CAM and whether they received services from a CAM provider. Because the data used to examine Aim 1 are collected for clinical purposes and available in the EHR for all patients admitted to the hospital, referred for CAM, and seen by a CAM provider, the sample for this portion of the study will be accessed through electronic health record extraction based on dates of admission and discharge within the study time period.

Aim 1b We will conduct an interview-based qualitative study among Abbott Northwestern employees/consultants in the same clinical service lines used for the other aims of the study: Cardiovascular, Mother Baby, Neuroscience & Spine, Orthopedics, and Oncology.

Research Director, Dr. Jeff Dusek, will initially propose the study to potential participants via an email letter. In the case of low response rates, a second contact may be made via hard copy letter or telephone call. A 'Common Questions' document and a consent information document will accompany the email letter and the hard copy letter (when applicable) and will provide additional details on the study. If a potential participant is interested in learning more about the study and/or scheduling an interview, they are asked to contact study staff.

In each of these service lines, we will interview the following: physicians and nurses who have the opportunity to refer patients for integrative medicine services; hospitalists who have the opportunity to refer patients for integrative medicine services; and administrators of the aforementioned service lines. In addition, we will interview Integrative Medicine practitioners who provide integrative services and research assistants (RAs) from the Integrative Health Research Center who are collecting the quantitative data for Aim 3.

One 30-45 minute visit will be required of each participant and it will take place at a scheduled appointment time convenient to the participant. For physicians and administrators, research staff will consent and conduct interviews in the physician/administrator's office. For nurses and IM practitioners, participants will be asked to come to the Integrative Health Research Center (IHRC) for consenting and interviews. IHRC has two private rooms available for patient consent and study procedures. For RAs, research staff will consent and conduct interviews in a private conference room located outside of the IHRC.

Aims 2a, and 2b In deciding which CAM therapy to provide to a patient, practitioners discuss the proposed treatment options with the patient prior to delivery of the therapy. Practitioners use their clinical judgment to provide whichever CAM therapies, within their scope of practice, they deem necessary and therapeutic to reduce pain in a given patient. CAM visits average 25 minutes in duration and are provided in patients' rooms at no expense to patients. Before beginning a treatment, CAM providers ask patients to rate, on a scale of 0 to 10, their current level of pain. After the treatment, CAM providers again ask patients to rate their pain on a scale of 0 to 10. Providers then discuss treatment and/or discharge goals and, before leaving a patient's room, set expectations for follow up treatment visits.

Aim 3 Aim 3 requires the collection of repeated follow up measures for the same group of patients as Aim 2a and 2b, but will require active consent. Once a patient is identified by the CAM provider as part of the target population for Aims 2 and 3, and a pre pain score of >0 is obtained, they will call and refer a patient to a research assistant (RA). The RA will then check the patient's EHR to see whether or not the patient has consented to release his/her EHR information for research purposes. The RA will also check other eligibility requirements at that time. Once a patient has been identified as eligible, the RA will enter the patient's room and go through a verbal consent process with the patient for collection of additional pain and anxiety scores in six scheduled visits over five hours. Within those scheduled time windows for visits, if a patient is awake and available, the RA will collect the pain and anxiety scores. If a patient is not available, the RA will record the reason scores were not collected (out of room, sleeping, with physician, etc.)

4. Participants

Aim 1a The target population for Aim 1 (describing CAM referral and service delivery decision making) is all Abbott Northwestern Hospital inpatients during the data collection period.

A. Inclusion Criteria

- Admission to Abbott Northwestern Hospital
- Consent to release of electronic health record for research purposes
- 18 years of age or older Length of stay greater than 24 hours

B. Exclusion Criteria

- None

Aim 1b The study population for Aim 1b is comprised of the following individuals:

- 24 physicians: two high and two low CAM referring physicians from Cardiovascular, Mother Baby, Neuroscience & Spine, Orthopedics, and Oncology Clinical Service Lines and the Hospitalist service.
- 20 nurses: two high and two low CAM referring nurses from Cardiovascular, Mother Baby, Neuroscience & Spine, Orthopedics, and Oncology Clinical Service Lines.
- 7 administrators of the Cardiovascular, Mother Baby, Neuroscience & Spine, Orthopedics, and Oncology Clinical Service Lines and the Hospitalist service.
- Integrative medicine practitioners who provide services to Cardiovascular, Mother Baby, Neuroscience & Spine, Orthopedics, and Oncology Clinical Service Lines inpatients.
- Research Assistants from the Integrative Health Research Center who enroll patients and collect data.

All Integrative Medicine practitioners and Integrative Health Research Center research assistants will be identified from the AKN or staff rosters provided by department management.

To identify prospective physician and nurse participants based on referrals, data will be obtained from the Electronic Data Warehouse (EDW). Using the 'Orders' file from EMR, three order codes will be retrieved: 207179-Acupuncture Evaluation and Treatment, 207180-IP Consult to Integrative Medicine, and 207853-

Nursing Consult to Integrative Medicine. Authorized provider and order writer names will be extracted from the file, and the physicians and nurses will be categorized according to specialty/location: hospitalist (MDs only) or clinical service line (Oncology, Cardiovascular, Mother Baby, Orthopedics and Neuroscience & Spine). Specialty/location designation will be determined by physician and hospitalist rosters obtained from the Medical Staff department and nursing rosters obtained from the Nursing department at Abbott Northwestern. Within each of the clinical service line/hospitalist and nurse groups, frequencies will be obtained to determine high, moderate, and low authorized providers for physicians and nurses. Within the high and low distribution groups, people will be randomly selected by a computer program for participation in the study. Random selection of participants will occur until two interviews are completed from both the high and the low referring groups. Dependent on accrual rates, a convenience sampling approach may be adopted.

To minimize the effects of employment length on referral rate, we will only count referrals from nurses and physicians who have continuously worked at Abbott Northwestern Hospital and had referral privileges for the previous year. Physician and nurse staff rosters will be used to identify years/dates of employment.

A. Inclusion Criteria:

- Abbott Northwestern Hospital administrator of one of the following Clinical Service Lines: Cardiovascular, Mother Baby, Neuroscience & Spine, Orthopedics and Oncology.
- Abbott Northwestern Hospital hospitalist, physician or physician with consulting privileges for one of the following Clinical Service Lines: Cardiovascular, Mother Baby, Neuroscience & Spine, Orthopedics, and Oncology.
- Abbott Northwestern Hospital nurse for one of the following Clinical Service Lines: Cardiovascular, Mother Baby, Neuroscience & Spine, Orthopedics, and Oncology.
- Abbott Northwestern Hospital Integrative Medicine practitioner who currently delivers services to patients or who delivered services to patients during a portion of quantitative data collection.
- Research Assistant at the Integrative Health Research Center, Penny George Institute for Health and Healing, Abbott Northwestern Hospital who enrolls patients and collects data on study AT006518-01 Phase II Abbott Northwestern Hospital Pain Study.
  And:
- For physician and nurse participants: Must have made at least one patient referral for integrative medicine services.

B. Exclusion Criteria:

- None

Aims 2a and 2b The target sample for Aim 2 is all Abbott Northwestern Hospital inpatients within the data collection period including both patients who did and did not receive CAM services.

A. Inclusion Criteria

- Admission to Abbott Northwestern Hospital
- Consent to release of electronic health record for research purposes
- 18 years of age or older
- Length of stay greater than 24 hours

B. Exclusion Criteria

- None

AIM 3 The target sample for Aim 3 is all Abbott Northwestern Hospital inpatients within the data collection period who received CAM services. It is anticipated that we will need to consent 7,000 participants in order to obtain enough data on approximately 3,575 participants.

A. Inclusion Criteria

- Admitted to Abbott Northwestern Hospital
- Length of stay greater than 24 hours
- Consent to release of electronic health record for research purposes
- 18 years of age or older
- Received CAM therapy in current hospitalization

- Pain level of 1 or greater at the pre-treatment assessment by practitioner
- English-speaking
- Integrative medicine therapy ended between 9:00 am and 4:00 pm

B. Exclusion Criteria

- Refuses consent
- Unable to provide consent due to competency concerns
- Has declined study participation 3 times during current hospitalization
- Has hard declined during current hospitalization
- Has been approached 6 times during current hospitalization
- Has been approached to consent earlier that day

5. Consent Process

Aims 1a, 2a, and 2b Since all the data required for Aims 1 and 2 are in the EHR, we will follow Allina Health system-wide policies for EHR data use for research. Under this policy, all patients are asked for permission to use their electronic health data for research purposes. Traditionally, the IRB approves a waiver of consent for these data. This means that data from any patient who has indicated they are unwilling to share their medical record data for research purposes (historically 4%) will be excluded from the sample. For patients who have provided general research consent, we will extract data from the EHR which includes such data as patient demographics (including street address), clinical diagnosis, age, pre-therapy and immediate post-therapy pain and anxiety scores as well as cost data (i.e., billing records).

Aim 1b The informed consent process will take place at the beginning of the scheduled interview appointment time. Staff will verbally consent the study participants for collection of interview data and separately for the recording of responses.

Research staff conducting the informed consent process will introduce the study as an investigation to describe the referral, triage, assessment, and therapy decision process for the delivery of CAM in a large hospital. Consent will be obtained for participants in a private area – either the administrator or physician's office, the Integrative Health Research Center participant rooms, or a private conference room. The consent information sheet will be reviewed with participants by the research staff, and participants will be encouraged to ask questions throughout the process. Staff will stress that this is a voluntary study and that a participant is able to withdraw from the study at any time and their employment/consulting privileges at Abbott Northwestern/Allina Health will not be affected. Only individuals able to consent of their own volition will be recruited.

Aim 3 If a patient has consented to release his/her EHR information for research purposes and meet all other eligibility criteria, they will be approached by a RA from the study. The RA will go through a verbal consent process with the patient and offer a study information sheet. The consent process will take place within the privacy of the patient's hospital room and time will be provided for the patient to ask any questions they may have. Only individuals able to consent of their own volitions will be enrolled in Aim 3. RAs will stress that this is a voluntary study and that a participant is able to withdraw from the study at any time without affecting the care they receive.

6. Data Quality and Safety Review Plan and Monitoring

A. Confidentiality

- Protection of Subject Privacy / Data – When information collected during the visit becomes part of the EHR, these data will become subject to all the privacy, confidentiality, and protection offered by Allina's EHR system, which is bound and protected by HIPAA. Although stored in an internal database separate from the EHR, the repeated pain scores (Aim 3) and interviews (Aim 1b) will be under the same level of protection. All Allina EHR data are strictly protected by password-only access, secure data archival practices, and data encryption. EHR data will only be extracted for patients who have a signed HIPAA data release form in the medical record indicating they have explicitly authorized use of their EHR data for purposes of research. Patient data that resides in the EHR will be accessed only by physicians and clinic staff and project investigators will not require access to data on an individually identifiable basis. Data security will be monitored through monthly scheduled audits, ensuring only staff from the research team are able to get to and use study data.

The majority of data used for this study is part of standard clinical practice data collection, and thus part of the patient's EHR. All EHR data will be subject to the same stringent access and security as currently applied to the EHR according to HIPAA standards. Additional measures, primarily follow-up pain scores for sub-study in Aim 3 will not become part of the patient's EHR, but will be stored in a secure database using an internal Allina application that is linked to the EHR via each patient's unique medical record number and hospital stay number. Data from these two sources (internal database and EHR) will be extracted and linked together for analyses. Data to be analyzed by the investigators of this project will have been stripped of personal identifiers and all results will be presented in aggregate.

Disruption of patients participating in the sub-study for Aim 3 will be minimized by not waking patients or interrupting care by medical providers. Additionally patients have the option of refusing any single measurement or dropping out of the study entirely.

Patients under the age of 18 will not be included in the study so there are no issues related to participation and protection of minors.

B. Confidentiality During AE Reporting

AE reports and annual summaries will not include subject-identifiable material. Each will include the identification code only.

C. Adverse Event Information

Definition – An adverse event (AE) is any untoward medical occurrence in a subject temporally associated with participation in the clinical study or with use of the experimental agent being studied. An adverse finding can include a sign, symptom, abnormal assessment (laboratory test value, vital signs, electrocardiogram finding, etc.) or any combination of these.

A Serious Adverse Event (SAE) is any adverse event that results in one or more of the following outcomes:

- Death
- A life-threatening event
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant disability/incapacity
- A congenital anomaly or birth defect
- Important medical event based upon appropriate medical judgment

Classification of AE Severity – The investigators will monitor participants, and document and report any undesirable experiences and/or events that occur during the course of the study. Severity will be determined by the PI using the following categories:

Mild: Does not adversely impact (in any way) the subject's course of wellness or illness.
Moderate: Impacts the subject's course of illness but is not life-threatening or incapacitating.
Severe: Fatal, life threatening, permanently disabling; severely incapacitating; requires/prolongs hospitalization.

AE Attribution Scale – AEs will be categorized according to the likelihood that they are related to the study intervention.

Not related: The event is clearly related to factors such as the subject's clinical state, not with therapeutic interventions associated with the study protocol.
Remote: The event was most likely related to factors such as the subject's clinical state, not with therapeutic interventions associated with the study protocol.
Possible: The event follows a reasonable temporal sequence from initiating the intervention, but is possibly related to factors such as the subject's clinical state.
Probable: The event follows a reasonable temporal sequence from initiating the intervention and cannot be reasonably explained by factors such as the subject's clinical state.
Highly Probable: The event follows a reasonable temporal sequence from initiating the intervention and cannot be reasonably explained by factors such as the subject's clinical state. In addition, the

event occurs immediately following intervention or as a direct result of intervention-initiated procedures.

Expected Risks – Due to the nature of this project, adverse events are expected to be minimal. Providing pain scores is extremely low risk for adverse events. There is potential risk for invasion of privacy, including use of personal information or the improper disclosure of information. Patients participating in the sub-study for Aim 3 with repeated follow-up pain measures may experience some disruption of their schedule. The risk and inconveniences are addressed in the protocol and consent form. Staff will be trained to keep all written and electronic data secure and confidential.

SAE Reporting – SAEs that are unanticipated, serious, and possibly related to the study intervention will be reported to the IRB and NCCAM in accordance with requirements.

Safety Review Plan – Study progress and safety will be reviewed yearly. AEs will be provided to the Independent Monitors yearly. An annual report will be compiled and will include a list and summary of AEs. In addition, the annual report will address (1) whether adverse event rates are consistent with pre-study assumptions; (2) reason for dropouts from the study; and (3) whether all participants met entry criteria. The annual report will be signed by the Independent Monitors and will be forwarded to the IRB and NCCAM. The IRB and other applicable recipients will review progress of this study on an annual basis.

D. Monitoring

Per NIH requirements, Dr. Dusek will submit the Data and Safety Monitor's annual report to NCCAM.

Data Quality and Management and Subject Accrual

Description of Plan – Data security will be monitored through monthly audits, ensuring only staff from the research team are able to get to and use study data.

Data integrity for Aim 3 relates primarily to the repeated measures collected by the RAs as well as study consent materials. After training, RAs will be shadowed by the PI, Co-Investigator, or Research Coordinator for a select number of patients to ensure that RAs are appropriately following the protocol for eligibility screening, study consent, and data collection. Repeated measures data quality monitoring will be examined by a senior research staff member to examine differences in the data collection protocol by RA. Any differences identified will be addressed through re-training, and more intense supervision of RAs.

Frequency of Data Review for this Study – Dr. Mary Jo Kreitzer and Dr. Patricia Herman will be the independent health care professionals serving as the Data and Safety Monitors. Dr. Kreitzer is the Director of Center for Spirituality and Healing at the University of Minnesota and Dr. Herman is a Research Scientist in the Health Outcomes and PharmacoEconomics Center at the University of Arizona. As shown in the table below, Drs. Kreitzer and Herman will monitor the quality of the collected data, summaries of study progress to ensure that the consent process documentation is properly obtained and stored on a quarterly basis. The monitors will also review subject accrual, enrollment and adverse events on a quarterly basis. The monitors will issue a report annually to the PI and the IRB, which will be forwarded to NCCAM.

Data type	Frequency of review	Reviewer
Subject accrual (adherence to protocol regarding demographics, inclusion/exclusion)	Quarterly	Principal Investigator, Independent Monitors

Adverse event rates (injuries)	Quarterly	Principal Investigator, Independent Monitors
Report	Yearly	Independent Monitors

7. Quantitative Statistical Analysis – Aims 1a, 2a, 2b, and 3

A. Data sources

Two sources of data will yield the information required to generate measures for analysis: **EHR data** generated by providers and **ancillary database records** generated by research assistants. Abbott Northwestern Hospital's electronic health record, an Epic product (Excellian®), contains patient demographic information, clinical information, CAM referral information, CAM provider triage outcomes, and CAM service delivery information (including detailed therapy information about each visit), and pre- and post-therapy pain and anxiety scores. ANW has had a fully-implemented EHR in place since July 2005.

In addition to data extracted from the EHR, research assistants will obtain verbal consent from patients who meet all eligibility criteria as noted above. If subjects consent, then the research assistants will collect six additional pain scores. The first pain score will be obtained from consented patients about 30 minutes after the immediate post-therapy pain score. The second pain score will be obtained 30 minutes after that, and then every hour after that up to five hours post-therapy. Anxiety scores will be collected similarly. The five hour follow-up time period was selected based on a synthesis of previous research.[12,13,16,19] Data for the pre and immediate post-service measures will be directly entered into the EHR. Subsequent pain and anxiety scores and information collected from the patient's EHR will be entered and stored into a password protected custom Microsoft Access research database along with a unique identifier to link to the EHR.

B. Data management & quality control

We will extract and create an analytic data set combining data from the EHR and the ancillary database, which will be imported into STATA (version 11), SPSS (version 18), or SAS (version 9.2) for analysis. In addition to the safeguards implicit in the electronic data collection we employ, we will conduct weekly quality checks to identify obviously erroneous and/or missing data. Validation rules will be imposed to detect invalid or out-of-range entries. Error reports will be generated and a research assistant will be charged with verification of proper values. Both missing and invalid data will be tracked to the original source of the data for verification. In cases where missing or invalid values cannot be corrected, we will use statistical methods to handle missing data (see end of analysis section).

C. Data elements

Dependent variables: For Aim 1a, we have four separate outcome variables: *CAMorder* is a classification of whether or not the patient had a CAM referral order entered into the EHR; *triage* is a three-category variable indicating the result of the triage process (i.e., patient seen; triaged to be seen, but not seen; and patient not seen); *pain* is a dichotomous variable indicating whether the patient was documented to have pain at the visit; and *CAM type*, which is an 8-category variable representing our seven CAM type(s) of interest (MB, MA, AQ, MB/MA, MB/AQ, MA/AQ, MB/MA/AQ) and a residual other.

For Aims 2a and 2b, our primary outcome variable is change in self-reported pain. *Pain change* will be modeled as the difference in self-reported pain from just before the CAM treatment and just after the CAM treatment (i.e. postpain-prepain). The pre and post pain scores will be collected by the CAM therapist. Nursing staff collect pain scores before and after all pain management interventions and these scores will be used in analyses comparing CAM and other pain management interventions on change in pain. For Aim 3, *duration of pain relief* is defined as the elapsed time from CAM therapy to sustained increases in self-reported pain. *Pain and anxiety scores* will be collected by the RAs as noted above. The corresponding curves will be modeled as a series of repeated measures up to five hours post therapy.

Independent variables and covariates: The primary independent variable and covariates for each analysis are shown in Table 2 below, where "DV" indicates dependent variable, "IV" indicates primary independent variable and "x" indicates covariate. For aims 2a, 2b and 3, the independent variables are *CAM type*, a set of

indicator variables for CAM therapy type (MB, MA, AQ, MB/MA, MB/AQ, MA/AQ, MB/MA/AQ) and *CAM dose*, which represents the amount of time (in minutes) the CAM therapy was delivered. Relevant covariates include: *demos* is a set of variables for patient demographic characteristics (e.g., sex, age, street address); *MDC* is a set of indicator variables representing aggregated medical diagnosis code groups; *M/S* is an indicator variable distinguishing medical and surgical patients; and *admtime* and *proctime* represent the time from admission and last major procedure, respectively, to CAM service; *referring unit* (refunit) is a set of indicator variables for the nursing unit that initiated the CAM referral; *camtime* is the time of day the CAM therapy was provided; *camprov* is an indicator for which CAM provider delivered the therapy; *camvis* represents the visit number (e.g., 1st, 2nd). *Opioid* and *NonOpioid* are two time-varying variables that represent the dose of either non-opioid or opioid analgesics translated into equivalent units of pain medication.[31]

Table 2. Summary of analytic variables by specific aim

			Specific Aims							
Variable	**Variable Description**	**Source**	**1.a**	**1.b**	**1.c**	**1.d**	**2.a**	**2.b**	**3.a**	**3.b**
camorder	CAM referral order (y/n)	EHR	**DV**							
triage	CAM triage outcome	EHR		**DV**						
pain	Pain as reason for visit (y/n)	EHR			**DV**					
camtype	CAM therapy type provided	EHR				**DV**	**IV**		**IV**	
camdose	Duration of CAM service	EHR						**IV**		**IV**
prepain	Pre-therapy pain score	EHR					**DV**	**DV**	**DV**	**DV**
postpain	Immediate post-therapy pain score	EHR					**DV**	**DV**	**DV**	**DV**
post30	Post pain 30 minutes	RA							**DV**	**DV**
post60	Post pain 1 hr	RA							**DV**	**DV**
post120	Post pain 2 hrs	RA							**DV**	**DV**
post180	Post pain 3 hrs	RA							**DV**	**DV**
post240	Post pain 4 hrs	RA							**DV**	**DV**
post300	Post pain 5 hrs	RA							**DV**	**DV**
DEMOS	Demographics (age, gender, etc.)	EHR	x	x	x	x	x	x	x	x
mdc	Major Diagnostic Category (MDC)	EHR	x	x	x	x	x	x	x	x
ms	Medical/Surgical indicator	EHR	x	x	x	x	x	x	x	x
admtime	Time from admission	EHR	x	x	x	x	x	x	x	x
proctime	Time from major procedure	EHR	x	x	x	x	x	x	x	x
refunit	Referring unit	EHR	x	x	x	x	x	x	x	x
camtime	Time of CAM assessment/service	EHR			x	x	x	x	x	x
camprov	CAM provider	EHR				x	x	x	x	x
camvis	CAM visit number	EHR					x	x	x	x
opioid	Time & dose of opioid analgesics	EHR							x	x
nonopioid	Time & dose of non-opioid analgesics	EHR							x	x

EHR = Electronic Health Record; RA = Research Assistant; DV = Dependent variable; IV = Indepndent variable; x = covariates

D. Analysis and interpretation of results

In this section, we briefly describe the analytic techniques to be used for Aims 1a, 2a, 2b and 3, followed by an overview of our statistical methods for handling missing data and our sample size estimates.

Aim 1a: Quantitatively describe a model for delivering CAM therapies so as to understand the selection of patients, and therapies, for pain management.

We will use a series of binomial and multinomial logit models to describe the process by which patients are referred, triaged, assessed, and finally treated with CAM for pain management. These models will allow us to predict: 1a) which patients are referred for CAM, 1b) of those referred, which patients are seen by a CAM provider, 1c) of those seen by a CAM provider, which patients are in pain, 1d) of those patients in pain, which CAM therapy is provided to address their pain. Below we outline the relevant patient population, dependent and independent variables for each of these questions.

1a.a Logistic regression model to predict who gets a CAM referral order

Population = all inpatients
Outcome = CAM referral order entered in EHR: yes or no
CAM order = demos + referring unit + MDC + M/S + admit time

1a.b Multinomial logistic regression model to predict who is seen by a CAM provider
Population = inpatients with EHR documented CAM order
Outcome = Triage status: 1-patient seen, 2-triaged to be seen but not seen, 3-patient not seen
Triage status = demos + referring unit + MDC + M/S + admit time

1a.c Logistic regression model to predict who is assessed with pain at CAM visit
Population = inpatients triaged for CAM service & assessed by CAM provider
Outcome = Practitioner assessed pain: yes or no
Pain status = demos + referring unit + MDC + M/S + admit time + camtime
(Note: We have added time of day (camtime) to control for the effects of circadian rhythm on pain)

1a.d Multinomial logistic regression model to predict what CAM therapy is provided
Population = inpatients assessed with pain as CAM visit focus
Outcome = CAM type: 1-MB, 2-MA, 3-AQ, 4-MB/MA, 5-MB/AQ, 6-MA/AQ, 7-MB/MA/AQ
CAM type = demos + referring unit + MDC + M/S + admit time + camtime + provider

For Aim 1a, all of our analyses are either binomial or multinomial logit. We will present for each model both the regression coefficients and the odds ratios for each category. We will use z-tests from the logistic regression output to assess the significance of the coefficients. Our discussion of these results will lie primarily with the odds ratios, because of their ease of interpretation. However, one disadvantage of odds ratios is that, because they are non-linear, they only reflect changes at the mean of the distribution. In our interpretation, we will also develop prototypic cases to illuminate effects at different points on the distribution.[32,33] In other words, we will calculate predicted probabilities for "ideal types" of patients, as defined by specific clinical and demographic characteristics.

Aim 1b: See Section 8 (Qualitative Data Analysis) below

Aim 2a: Examine the effects of selected CAM therapies on immediate change in pain.

We will examine the effects of MB, MA, and AQ therapies alone or in combination on self-reported pain change measured just before and immediately after service delivery. Analyses will include an assessment of the effects of type(s) of CAM therapy and amount of CAM therapy dose (i.e., minutes of service) on self-reported immediate pain change accounting for differences in demographic, clinical, and CAM visit characteristics among patients. Differential effects of CAM on immediate pain change will also be examined for selected subgroups (e.g., clinical community, initial pain status).

2a.a OLS model to estimate effect of CAM therapy type on amount of immediate pain change
Population = inpatients receiving MA, MB, AQ or any combination for pain
Outcome = amount of pain change (prepain - postpain)
Pain change = **CAM type(s)** + visit + demos + clinical

2a.b OLS model to estimate effect of CAM dose (in minutes) on amount of immediate pain change
Population = inpatients receiving MA, MB, AQ or any combination for pain
Outcome = amount of pain change (prepain - postpain)
Pain change = **CAM minutes** + visit + demos + clinical

Where: VISIT is a set of CAM visit characteristics (e.g., CAM provider, visit number [1st, 2nd, 3rd], time of day)
DEMOS is a set of patient demographic characteristics (e.g., age, sex)
CLINICAL is a set of clinical characteristics (e.g., referring unit, MDC, med/surg, admit time)

In addition to modeling results for the stated population, each model will be stratified by selected clinical communities and by initial pain score where sample size permits.

For aims 2a.a and 2a.b we will examine the data for violations of normality of the dependent variable using the Box-Cox procedure to determine the appropriate transformation as needed. For ease of interpretation, all results will be discussed in appropriately retransformed form.[34] We will estimate all standard errors using Stata's robust variance estimation option (Huber/White/sandwich estimator) to correct for violations of the

homoscedasticity assumption. We will also examine the possibility of non-linear relationships between the independent and dependent variables by introducing and testing various polynomial forms.

Interpretation of the effects of our analyses for Aim 2a is straightforward because the OLS estimators are linear. We will examine unstandardized effects (when comparing across populations) and both unstandardized and standardized effects when comparing within equations. This allows us to examine the effect of differing metrics of the independent variables.

Aim 2b: Comparison of the effects of CAM therapies vs other pain management strategies (i.e., pain medications) on self-reported pain.

2b.a OLS model to estimate effect of CAM therapies versus other pain management on amount of immediate pain change.
Population = all Abbott Northwestern Hospital inpatients
Outcome = Amount of pain change (pre-pain – post pain)
Pain change = **CAM type(s)** + demographics + clinical + opioid + nonopioid

Aim 3: Examine the effects of selected CAM therapies on duration of pain change.

We will examine the effectiveness of MB, MA, AQ alone or in combination on repeated measures of self-reported pain status over five hours after therapy to assess the distribution and decay of the pain change effect. Assessment of the effects of type(s) of CAM therapy and CAM therapy dose (in minutes) on duration of pain change will be explored using techniques for repeated measures and accounting for differences in patient characteristics as above. Growth curve modeling techniques are the current method of choice for estimating change over time.[35-38]

We will employ growth curve techniques as they overcome the many problems posed by traditional approaches such as repeated measures ANOVA and MANOVA. They are flexible and accommodate a number of problems typically encountered in repeated measures data collection, such as missing data and unbalanced designs. In addition, they are statistically more efficient than their predecessors and allow for both linear and non-linear estimation.

3.a Bayesian growth curve analysis to estimate the duration of pain change and the shape of the pain curve by CAM therapy type
Population = inpatients receiving MA, MB, AQ or any combination for pain
Outcome = repeated measures of pain change over time
Pain change = **CAM type(s)** + visit + demos + clinical + pain meds

3.b Bayesian growth curve analysis to estimate the duration of pain change and the shape of the pain curve by CAM therapy dose
Population = inpatients receiving MA, MB, AQ or any combination for pain
Outcome = repeated measures of pain change over time
Pain change = **CAM dose** + visit + demos + clinical + pain meds

Where: VISIT is a set of CAM visit characteristics (e.g., CAM provider, visit number [1st, 2nd, 3rd], time of day)
DEMOS is a set of patient demographic characteristics (e.g., age, sex, etc.)
CLINICAL is a set of clinical characteristics (e.g., referring unit, MDC, med/surg, admit time)
PAIN MEDS is two time-varying covariates that represent non-opioid and opioid analgesics

Similar to Aims 2a and 2b, in addition to overall models for Aim 3, we will stratify each by selected clinical communities and by initial pain score as sample size permits.

The interpretation of results for aim 3 will be presented in graphical form. Using the estimated parameters from the growth curve we will draw the curve for each population of interest. This provides a more intuitive view of the results than simply reporting the coefficients and very clearly illustrates both the amount and duration of pain reduction for each analysis. Duration of pain reduction will be defined as the inflection point of the growth curve after smoothing.

E. Treatment of missing data

As noted previously, during the data collection and quality control process, research assistants will attempt to verify any missing data through chart review or follow-up. Missing values will be flagged, documented, and manually corrected in the analytic database. When no additional information can be used to manually correct missing information, a statistical approach will be used.

Analytic datasets will be assessed to understand patterns of missing data (i.e., MCAR, MAR). Even in cases where data are missing completely at random (MCAR), we prefer not to case-wise delete because of the impact on sample size and standard errors. Rather, we will use accepted "hot deck" methods to impute missing data for the independent variables and covariates.[39] Specifically, we will use the *hotdeck* procedure for Stata to impute missing values.[40,41] Following standard practice, we will not impute missing dependent variables.

In the case of missing repeated pain measures for Aim 3, the approach to growth curves that we propose to use accommodates unbalanced designs and thus reasonable amounts of missing data pose no problem to the estimation of effects. As long as each subject has 2 or more repeated pain measures, they can be included in these models without biasing estimates of the models' coefficients.

F. Sample size estimation

Given our 5+ years of providing CAM at Abbott Northwestern Hospital, we have a reasonably good estimate of the number of patients who will receive each of the three CAM therapies to relieve their pain. We anticipate that, based on our current workflow, we will see approximately over 200 patients per month who receive a CAM therapy for pain management. We are planning for a 30 month data collection period, which will yield approximately 6,000 patients in our target population. There will of course be attrition at several steps of the process. The first is a patient's refusal to sign the general research consent for use of medical records for research purposes, which all patients are asked to sign at admission. At Abbott Northwestern Hospital, roughly 96% of all patients sign this consent. Data from individuals who do not provide this consent will neither be approached for study participation (Aim 3), nor will their medical records be used (Aims 1a, 2a, 2b). The second point of attrition will be missed opportunities, which result from the inability of an RA to respond to a therapist's request to recruit and consent a patient. We estimate this, from our experience shadowing therapists as they provide the CAM intervention, to be not more than 20% lost. Our last point of attrition is the patient's refusal to consent to the collection of additional pain scores (Aim 3). We estimate this to be no more than 25% as the additional data collection is both nominal and non-intrusive. Note that the second and third points of attrition do not affect the sample size for Aims 1a, 2a and 2b. **This approach yields an anticipated sample size of approximately 5,900 subjects for Aim 2 and 3,575 for Aim 3.**

We performed a traditional power analysis for our anticipated Aim 3 sample size, a more conservative approach than powering for Aim 2, using the historical number of patients by CAM therapy type. This yields an anticipated sample of 793 patients receiving mind/body, 627 patients receiving acupuncture, and 2,157 patients receiving massage. Using the smallest of these, acupuncture, and assuming a type I error rate (alpha) of 0.05 and a power of 80%, we can estimate average immediate pain reduction within plus/minus 4%. Because of the Bayesian repeated measures techniques that we will employ to analyze the duration of pain data, we are confident that these sample sizes will provide estimates that are at least as precise as the plus/minus 4% obtained for the immediate pain change analysis.

Aim 1a is a purely descriptive analysis, which serves to provide context for Aims 2 and 3. As such, we did not perform a power analysis. However, with an estimated sample size of more than 83,000 patients over 30 months, we feel confident these equations are adequately powered to address substantive differences.

In our research experience, it is sometimes the case that our attrition assumptions are not accurate. We have powered this study for 30 months of data collection, but our timeline allows for up to 36 months of data collection. We did this to assure that at the end of our data collection period, we can reasonably expect to have met our sample size goals.

8. Qualitative Data Analysis – Aim 1b

Our analytical methods will adhere to common practices in the field of qualitative analysis; as such, statistical tests are not applicable.

Investigators and study staff will read the transcripts from all interviews conducted, identifying themes that emerge from the transcripts relating to the research questions. Atlas.ti version 7 software will be used to organize and code transcripts and visually represent relationships between codes and themes as they emerge. This process will occur sequentially, as typed interview transcripts become available, so that we can use insights

from earlier interviews to inform later interviews. Interview questions will be used to establish a basic coding structure, which will be combined with inductive analysis, as described by Patton[42] and drawing from Glaser and Strauss's "grounded theory."[43] The inductive analysis process involves open coding to develop codes, categories, patterns, and themes. These elements are then refined, finally using deductive processes to form analytical hypotheses about the data. Within each of the five types of interviewees, the themes identified in the first few interviews will be tested against evidence gathered in subsequent interviews and against the data gathered in interviews with respondents in the other three respondent categories. Themes will be refined and modified as data accumulate throughout the interviewing process. The evolving coding scheme will be discussed during periodic team meetings.

All transcripts will be verified to assure accuracy by comparing the transcript to the audio file. Should we find significant quality problems in the early transcripts, we will address these problems by working with the transcriptionist or hiring a new transcriptionist.

Intercoder reliability (i.e., consistency in the application of codes to the text) will be measured on a subset of data (15%) by computing the ratio of the total number of disagreements in code applied to the total number of items coded by the two coders. If necessary, discrepancies will be resolved with the assistance of a third investigator, and a second round of intercoder reliability testing will be conducted until we reach a reliability level of .90, before the two primary coders code the remaining transcripts.

9. Anticipated Results and Potential Pitfalls

This research, if positive, will help focus attention on leveraging integrative medicine, which adds CAM as an adjunct to traditional care, as a mechanism to address pain management. In addition, the methodological approaches employed in this research can be transferred to other outcomes, many of which are related to pain, including anxiety, stress and nausea. This research will also enable a long-term focus on the cost effectiveness of an integrative model.

The results of the proposed study will provide critical guidance to both physicians and CAM practitioners on how best to balance the use of pharmaceutical interventions and CAM to manage patients' pain. In addition, managing patients' pain remains one of the highest priorities in hospitals. If we demonstrate CAM is an effective adjunct to traditional pain management, hospitals will have a new tool, and the beginnings of an evidence base to use that tool, in meeting the pain management goals of the Joint Commission[44,45] and ultimately, of patients.

We have carefully considered several challenges in the design of this study. First, since we propose collecting additional pain scores on a large number of patients, it is possible that the attrition rate will exceed our anticipated 25% and require a longer data collection period. While this might be a concern for applicants proposing to implement a new CAM service, our estimates are based on 5+ years of providing CAM at Abbott Northwestern Hospital. Regardless, should it be necessary, we could recruit the required patients in 36 months rather than the 30 months proposed and still meet our enrollment goals.

Second, since we will be studying the effectiveness of CAM therapies on pain management in a non-controlled research setting, patients will receive opioids and other pain analgesics as part of their standard clinical care. The issue is whether the provision of pharmacologic pain interventions will interfere with our ability to examine the effects of CAM therapies on duration of pain change. Anticipating this possibility, we can reliably access the EHR to document the time/day of all pain medications provided during patients' hospital stay. We have included in our analytic plan accepted procedures for comparing differences in type and dose of these opioid and non-opioid analgesic medications.

Third, it is possible that collecting repeated pain scores for up to five hours may not capture the complete pain reduction curve. However, the decision to use a five hour duration was based on 3 factors: (1) we used comparable timepoints as previous studies;[12,13,16,19] (2) five hours is approximately the same duration of typical dosing of narcotic pain medications;[46-48] and (3) there are logistical barriers to longer data collection (e.g., patients sleeping), which would lead to an unacceptable amount of missing data.

Finally, our proposed study will result in data based on the experience of patients in one hospital, which raises the concern of generalizability. While this may be a concern for a hospitals serving one type of patient population (e.g., cancer or pediatrics), our study would take place in a typical tertiary hospital suggesting that its experience will be generalizable to a considerable degree to other tertiary hospitals across the US.

10. Risk/Benefits and Reporting

This study involves no physical or psychological risks. There are minimal risks to the confidentiality and privacy of participants. Risk is limited to the possible breach of confidentiality of the pain and anxiety scores and interview data. The probability and magnitude of risk is small. Risks are minimized by using a limited access, password protected database as well as using the smallest number of identifiers necessary. The Data Safety Monitoring Plan outlines the procedures for identifying and reporting any adverse events. There are no direct benefits to participants. We hope that information learned from this study will help us better understand CAM therapies for pain and anxiety management.

11. Regulatory and Ethical Considerations

This study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with the Belmont Report, Good Clinical Practice and applicable regulatory requirements. The study will be conducted in accordance with the regulations of the United States Food and Drug Administration (FDA) as described in 21 CFR 50 and, applicable laws and the IRB requirements. The study's data will be made available for monitoring, auditing, IRB review, and regulatory inspection by providing direct access to study-related source data.

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Interview Protocol

Physician/Nurse

I am going to start by asking you some questions about your background and present position. Then we will discuss the considerations that go into making a referral for integrative medicine services and discuss your feelings about how the process is working, and how it could be improved. There will be time at the end of the conversation for you to add your thoughts on any relevant topics that we have not covered. Can we begin?

1. How long have you been at Abbott? How about in your present position? Please briefly describe your responsibilities in the Hospital. **(IF PHYSICIAN)** Are you employed by Abbott Northwestern Hospital or employed by an outside practice and affiliated with Abbott Northwestern?
2. Have you or your family members ever received integrative services? Which modalities have you/they utilized?
3. Do you ask your patients about any potential integrative therapies they may be utilizing outside of the hospital?
4. **(IF NURSE)** Have you taken the Transformative Nurse Training (TNT) program?
5. Please describe training (other than TNT) that you have received regarding integrative medicine services at Abbott? When did that training occur? What were the most valuable features of the training?
6. For Nurses: Do you personally use any integrative medicine therapies on your patients (such as aromatherapy or massage)?

ASK QUESTION 7 IF THIS IS A LOW-REFERRING PHYSICIAN/NURSE
ASK QUESTIONS 8-13 IF THIS IS A HIGH-REFERRING PHYSICIAN/NURSE

7. Our records indicate you refer patients infrequently for integrative medicine services. Are you aware that your patients currently can receive integrative medicine services? Approximately how many referrals for integrative medicine would you estimate you have made in the last three months?
   a. What factors have been the most important to you when deciding not to make a referral? (probe: patient characteristics, time required, hassle, concern about effectiveness of treatment, other)
   b. Are there circumstances that make it more likely that you would consider making a referral? If so, what are they?
   c. **(IF PHYSICIAN)** Do you work regularly with any nurses who make referrals on your behalf? If so, for what services?
   d. Do you feel as though you have been provided sufficient evidence to support the safety/efficacy of integrative therapies? Do you seek out information about integrative therapies?
   e. Is there anything else I should know about your views concerning referring patients for integrative medicine services?
   f. What is your overall impression of the usefulness or value of having integrative medicine services available to patients at Abbott? How do you think other [physicians/nurses] feel about the integrative medicine services? (Does the referral system, e.g. the time between referrals and service for inpatient integrative medicine services, affect how you utilize this service?)
   g. Is there anything we haven't covered that you think I should understand? Thanks, I appreciate your willingness to talk with us.

[END INTERVIEW]

8. About how many referrals for integrative medicine would you estimate you have made during the last three months? Can you recall the approximate percentage of these referrals that were for acupuncture? For other services?
9. How do you identify patients who seem appropriate for referral versus those who do not? Please describe a recent patient referral.
    a. Do you use any specific criteria related to a patient's medical condition when deciding to make a referral?
    b. Are patients generally aware of the availability of integrative medicine services? About what proportion of the referrals you make are in response to the requests of patients who are aware of the services before you mention them? When this is the case, what are typical patient expectations about integrative medicine services?
    c. For patients who are unaware of the services, do you generally discuss the services with them before making a referral? Or, do you refer without discussing the services with patients first? What factors would lead you to refer to integrative medicine services without first discussing the services with patients? Can you describe a recent referral that occurred in this way?
    d. Once a referral is made, is the referral communicated to the patient or the patient's family? If so, how? What proportion of the referrals you make do you typically communicate the referral to the patient?
    e. What proportion of the referrals you make do family members play a role in the referral process? When they are involved, do family members generally support referrals to integrative medicine services or do they oppose them?
    f. What proportion of the referrals you make does the patients' family initiate the discussion about a referral? What happens when you disagree with the family's request for service in general or a type of service in particular? How do you resolve differences in opinion about the referral?
    g. Please describe a recent instance of family involvement in the referral process?
    h. **(IF PHYSICIAN**) In what proportion of the referrals you make do the nurses play a role in the referral process? When they are involved, do the nurses generally support referrals to integrative medicine services or do they oppose them? In what proportion of the referrals you make do you initiate the discussion about a referral as opposed to a nurse initiating the discussion? What happens if you and the nurse disagree with a request for a referral in general or a type of service in particular? How do you resolve differences in opinion about the referral?
    i. **(IF NURSE)** In what proportion of the referrals you make do physicians play a role in the referral process? When they are involved, do physicians generally support referrals to integrative medicine services or do they oppose them? In what proportion of the patients initiate the discussion about a referral as opposed to a physician initiating the discussion? What happens if you and the physician disagree with the request for a referral in general or a type of service in particular? How do you resolve differences in opinion about the referral?
10. Generally, after you make a referral, are you aware of when (if) integrative medicine services were delivered?
    a. How do you become aware that services were delivered? By asking patients if they have received the services? By checking the patient's record? By asking staff?
    b. Have any patients complained to you that services were not delivered? (How often do you think this occurs?) If this happens, how do you respond?
    c. Do you ever check the notes of integrative medicine providers? If so, what do you find the most useful features of these notes? If not, why don't you check their notes?
11. In general, how well has the referral process for integrative medicine services worked for you?
    a. What works particularly well about the process?

b. What parts of the process could be improved? What issues have you encountered? What is the single most important thing that could be done to improve the referral process?

12. What is your overall impression about the usefulness or value of having integrative medicine services available to patients at Abbott? How do you think other [physicians/nurses] feel about the integrative medicine services?
13. **(IF THERE IS TIME)** Have you interacted with research assistants from the Pain Study? What are your impressions of the interactions between the RAs and yourself/your team? What are your impressions of interactions between the RAs and patients?
14. Is there anything we haven't covered that you think I should understand? Thanks, I appreciate your willingness to talk with us.

[END INTERVIEW]

Interview Protocol

Clinical Service Line Administrator

I am going to start be asking you some questions about your background and present position. Then we will discuss your views about the usefulness of having integrative services (massage, acupuncture, aromatherapy, guided imagery or meditation) available for hospitalized patients in your service line, your assessment of physician knowledge of these services and their receptivity to using them, and the differences in views between physicians in your service line who are regular users of integrative services versus those who do not use these services. There will be time at the end of our conversation to discuss any topics relevant to use of integrative services in your service line that we may not have covered. Can we begin?

Personal background:

1. Please describe your responsibilities in your current position at Abbott. How long have you been in this position? What did you do prior to this?
2. Have you or any of your family members ever used integrative services either outside of the hospital or while hospitalized? What services were used? What was your experience? Were the services judged to be effective or ineffective?

Knowledge of integrative services and their use by service line physicians and nurses:

3. In general, do you believe that physicians in your service line are aware of the availability of integrative services for their patients hospitalized at Abbott? About what percent do you think are aware? What is your basis for assessing physician awareness?
4. In your experience, has there ever been any discussion of integrative services at any staff meetings attended by physicians in your service line? If so, what was the nature of that discussion?
5. Have you received any feedback from your physicians about the availability of integrative services? The referral process used to access these services for their patients? Patient satisfaction with the services received as a result of a referral? Please discuss the type of feedback (if any) that you have received from your physicians. Is there a consensus or a consensus that seems to be forming? If so, what would that be?

Assessment of integrative services by service line physicians and nurses:

6. In general, do you believe the physicians in your service line support having integrative services available for their patients hospitalized at Abbott? Can you provide a sense of the range of support or opinions on this issue? What issues are typically raised regarding physician support, or lack of support, for integrative services? (e.g. time and hassle required to order services, concern about evidence basis supporting treatment, concern about effectiveness of treatment, other).
7. Can you provide a recent example of a discussion with a physician in your service line about any aspect of integrative services at Abbott?

Personal perspective on integrative services:

8. What is your own opinion about the value of having integrative services available at Abbott for patients in your service line? What do you see as the pros and cons?
9. In your own practice, have you referred patients for integrative services?
   If referrals were made:
   a. What factors typically are the most important to you when making a referral?

b. In general, how well has the referral process for integrative services worked for you?Is there any part of that process that worked particularly well? How could the process be improved?
c. How do your patients react to the services?

Summary questions:

10. What is your overall impression of the usefulness or value of having integrative medicine services available to patients at Abbott?
11. Overall, do you think these services provide value to you as a physician? To your patients? To the hospital?
12. Is there anything we haven't covered that you think I should understand?

[END INTERVIEW]

Referrals to Integrative Medicine in a Tertiary Hospital: Methods Appendix

Selection of Interview Participants

We set out to recruit 46 participants, comprised of physicians, nurses, and administrators at Abbott Northwestern Hospital (ANW). Our goal was to interview individuals representing various clinical service lines in the hospital: Cardiovascular, Mother Baby (maternity care), Neuroscience and Spine, Orthopedics, and Oncology, as well as physicians and an administrator in the Hospitalist Service. Physician and nurse participants had to have made at least one patient referral for integrative medicine services in the year before we created our list of prospective participants. Additionally, for nurses and physicians, we were interested in speaking with both "high referring" and "low referring" providers, that is, those who had a recent history of placing either many or very few orders for integrative medicine. The prospective study sample was as follows:

- 24 physicians: two high and two low IM referring physicians employed by or affiliated with Abbott Northwestern Hospital from the Cardiovascular, Mother Baby, Neuroscience and Spine, Orthopedics, and Oncology clinical service lines and the Abbott Northwestern Hospitalist Service.
- 16 nurses: two high and two low IM referring nurses from the Abbott Northwestern Hospital Cardiovascular, Mother Baby, Neuroscience and Spine, and Oncology clinical service lines. (It was decided the orthopedics nurses would not be included because their department generally relies on standing orders for IM, a process in which they do not have a role in decision making or placing orders.)
- 6 administrators (i.e., the acting physician lead) of the Cardiovascular, Mother Baby, Neuroscience and Spine, Orthopedics, and Oncology clinical service lines and the Hospitalist service.

Administrators were identified based on the study PI's (JD) knowledge of who the acting physician leads were for each service line. To identify prospective physician and nurse participants based on referrals, data were obtained from the hospital's Electronic Data Warehouse (EDW). To minimize the effects of employment length on referral rate, we only counted referrals from nurses and physicians who had continuously worked at Abbott Northwestern Hospital and had had referral privileges for the previous year. Nurses were required to be FTE>.6 at the time of the study to be considered eligible. Physician and nurse staff rosters were used to identify years/dates of employment and FTE. Using the 'Orders' file from the EHR, three order codes were retrieved: 207179-Acupuncture Evaluation and Treatment, 207180-IP Consult to Integrative Medicine, and 207853-Nursing Consult to Integrative Medicine. "Authorized provider" and "order writer" names were extracted from the file. A list of eligible nurses was generated by comparing a roster of nurses with a list of orders placed for IM services. The same process was used for physicians. Physicians and nurses were categorized according to specialty/location: hospitalist (physicians only) or clinical service line (Oncology,

Cardiovascular, Mother Baby, Orthopedics [physicians only], and Neuroscience and Spine). Specialty/location designation was determined by physician and hospitalist rosters obtained from the Medical Staff department and nursing rosters obtained from the Nursing department at Abbott Northwestern. Within each of the clinical service line/hospitalist and nurse groups, frequencies were obtained using SAS to determine high, moderate, and low referring provider status for physicians and nurses. High and low referring providers were identified (again, using SAS) by way of randomly ordering each list and isolating the top 10 percent most frequent referrers (high) and anyone with two or one referrals (low: two or fewer referrals constituted the bottom 50 percent of the population).

Random selection of physician and nurse participants was intended to occur until two interviews were completed from both the high and the low referring groups for each clinical service line. However, because interview transcripts were coded and analyzed as they became available (see Processing, Coding, and Analyzing Data below), data saturation was reached before completing all 24 physician and 16 nurse interviews.

Recruitment and Scheduling

JD initially proposed the study to all potential participants via an emailed letter. A "Common Questions" document and a consent information document accompanied the email letter and provided additional details on the study. Following low initial response rates in all groups, follow-up contacts were made in the following ways:

- Administrators: Follow-up phone calls or emails from JD to administrators and/or their administrative assistants.
- Physicians: A hard copy packet sent by FedEx or internal mail, depending on office location. Packets contained a signed copy of the invitation letter from JD, a signed copy of a generic support letter for the study (addressed "Dear Colleague") from the clinical service line administrator to any physician in that administrator's service line, the common questions sheet, and the verbal consent information. These packets were followed by a phone call and/or email from study coordinator KG asking for confirmation of receipt and inquiring as to interest in participation.
- Nurses: A hard copy packet sent by internal mail. Packets included a signed copy of the invitation letter from JD, a signed copy of a generic support letter for the study from the head of nursing at ANW, the common questions sheet, and the verbal consent information. These packets were followed by an email from KG inquiring as to interest in participation.

If a potential participant was interested in learning more about the study and/or scheduling an interview, they were asked to contact KG. KG scheduled all interviews and tracked recruitment status in a private Excel spreadsheet. Those who declined to participate communicated to KG that they were not interested (no reason given); had family/scheduling commitments or were too busy; or had recently retired. Other individuals provided no response after the initial invitation

and a series of follow-up communications, and were considered not interested in participation. Seventy invited individuals either did not respond or declined to participate (36 physicians and 34 nurses). Decisions to participate were communicated either to JD or KG via email or telephone. A total of 37 individuals participated (also see Figure):

- 15 physicians
- 15 nurses
- 7 administrators. This group included two administrators associated with the Neuroscience and Spine service line, because this service line was undergoing a leadership transition during the study period. One of the two neuroscience and spine interviews was not used when it was determined that that administrator's duties were primarily outpatient-focused.

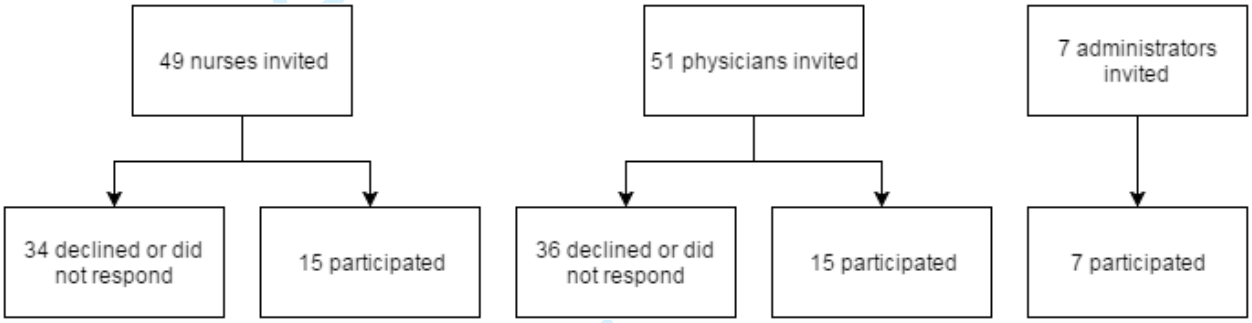

Figure: Recruitment of interview participants

Eight of the physicians, two of the administrators, and all of the nurses interviewed were women.

Recruitment began on March 19, 2014 and was completed on April 7, 2015. As mentioned above, data saturation was reached before completing all 24 physician and 16 nurse interviews. These two groups were also more challenging and time-intensive to recruit and schedule. Recruitment was completed for administrators.

Interviews and Consent Process

Interviewers

KG began the study as a Research Coordinator and her title changed to Associate Scientific Advisor during the course of the study. KG was trained in qualitative research methods and analysis and participated in qualitative data collection, management, and analysis on a range of projects for several years before this study. JC was an experienced qualitative researcher. As a consultant on the study, he designed the protocol and interview questions. Before data collection, the interviewers participated in a practice interview session to establish similar approaches to using the interview protocol with prospective participants. Neither interviewer had any interaction before the study with the participants interviewed.

Interviews

KG conducted 35 interviews among the administrators, physicians, and nurses. JC was in attendance for one of the nurse interviews. JC conducted two administrator interviews (with KG in attendance). Interviews were conducted between May 1, 2014 and April 16, 2015. Nurse interviews were conducted either in a private room at the study team office or in a quiet and unoccupied seating area near the hospital's main lobby. Nurse interviews were generally scheduled for a window of time before or after the nurse's shift. Physician interviews were conducted either at the physician's office or in a quiet and unoccupied seating area near the hospital's main lobby or another lobby area in the hospital (e.g. lobby of the Mother Baby Center). One physician interview was conducted in an unoccupied examination room near where the physician was working that day. Physician interviews were frequently conducted on same-day short notice, when the physician had a window of availability during a shift. Administrator interviews were held either at the administrator's office or in a private meeting room elsewhere in the hospital.

Separate interview protocols were used for each type of participant, having been created by the research team and approved by the IRB. Questions went through several rounds of revisions by the team, and were tested in practice interview sessions among the interviewers. An interpretivist paradigm was used in creating the interview guides and subsequently in analyzing the data. As data collection was underway, some commonly-used prompts were added after receiving approval from the IRB. Administrator questions addressed professional background, personal experience with IM, their assessment of the knowledge and support of IM services by providers in their service line, and personal perspectives on IM. Nurses were asked about professional background/role, personal and professional experience with IM, use of the IM referral system, and interactions with patients and patients' family members regarding IM services.

Interviews ranged from six to 28 minutes. Interviews were shorter than the estimated 30 to 45 minutes, due to time constraints of the participants (e.g., most physicians fit the interviews into the midst of a clinic day or on-call shift at the hospital). Each participant was interviewed only once. All interviews were recorded on a handheld Olympus DM-620 digital voice recorder, and immediately following the interview the digital files were saved to a private folder on the server only accessible to interviewers, and erased from the recording device. Notes were made by the interviewer during and/or after each interview. Immediately following each interview, these notes were scanned and saved to a private folder on the server only accessible to interviewers, and hard copies were securely destroyed.

Consent Process

The verbal informed consent process took place at the beginning of each interview, before recording was begun. Participants were asked if they had read and understood the consent information (provided during recruitment) and were given the option to take another hard copy of the information with them. For participants who had not read the information or wished to be

reminded of its contents, the interviewer reviewed key points of the document. Participants were asked if they agreed to be audio-recorded. All said yes without hesitation. Once recording began, each participant was asked again to confirm that she or he agreed to be recorded. At the conclusion of each interview, the interviewer confirmed that she was stopping the recording device. Only individuals able to consent of their own volition were recruited and interviewed.

Processing, Coding, and Analyzing Data

Interview audio files were transcribed in batches by two experienced transcriptionists hired through a local temporary employment agency. Either Olympus Sonority or Olympus DSS Transcription Module software was used for audio file playback, with files removed by KG from the playback software immediately after each transcriptionist's workday concluded. Only one transcriptionist worked at a time; the second was hired when the first moved away and was no longer available. A transcription protocol[1] was used to ensure consistency, and all transcripts were checked against the corresponding audio file by KG, with corrections made as necessary. Completed transcripts were saved in a secure and private folder on the server only accessible to the interviewers. Transcripts were not returned to participants for review.

KG and KCN used Atlas.ti version 7 to organize and code transcripts. This process was ongoing, as transcripts became available. The interview protocol questions were used to establish a basic coding structure, to which inductive analysis[2] principles then were applied. The inductive analysis process involves open coding to develop codes, categories, patterns, and themes. These elements then are refined, using deductive processes to form analytical hypotheses about the data. Different code catalogues were created for each participant group (i.e., physicians, nurses, and administrators). KG and KCN met regularly (weekly, in most cases) to discuss the coding process and the emerging catalogue of codes. Intercoder reliability was established early in the coding process by way of KG and KCN coding several of the same transcripts and comparing findings, which were overwhelmingly similar. JC and another consultant, Dr. Michael Finch, also met once with KG to review a sample of transcripts and review the accompanying codes that were associated with each interview question. KCN completed the majority of the coding and then created documents for each participant type in which he summarized primary findings by question, in addition to any other notable themes that had emerged in each participant group.

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