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Adapting Productivity Models to Improve Efficiency and Progress in Clinical Research Practice

Kara Lorduy, PhD, CCRP; Victoria Brown, PhD, MBA, CIP, CCRP; Suzanne J. Rose, MS, PhD, CCRC

According to a recent report on “U.S. Investments in Medical and Health Research and Development,” the biopharmaceutical industry spent approximately $15 billion in direct costs in the establishment of roughly 4,500 clinical trials in the United States in 2017. These sponsored trials included more than 920,000 participants.\(^1\) Considering that 86% of trials in the United States fail to enroll before the contracted period,\(^2–4\) a research program’s stewardship of qualified and well-trained study coordinators, who are tasked with balancing ever-increasing regulatory demands and protocol complexity,\(^5\) is paramount to its success.
This paper surveys the current state of the field and compares two similar adaptations of the Ontario Protocol Assessment Level (OPAL) in tracking productivity at their respective research programs. The findings provide a compelling case for improved efficiency and productivity, increased job satisfaction and retention, and higher levels of funding over prolonged use of adaptive productivity metrics.

**Background**

It is well known that coordinating a successful research program has become very challenging in today’s clinical research environment, due in part to greater protocol complexity, fewer available studies, decreasing site budgets, high levels of staff burn-out, and an increased regulatory burden. In addition, research sites are often expected to project staffing needs in order to bring on new trials, maintain existing ones, and stay abreast of the regulatory demands for multiple studies. In order to manage the workload of these studies, there is a need to better understand the time, personnel, and financial resources needed to conduct clinical trials. The benefits of this focus include increased enrollment success, funding, efficiency, quality, and job satisfaction and retention of study coordinators.

Historically, federally funded research programs have been guided by the 1992 National Cancer Institute (NCI) Cancer Clinical Investigations Review Committee algorithm of 1.0 full-time equivalents per 40 enrollments. However, meta analyses across 51 research programs alongside many other pivotal developments in this arena have led to a growing consensus that productivity models should incorporate complexity, or acuity, as well as the regulatory and administrative tasks in their metrics.

Recent attempts have been made by various groups and sites to develop workload tools that adequately address the true workload of clinical research coordinators (CRCs). The tools formulate the workload effort through various mathematical calculations. In an effort to portray the evolution of efficiency in clinical research practice, we depict the replication of the OPAL metrics on improved efficiency at one site (Children’s Health System of Texas) following one year of implementation productivity metrics, while another site (Stamford Health)
presents the compounding benefits of adapting the OPAL protocol acuity rating metrics to comprehensively include additional workload factors, coordinator roles, and phases of the study cycle in the Clinical Research Workload Tool (CRWT) across eight years.

OPAL and the CRWT overlap in terms of using an eight-point protocol score, or multiplier toward the total enrollment number, with simple studies (e.g., registries) rating “1” and complex studies (e.g., Phase I) rating “8.” Comprehensive, the CRWT model adjusts the protocol score considering the study role contributions (i.e., data, regulatory, nurse, and coordinator) and adds weights to the score for each additional workload factor (e.g., industry trials, duration or number of visits) to comprise a CRWT score or multiplier toward total number of active enrollments before adjusting for the phase of the study (e.g., start-up, enrolling, follow-up).

Importantly, our findings support the growing body of knowledge regarding the adaptation of metrics originally explored in oncology research programs for use in these two non-oncology research programs at two distinct phases in their development of adapting OPAL-based metrics. The non-oncology programs aimed to develop a common currency of productivity that could be benchmarked and leveraged to improve efficiency and progress in their clinical research practice.

**Methods**

To reiterate, we present two research programs utilizing an adaptation of the OPAL productivity metrics. The first site, Stamford Health, collects data relational to use of the CRWT model across eight years. The second site, Children’s Health System of Texas, collects data relational to use of another adaptation of the OPAL metrics in the first year of implementation.

*Stamford Health*

The CRWT was developed based on the OPAL workload planning tool. Stamford’s model also allowed for an “other” category, which was determined at the site level for an extenuating circumstance that added protocol complexity. With the addition of the complexity modifications, the total CRWT score could amount to as high as 12.
In addition, another novelty the CRWT accounts for is that, at Stamford, regulatory coordination and data management tasks are assigned to other personnel than CRCs. To account for the regulatory and data management burden not being part of the typical CRC’s daily workload, the CRWT offers additional reductions in workload by 25% per additional resource based on a previous workload study in which coordinators recorded their time spent on protocol management, eligibility, and entry, treatment, follow-up, and final stage. Approximately 25% of clinical research associate (study monitor from a sponsor or contract research organization) time recorded was spent on protocol management (regulatory coordinator responsibilities) and 25% of time on follow-up and final stage (data manager responsibilities).{19}

Data were collected over an eight-year period. CRWT scores for 14 coordinators were recorded on a monthly basis. A total of 606 CRWT scores were calculated in this time period ($M=117$, $SD=57.47$).

*Children’s Health System of Texas*

In a similar adaptation of OPAL, the enrollment-derived productivity of a separate, non-oncology clinical research program in the first year of implementation (T1=January 2017; T2= January 2018). Consistent with the methodology defined previously,{6} all protocols included in the research program’s portfolio were scored. Children’s Health then examined the workload of 10 experienced CRCs. The total workload (the DEVO score) for each coordinator was constituted by two components: 1) enrollment derived productivity using the OPAL (i.e., the OPAL score) apprised workload method{9} and 2) all contributions made to the developmental department initiatives (the DEV score) including, but not limited to, writing standard operating procedures, internal quality reviews, and training (see Figures 6 and 7).

The DEV scores were computed by adding additional points to overall workload score by counting the total number of hours spent across four primary categories (regulatory, training, developmental, and patient care) reported in a time tracking system and dividing them by a factor of two. Additionally, coordinators completed a five-point Likert scale assessing their perceived fairness of the metrics system, as well as how likely they were to “still be working at the department two years from now” and their overall job satisfaction.
Results

Study Conducted at Stamford Health

Figure 1 shows characteristic CRWT monthly score profiles over a four-year period for two full-time oncology (CRC 2 and CRC 3) and three non-oncology (CRC 1, CRC 4, and CRC 5) coordinators who worked four years contiguously.

![Figure 1](image)

**Figure 1**: Workload is highly variable among full-time oncology and non-oncology coordinators.

Oncology coordinators average a higher workload ($M=193.5$, $SD=17.78$) than non-oncology coordinators ($M=104.5$, $SD=36.13$). The difference in means was highly significant by a $t$-test for two independent groups, $t(45)=-10.13$, $p<.001$. This can be attributed in part to the higher number of trials that oncology coordinators ($M=19.25$, $SD=1.86$) conduct versus non-oncology coordinators ($M=8.14$, $SD=4.06$). The difference in means was highly significant by a $t$-test for two independent groups, $t(45)=-11.34$, $p<.001$.

Based on frequent coordinator assessment of their workload (too light, moderate, heavy, or unbearable) and capability of conducting assigned studies (yes, somewhat, no), four categories were assigned (see Table 1).
### Assigned Study Coordinator Ranges

<table>
<thead>
<tr>
<th>Range</th>
<th>Zone</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;100–125</td>
<td>light green</td>
</tr>
<tr>
<td>126–150</td>
<td>Green</td>
</tr>
<tr>
<td>151–175</td>
<td>Orange</td>
</tr>
<tr>
<td>175–200+</td>
<td>Red</td>
</tr>
</tbody>
</table>

**Table 1**: Coordinators in the light green zone were usually new research coordinators. Coordinators in the green and orange zones were more confident with workload and most capable of taking on new studies. Coordinators in the red zone often felt overworked.

In addition to calculating monthly CRWT numbers, annual revenue productivity per coordinator was calculated and adjusted according to whether the coordinator left the institution. A scatter plot of annual revenue and average annual workload was created, and Pearson’s Correlational analyses were used to examine the relationship between the annual revenue and average annual workload (see Figure 2).

![Figure 2: Scatter plot showing the relationship between annual revenue and average annual workload.](image)

**Figure 2**: For non-oncology coordinators, a higher workload correlated to greater revenue generation. There was a strong statistically significant positive correlation between average annual workload ($M=104, SD=36.13$) and annual revenue ($M=$121,697; $SD=$63,681), $r=.62$, $p<.001$, $n=27$. 

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---
The positive correlation does not appear to be related to variation in study characteristics, as they did not vary greatly during the eight-year period, as shown in Table 2. Studies are categorized as Device (Pre- and Post-Market as well as total Device), Drug (Phases I–IV) and Registry trials not categorized as Phase IV trials. As evident in the data, Stamford focuses primarily (in order) on Phase III drug trials, Pre-Market device studies, and Registry-type trials.

Table 2: Study Characteristics for Non-Oncology Enrolling Trials

<table>
<thead>
<tr>
<th>Study Type</th>
<th>n</th>
<th>Mean</th>
<th>SD</th>
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</thead>
<tbody>
<tr>
<td>Total Device</td>
<td>8</td>
<td>6.50</td>
<td>1.60</td>
</tr>
<tr>
<td>Pre-Market</td>
<td>8</td>
<td>5.13</td>
<td>0.83</td>
</tr>
<tr>
<td>Post-Market</td>
<td>8</td>
<td>1.88</td>
<td>0.64</td>
</tr>
<tr>
<td>Total Drug</td>
<td>8</td>
<td>9.88</td>
<td>4.76</td>
</tr>
<tr>
<td>Phase I</td>
<td>8</td>
<td>0.63</td>
<td>0.74</td>
</tr>
<tr>
<td>Phase II</td>
<td>8</td>
<td>1.38</td>
<td>1.51</td>
</tr>
<tr>
<td>Phase III</td>
<td>8</td>
<td>7.88</td>
<td>3.64</td>
</tr>
<tr>
<td>Phase IV</td>
<td>8</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Registry</td>
<td>8</td>
<td>3.25</td>
<td>1.83</td>
</tr>
</tbody>
</table>

For oncology coordinators, a scatter plot of annual revenue and average annual workload was created, and Pearson’s Correlational analyses were used to examine the relationship between the annual revenue and average annual workload (see Figure 3). This was despite a dramatic increase in the number of subjects accrued to industry-sponsored trials in the last two years (see Figure 4).
Figure 3: For oncology coordinators, a higher workload negatively correlated to revenue. There was a strong statistically significant negative correlation between average annual workload ($M=196$, $SD=15.4$) and annual revenue ($M=$106,094; $SD=$49,588), $r=-.71$, $p<.001$, $n=20$.

Figure 4: Enrollment for Oncology Coordinators by Trial Type

For all coordinators, no correlation was found between average annual workload ($M=142$, $SD=53.36$) and annual revenue ($M=$115,057; $SD=$58,039), $r=.065$, $p=.666$, $n=47$ (data not shown).
Two-sample, paired t-tests were conducted to test the hypothesis that tracking productivity would improve the efficiency of a clinical research program’s enrollment-derived productivity over the course of a year (T1=January 2017; T2=January 2018) holding total coordinator hours worked constant (see Figure 5). Additionally, we tested the effectiveness of our productivity tracking metrics to improve study coordinator efficiency, using two-sample, paired t-tests to compare mean percentages of study coordinator time spent for non-enrollment derived activities (regulatory, training, departmental initiatives, patient-facing) at two distinct time points (T1; T2) holding total coordinator hours worked constant (see Figure 6).

**Figure 5:** Total cumulative enrollment was significantly increased from T1(M=295.30, SE=135.79) to T2(M=350.90, SE=151.49), \( t(9) = -2.80, p < .01 \).
Figure 6: Mean monthly productivity scores significantly increased in enrollment-derived productivity (OPAL) from T1 (M=52.23, SE=10.60) to T2 (M=103.10, SE=24.98), t(9)=-2.35, p=.02, demonstrating increased productivity over time as expected. As expected, overall productivity (DEVO), including enrollment-derived productivity (OPAL) and developmental activities (DEV), significantly increased from T1 (M=87.86, SE=11.49) to T2 (M=141.70, SE=22.79), t(9)=-2.37, p=.02.

Together, these results demonstrate that increases in enrollment-derived activity coincided with significant increases in the mean percentage of time study coordinators spent in patient-facing activities in the first year (see Figure 7).
Mean percentage of time spent toward patient-facing activities was significantly increased from T1 (M=.30, SE=.05) to T2 (M=.51, SE=.08), \( t(9) = -3.19, p < .01 \), demonstrating increased efficiency over time as expected. Additionally, the increase in patient-facing activities coincided with a significant decrease in mean percentage of time spent toward regulatory from T1 (M=.45, SE=.07) to T2 (M=.29, SE=.07), \( t(9) = 2.02, p < .05 \).

Additionally, the retention rate of our coordinator staff increased from 40% (2016–17) to 86% (2017–18) post-implementation of the aforementioned productivity metrics system. Pearson correlations of the self-reported perceived fairness of the procedures for measuring and administering study workload assignments to the self-reported job commitment and satisfaction levels are presented in Figure 8.
Discussion

This paper focused on two adaptations of the OPAL productivity model considering protocol complexity, the number of procedures, and additional regulatory and administrative tasks to build a more comprehensive model and representation of coordinator workload.

Where the reproducible results of OPAL to improve efficiency and productivity in clinical research practice can be gathered from the data presented concerning two study sites, this paper elucidates how the benefits of efficiency are fostered through adapting certain metrics. Specifically, these metrics capture the redistribution of workload across study roles to optimize and specialize staff, and more centrally, the value of encompassing additional workload factors for a more comprehensive and accurate model.

Moreover, a robust relationship between perceived procedural fairness of study assignments and workload distribution to self-reports of job commitment and satisfaction was presented, and is further bolstered by the 46 percentage point increase in retention following the introduction of
adaptive productivity metrics to a novel site (Children’s Health System of Texas). It is confirmed that understanding what additional workload factors the coordinators are managing and incorporating them in your adaptive metrics helps gain their buy-in and perception of fairness to improve their work-life balance, job commitment, and satisfaction to retain them as an asset to your program.

Additionally, the maturation of benefits that can be expected after several years using an adaptive productivity metric system (CRWT) includes increased funding support, as evident from the eight years of data presented from Stamford Health.

**Conclusion**

The model shown here offers great flexibility in both oncology and non-oncology settings, as it allows for continuity of care amongst study coordinators for their study participants. These metrics can be used to justify new and existing employees for research programs running clinical trials predominately on the high end of the acuity continuum. In addition, the metrics can be used to increase funding for additional coordinator and support staffing while improving study coordinator job satisfaction and retention at sites. This allows sites to achieve their enrollment goals and promote progress in their clinical research practice. In the wake of such improvements, research programs can expect more funding opportunities and greater success.

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Changing behavior—to some, it’s “second nature.” You just do it. As you grow up, you learn to pay your bills on time, you start calling your mom every Sunday, and you recognize the value of creating to-do lists. However, for some groups, or for more complex changes, the idea of changing behavior provides challenges each step of the way.

As a society, we sometimes attribute lack of follow-through to just forgetting. While that’s absolutely valid, people don’t just do or not do things because they forget, or because they remember. In fact, people follow through on things because it’s easy (online shopping), there’s risk if they don’t (paying bills so they can continue to use their phone), their friends are doing it, or simply—they just enjoy it.

In the context of healthy behaviors, there are many tactics that health professionals employ to motivate their patients. These may include promoting tiny habits, such as “prescribing” a single, simple exercise, or explaining how medication can improve their symptoms. Patients may be especially driven when they start to experience the outcomes of being compliant, such as a reduction in disease symptoms.
With all that said, the ecosystem of what influences behaviors is highly complex, and can’t always be attributed to a single thing. In the context of clinical research, taking a “health behavior” approach to help the person lends to this complexity. The intent of the trial isn’t necessarily to make a person better, it’s to answer questions. What makes this even more tricky is that patients in trials may not be getting better, either because they’re in a control group or because there’s no proof of effectiveness of the intervention.

**How are Behavioral Tactics Currently Used?**

With the rise in behavioral economics, we’re now seeing industries begin to use and implement psychological insights to influence behavior through minute levels of persuasion, instead of coercion. It’s clear that this has improved desired outcomes for those who are implementing these tactics.

For example, there are some software services that default to a more expensive, yet unnecessary option upon checkout. The preselected offering isn’t something you would have proactively chosen, but when it’s the default, it feels like the standard. This may lead you to exhibit loss aversion. You now perceive your originally intended purchase as inferior, and a “downgrade” to be avoided. This revenue-generating tactic still provides choice, but nudges consumers to paying more than planned.

Conversely, we’ve also been seeing these tactics applied for good, such as default opt-in for organ donations and retirement saving plans, thus saving lives and building financial security.

**Constructs of Behavioral Change Models**

A behavioral change model relies on constructs to drive a framework that helps to understand the psychology of why people do the things they do. This can be used to drive strategies on how to influence those behaviors in a more desired direction, similar to the tactics previously described.
While there are many behavioral models, most share the same or similar constructs. Table 1 lists a few of the key ones, and how to independently incorporate them into your patient engagement plan.

**Table 1: Key Constructs of Behavior Change Models**

<table>
<thead>
<tr>
<th>Construct</th>
<th>What Patients Might be Thinking</th>
<th>Strategies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perceived Risk</td>
<td>What is the likelihood something bad will happen? If something bad happens, how extreme will it be?</td>
<td>Inform patient of risks, focusing on susceptibility and severity of the condition or behavior (fear appeal) to convey importance of diligence, but emphasize methods for prevention and treatment to overcome risk to reinforce perceived efficacy. {5}</td>
</tr>
<tr>
<td>Knowledge</td>
<td>Do I understand what is being asked of me and why it’s being asked?</td>
<td>Provide basic information about a medical condition that might include how the disease develops, its expected course, and how specific strategies can help manage it. Apply this same approach to study requirements, such as explaining why{6} patients need to take all their medication at the specified time.</td>
</tr>
<tr>
<td>Skills/Ability</td>
<td>Can I stay organized and do I have the tools I need to be effective?</td>
<td>Provide patients with intuitive{3} take-home instructions and tools, such as easy-to-use pill boxes,{1} visit schedules, and preparation guides, along with reminders on their own phone. Help patients build good habits early in the study by anchoring to known habits that already exist. For example, if patients need to take a pill once a day, you could instruct them to take the pill just before brushing their teeth.</td>
</tr>
</tbody>
</table>
| Perceived Self-Efficacy | Am I confident in my ability to reduce the risk or attain the benefit? | Try the “foot-in-the-door” technique. First make a small, attainable request to build efficacy.{7} For example, have the patient complete a training diary at the site or review the technology with them so they }
will feel more confident about using it at home or on their own. Technology training is particularly valuable with older populations. [8]

| **Response-Efficacy** | Will the outcome reduce the risk or increase the benefit? | Provide concrete examples of how risk could be averted. [5] In some trials, for example, a patient might be instructed to avoid certain medications. While it’s important to make them well aware of the risk, it should also be made clear that avoiding the drug can reduce the chance of a bad reaction. Giving specific examples, like brand names, makes it more concrete for the patient. |
| **Subjective Norms** | What are others doing? What do they think I should do? | Convey basic characteristics about others in the trial, such as how many are participating and what countries are involved, or show videos of former clinical trial participants describing their experience. Incorporate social incentives, [7] such as involving the caregiver in discussions to help provide additional encouragement and support throughout the study. |
| **Attitudes** | How do I feel about all that is required of me in the study? | Attitude may extend beyond self-efficacy, as it is shaped by beliefs and factors associated with a behavior. [5] For example, if a patient dislikes sitting in traffic and lives far away, he or she may be less likely to attend required visits. It can be valuable to measure attitudes at the beginning, and throughout the study, [5] via questionnaire, to determine how attitudes are shifting around the required study activities and to determine if intervention may be required. Explaining why patients need to do certain things can reduce perception of just being told what to do, decreasing resistance to change. [6] |
| **Motivation** | Do I have desire? Is it compelling, helpful, or interesting? | Get to know your patient to understand what drives them—intrinsically and extrinsically. {1,3} For those who are extrinsically motivated, praise them for completing compliance-based activities. You can also leverage reminder services to pre-program “why” and “affirmation” messages, so patients receive this reinforcement throughout the study. Help them feel a sense of accomplishment by showing progress in the study, or by conveying how their participation is helping research and may potentially help others like them, to motivate those who may be driven by altruism. This may be especially valuable when asking patients to participate in “extra” activities, like consenting to additional biopsies that aren’t required for trial participation. |
| **Intentions** | Am I committed to following through? | Intentions are largely driven by a combination of motivation, attitude, and subjective norms.{1} Work closely with patients to understand their intentions to follow through with study requirements. Use specific examples and outline a concrete plan of how they will achieve them. |
| **Triggers/ Cues** | How will I remember to do these things, or when I need to do them? | Incorporate nudges that are anchored to a desired action,{3} such as sending reminders near or at the time patients need to complete a diary entry. As habits begin to form, patients may need fewer prompts, as constant reminders may create message fatigue. Shifting to targeted behavior-based notifications can help reduce this. For example, if patients are required to wear an activity monitor, only send targeted messages to those who are at risk of dropping below the required wear threshold. |
While addressing these elements independently has value, it’s sometimes helpful to incorporate them into an overarching strategy using the model to drive a more holistic strategy around engaging your patients. The model(s) you reference may vary based on needs:

- Stage of the study (recruitment vs. in-trial)
- Protocol requirements (complexity and number of assessments)
- Study aims (prevention vs. treatment trials)
- Patient population (age, gender, indication)
- Region and associated culture (social constructs, motivations)
- Successful previous applications of the model in similar studies/populations

While there is an extensive list of behavioral models that could be leveraged, Table 2 presents a few worth considering. The sections following this table provide descriptions of the four models.

**Table 2: Constructs Found in Behavioral Models to Consider for Patient Engagement**

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<tr>
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</thead>
<tbody>
<tr>
<td>Perceived Risk/Threat</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knowledge</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skills/Ability</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perceived Self-Efficacy/Behavioral Control</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
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<tr>
<td>Response-Efficacy</td>
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<tr>
<td>Subjective Norms</td>
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<tr>
<td>Attitude</td>
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</table>
Extended Parallel Process Model

The Extended Parallel Process model is intended to predict how people will respond to fear of a risk, given their level of perceived efficacy. Risk is inclusive of perceived susceptibility and severity, while efficacy includes self and outcome efficacy.

The model predicts that if people have high perceived risk and low efficacy, they will begin fear control behaviors by avoiding or denying the issue. Those with high perceived risk, but even higher perceived efficacy, are motivated to begin danger control activities by taking action to reduce the risk. This model is more often used to drive fear appeals by creating just enough fear to motivate someone to act.

This may be applied to communication strategies for those with rare diseases or patients on their last line of treatment, who may tend to have lower risk perceptions to trial participation, given the alternative. With that said, perceived outcome efficacy may be low in these populations, but potentially still higher than the perceived risk of the study, thus motivating them to participate.

Furthermore, within the trial, it can be valuable to heavily reward these patients for completing self-efficacy building activities, such as basic compliance requirements. In this context, patients in a Duchenne muscular dystrophy trial may experience learned helplessness, or a sense of powerlessness. It may be that physical therapy does not lead to progress for the patient, and no matter how hard the patient works, physical functions continue to decline.

When patients don’t see a positive outcome from all their hard work, they may be more inclined to give up. This is where focusing on compliance, such as rewarding patients by doing something within their control (e.g., wearing their activity sensor), can help to reinforce self-efficacy. It’s also valuable to continue reminding them of how their participation is helping
researchers find a treatment for others like them (outcome efficacy). This may motivate patients to stick with it, even if they’re not feeling better.

Theory of Planned Behavior

This theory posits that a person’s attitude, social perceptions, and self-efficacy can drive them to act.\(^5\) A potential patient population to apply this model to would be children and adolescents, who are typically more susceptible to and impacted by social influences than other age groups.

Although children are required to consent to participate in a study, consent is also necessary from a caregiver. This could serve as an opportunity to emphasize to the patient that while he or she needs parental consent, the child also has a say in participation.

Targeting a child’s attitude toward the behaviors (visits, medication, tracking) may be more effective than just instructing them on what to do.\(^6\) With that said, education and assigning achievable tasks, with support from caregivers, can help build confidence early on in the trial.

As school-age children grow, they are increasingly more influenced by their peers and social environment.\(^2\) Leveraging social influences,\(^7\) such as describing basic characteristics about others in the trial (e.g., age and country), highlighting celebrities with the same or similar condition, or showcasing commercials or PSAs, helps reduce the stigma. This can help make trial participation feel more mainstream and “socially acceptable.” Caregivers can also serve as a source of social reward when young children feel like they are pleasing their parents by doing what is asked of them.

However, it’s important to use social strategies carefully. While positive reinforcement from a social network for high compliance can drive positive behaviors, it might prompt certain patients to feign compliance activities to please those in their social network. Therefore, one must find the right balance of rewarding compliance, while also rewarding honesty.
Fogg Behavior Model

The Fogg Behavior Model states that for people to be successful in performing a behavior, they need to be motivated, have the skills and ability to perform the behavior, and be prompted by a trigger. Strong presence of all three constructs equates to a higher likelihood of success. While a trigger must always be involved, motivation and skills do not both necessarily need to be high, so long as one of these constructs is compelling enough.{3}

If someone is highly motivated, but has minimum skills to perform a task, motivation in itself might drive the person to acquire the necessary abilities. On the flip side, if something is easy, people might just do it.{3} Take the case of store clerks who ask if you would like to donate your change or a certain small dollar amount to charity upon checkout. On your own, you may never have been motivated to donate, but in this instance, it is so easy that you agree when prompted.

Motivation can be quite elusive, given it is so unique to the individual. According to the Center for Information and Study of Clinical Research Participation, motivators for participating in trials are to help advance science and treatment of disease/condition, help others (altruism, or family), receive compensation, and to obtain better treatment. The top burden impacting ability is traveling to the study clinic. In fact, the top voluntary reason for leaving a study is the location of the study center.{12}

In clinical research, sponsors and vendors are working on various ways to remove friction and address the “time,” “money,” and “effort” abilities by presenting opportunities for patients to participate in studies more easily, whether by introducing remote visits, offering smartphone apps, or even providing childcare.

The Fogg Behavior Model may be applied to patients on two sides of the spectrum. For example, patients who are seeking last-line oncology treatment may be more motivated to participate, comply, and stick with a trial. Healthy participants, like in the case of certain vaccine trials, may not be highly motivated, but if it’s easy for them to do, they may be more likely to participate. This is especially the case if some extrinsic motivation can be addressed through compensation, including compensation associated with compliance activities.
In these scenarios, both groups need a prompt to participate, whether it be from a doctor for the highly motivated, or by passively being exposed to an online ad that makes it easy to sign up. Both groups would benefit from in-trial patient engagement strategies to trigger an action, like reminders anchored to the timing of an expected behavior (e.g., filling out a diary) and apps that prompt a call-to-action on a patient’s phone, which 90% say they “frequently” carry with them.\(^{13}\)

The Information–Motivation–Behavioral Skills Model

This model suggests that factors that influence behavior include knowledge about the behavior, motivation to take action, and behavioral skills necessary to complete it. Not only must information and motivation be tied to skills, they must also link to the behavior change outcome.\(^1\)

Information can motivate.\(^2\) An obesity study protocol may prescribe that patients complete specific health-behavior regimens, such as exercising and eating right. Patients need to be informed on what it means to eat right, and what type and level of exercise is most appropriate. They must also understand why and how this helps in the study. These guidelines, regardless of what arm of the study the patient is in, can reduce the patient’s weight, therefore motivating them to comply.

Behavioral skills can be reinforced by providing tools such as pedometers or food scales,\(^1\) and “tiny habit” exercise reminders can be added into a patient’s daily routine (taking the stairs instead of elevator, walking to a colleague’s desk rather than messaging them, etc.).

Research has shown that patients immediately forget 40% to 80% of the medical information they receive, and about half of what is retained is incorrect.\(^14\) Therefore, these details must be made available to patients after their visits. Critical study information, presented in various formats, such as combinations of text, images, and interactive modules, can also be conveyed through the use of technology to target the diverse learning styles of patients.\(^14\) Questionnaires can evaluate comprehension, and the results can be then used for targeted training to ensure knowledge is maintained.
Key Considerations

The common thread in these models is that many of the constructs can be leveraged to influence patients’ way of thinking to promote specific behaviors. However, in some studies in which the endpoint is to measure changes in thinking, such as psychological symptoms of depression, initiating tactics to improve self-efficacy may be considered as interventional, and therefore needs to be navigated carefully.

Patients who are motivated by knowing they are helping to potentially take a drug to market may be inclined to report more positive results about how they are feeling, in hopes that it can help facilitate that process. While placebos can help offset this, it’s important to reinforce to patients the value of answering honestly and to describe the benefits of being truthful when there are issues.

We also know that participation may be driven by motivation to potentially treat the disease. Again, it’s critical to remind patients the intention of clinical research is to answer questions, and while the goal is to identify an intervention that is safe and effective, that is not the sole intention of the study.

Additionally, one must be careful in how fear appeals are leveraged to initiate behaviors. While it is important to emphasize to patients the importance and criticality of preventing and reporting adverse events, conveying such information must be objective and balanced relative to the risk. The key is to not overly and unduly communicate risk without emphasizing mitigation and escalation strategies.

To summarize, constructs and behavioral models are not prescriptive, but are intended to be referenced alone or in combination to help guide patients throughout the trial, and to help predict and reinforce or mitigate certain behaviors. So, whatever you opt for, approaching your patient engagement and retention strategies with a plan in mind can help improve the trial effectiveness and patient satisfaction. Why not give it a try?
References


![Mindy Gruba, MPH](image)

**Mindy Gruba, MPH**, is a Senior Product Manager with Signant Health.
AIMING FOR ACCURACY IN THE WORLD OF SUBJECT RECRUITMENT

Article 1: Adapting Productivity Models to Improve Efficiency and Progress in Clinical Research Practice

LEARNING OBJECTIVE

After reading this article, the participant should be able to compare two similar adaptations of the Ontario Protocol Assessment Level at their respective research programs, and to describe the resulting improvements in efficiency and productivity, increased job satisfaction and retention, and higher levels of funding over prolonged use of adaptive productivity metrics.

DISCLOSURE

Kara Lorduy, PhD, CCRP; Victoria Brown, PhD, MBA, CIP, CCRP; Suzanne J. Rose, MS, PhD, CCRC: Nothing to disclose

1. High failure rates in terms of trial enrollment goals spotlight the importance of qualified and well-trained professionals in what functional area?
   A. Regulatory affairs
   B. Study coordination
   C. Grants and sponsorships
   D. Research publications

2. Which of the following is the traditional level of full-time equivalent (FTE) staff per trial enrollments?
   A. 0.5 FTE per 10 enrollments
   B. 0.75 FTE per 25 enrollments
   C. 1.0 FTE per 40 enrollments
   D. 1.25 FTE per 55 enrollments

3. In developing a total enrollment number, what is the focus of a rating practice overlapped by the OPAL metrics and Clinical Research Workload Tool described in the article?
   A. To indicate protocol complexity.
   B. To balance efficiency with speed.
   C. To deliver study results under budget.
   D. To screen the maximum number of subjects.
4. **CRCs at Stamford are not responsible for which of the following study-related duties?**
   A. Following the protocol and collecting data.
   B. Conducting informed consent and subject follow-up.
   C. Outreach to potential subjects and screening.
   D. Regulatory coordination and data management.

5. **What aspects of CRCs’ experiences were a Likert scale used for assessing at Children’s Health System of Texas?**
   A. Regulatory knowledge, certification status, and productivity.
   B. Training retention, therapeutic range, and career aptitude.
   C. Metrics system fairness, job longevity intentions, and job satisfaction.
   D. Suitability for promotion, interpersonal relations, and organizational loyalty.

6. **At Stamford Health, a higher workload correlated to greater revenue generation for which coordinators?**
   A. Non-oncology
   B. First-year
   C. Certified
   D. Oncology

7. **At Children’s Health System of Texas, increases in enrollment-derived activity coincided with which of the following in a CRC’s first year?**
   A. More time spent in online training programs.
   B. Less time spent on informed consent per patient.
   C. More time spent in patient-facing activities.
   D. Less time spent in writing standard operating procedures.

8. **CRC retention rates increased by how much following adoption of the productivity metrics at Children’s Health System of Texas?**
   A. 14 percentage points
   B. 30 percentage points
   C. 46 percentage points
   D. 62 percentage points

9. **Using metrics to capture the redistribution of workload across study roles helped to achieve which of the following?**
   A. Simpler protocols and higher study budgets.
   B. Optimized and specialized study staff.
   C. Greater subject retention and compliance.
   D. Improved CRC satisfaction with PI oversight.
10. Incorporating more of the workload factors identified in the article into adaptive metrics for CRCs leads to improvements in which of the following?

A. Work-life balance, job commitment, and satisfaction.
B. Financial security, job referrals, and healthy behaviors.
C. Coworker relations, job overlap, and proactivity.
D. Certification status, job generation, and timeliness.

Article 2: Applying Behavior Change Strategies to Patient Engagement in Clinical Research

LEARNING OBJECTIVE

After reading this article, the participant should be able to summarize several behavioral change models and describe their applications to health behaviors in terms of patient engagement strategies.

DISCLOSURE

Mindy Gruba, MPH: Nothing to disclose

11. Which of the following may convince patients to be especially driven to adhere to healthy behaviors?

A. Threats of higher bills from primary care physicians for non-compliance.
B. Refusal to admit uncooperative patients into available clinical trials.
C. Opportunities to make money promoting effective healthcare products.
D. Experiencing positive outcomes from following the suggested behaviors.

12. Which of the following is a likely reason for patients in a trial not getting better?

A. They are in a control group.
B. Error on the PI’s part.
C. Illegal conduct of the trial.
D. They lied about their symptoms.

13. How can a Skills/Ability construct be applied to patient engagement goals?

A. Mandate that the patient complete online learning modules to participate in a trial.
B. Anchor a desired habit for a study to a habit in which the patient already engages.
C. Publicly penalize the patient for not adhering to the desired health behavior.
D. Have the patient simulate the desired habit until the PI is confident they will follow through.
14. What are the two major aspects to understand about patients under the Motivation construct?
A. Higher and lower level motivations.
B. Compliant and non-compliant motivations.
C. Intrinsic and extrinsic motivations.
D. Monetary and non-monetary motivations.

15. What is the goal of an Extended Parallel Process model?
A. Assigning patients to either active treatment or control groups.
B. Determining the inclusion/exclusion criteria for a new study.
C. Predicting how people will respond to fear of a risk based on efficacy.
D. Blinding both patients and PIs to treatment results throughout a study.

16. Which of the following is a potential trial-related population to which the Theory of Planned Behavior may be applied?
A. Regulatory authorities and IRBs.
B. Study coordinators and monitors.
C. Patient recruitment specialists.
D. Children and adolescents.

17. What is the top burden impacting patients’ ability to participate in clinical trials?
A. Travel to the study site.
B. Fear of reprisals at work.
C. Attitudes of friends and family.
D. Misunderstanding therapeutic intent.

18. How much medical information received by patients is retained?
A. 10% to 50%
B. 20% to 60%
C. 30% to 70%
D. 40% to 80%

19. Which of the following is a risk from patients’ desire to see an experimental medication reach market?
A. Closure of study sites involved in the trials.
B. Self-reports of more positive results from the study.
C. Regulatory authorities demanding extra trials.
D. Failure to publish study results due to bias.

20. Communication about study risks to patients should go hand-in-hand with which of the following?
A. Offers of greater financial remuneration.
B. Promises about the efficacy of the treatment.
C. An emphasis on mitigation and escalation strategies.
D. Opportunities to switch to the placebo group on demand.