USDRN Engages with Patients to Simplify a Complex, Technical Trial for Improved Retention

USDRN Applies CTTI's Patient Group Engagement Recommendations

SUMMARY

The Urinary Stone Disease Network (USDRN) wanted to bring in patient insights to improve its clinical trial of kidney stone prevention. The organization applied CTTI's Patient Group Engagement (PGE) recommendations to develop a fit-for-purpose model of patient integration across its study.

GOAL(S)

An analysis recently published in Mayo Clinic Proceedings shows that the rate of kidney stones is skyrocketing-- in fact, it has nearly doubled in men and quadrupled in women over the past thirty years due, in part, to lack of proper hydration. As the nation seeks answers on how to quell this unwelcome spike, researchers at the USDRN have been testing their own kidney stone hypothesis; namely, that a high-tech water bottle might be one key to reducing kidney stone recurrence. Can a water bottle that alerts users to sip up be reasonably used on a day-to-day basis to reduce kidney stone incidence? USDRN needed patient insights to find out.

CHALLENGES

USDRN's randomized trial, known as the Prevention of Urinary Stones with Hydration study, or PUSH, already had a protocol established by the time its sponsors considered how the study might employ CTTI's recommendations to improve patient engagement. Since the study's primary aim is to determine whether use of a "smart" water bottle to stay hydrated will result in reduced risk of kidney stone recurrence, the practicality of the water bottle in question is key. The team needed to act quickly to bring the patient voice to the fore of the study.

SOLUTION(S)

The study sponsor met with CTTI to learn how the PGE recommendations could be used in the trial. The recommendations, which were released in 2015, support patient engagement across the research and development continuum. USDRN hoped they could be used to engage patients as the essential partners the organization needed to bring the PUSH study to successful completion.

TAKING ACTION

Per CTTI's recommendations for research sponsors and patient groups, USDRN began implementing patient feedback in meaningful ways to ensure they were not simply "token" voices. That meant study leads reaching out to patients individually and collecting feedback on PUSH's protocol design. What about the study was particularly burdensome? How did patients feel about using a "smart" water bottle? One thing they learned during this exercise was that patients felt confused about the 24-hour urine collection the protocol required. In response, USDRN created a "how-to" video to clarify the process for patients.

IMPACT

The PUSH study is still underway, but USDRN found the use of CTTI's PGE recommendations helpful and intend to use them in the future-- although they will start at the very onset of future study design discussions to reap optimal value.

ADVICE

In this study, the involvement of technology complicated both the protocol and the application of the patient voice more than a traditional study. However, complex protocols also need the patient perspective more than most. The challenge of bringing in patients early on in the process is well worth the investment down the road when larger complications are thwarted by the patients' valuable input.

ORGANIZATION

Urinary Stone Disease Research Network

CONTACT

Charles Scales

ORGANIZATION TYPE

Clinical Investigator/Site

IMPLEMENTATION DATE

2017

TOPIC

Patient Engagement

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CTTI RESOURCES

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