Maximizing Clinical Trial Operations: Pharmacy Perspective

Noor Sabagha
Research Pharmacist
Manager | NIH NCC StrokeNet Central Pharmacy
Adjunct Assistant Professor | School of Medicine and Pharmacy Practice
University of Cincinnati
Email: Noor.Sabagha@uchealth.com

What defines an ideal clinical trial site?

There is no absolute ideal

Each site has its unique strengths and weaknesses when it comes to patient randomization.

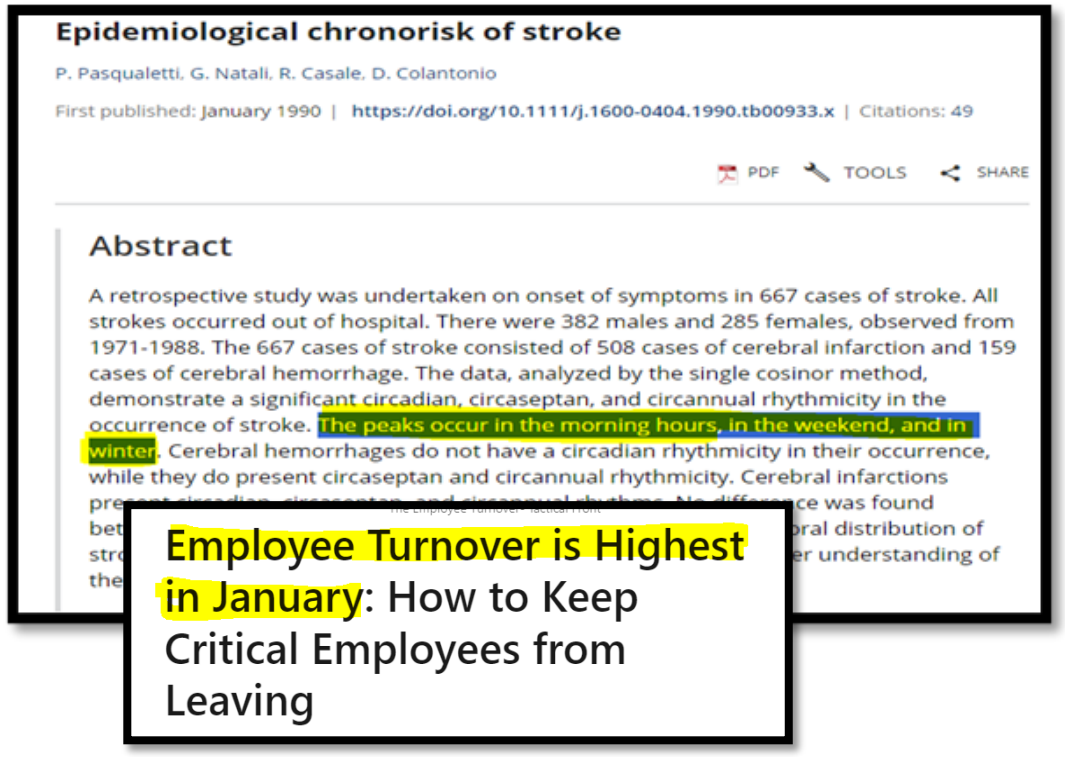
Examples of weaknesses and strengths

<u>Weaknesses:</u>
Limited resources
Inadequate training
Protocol deviations
Patient recruitment challenges

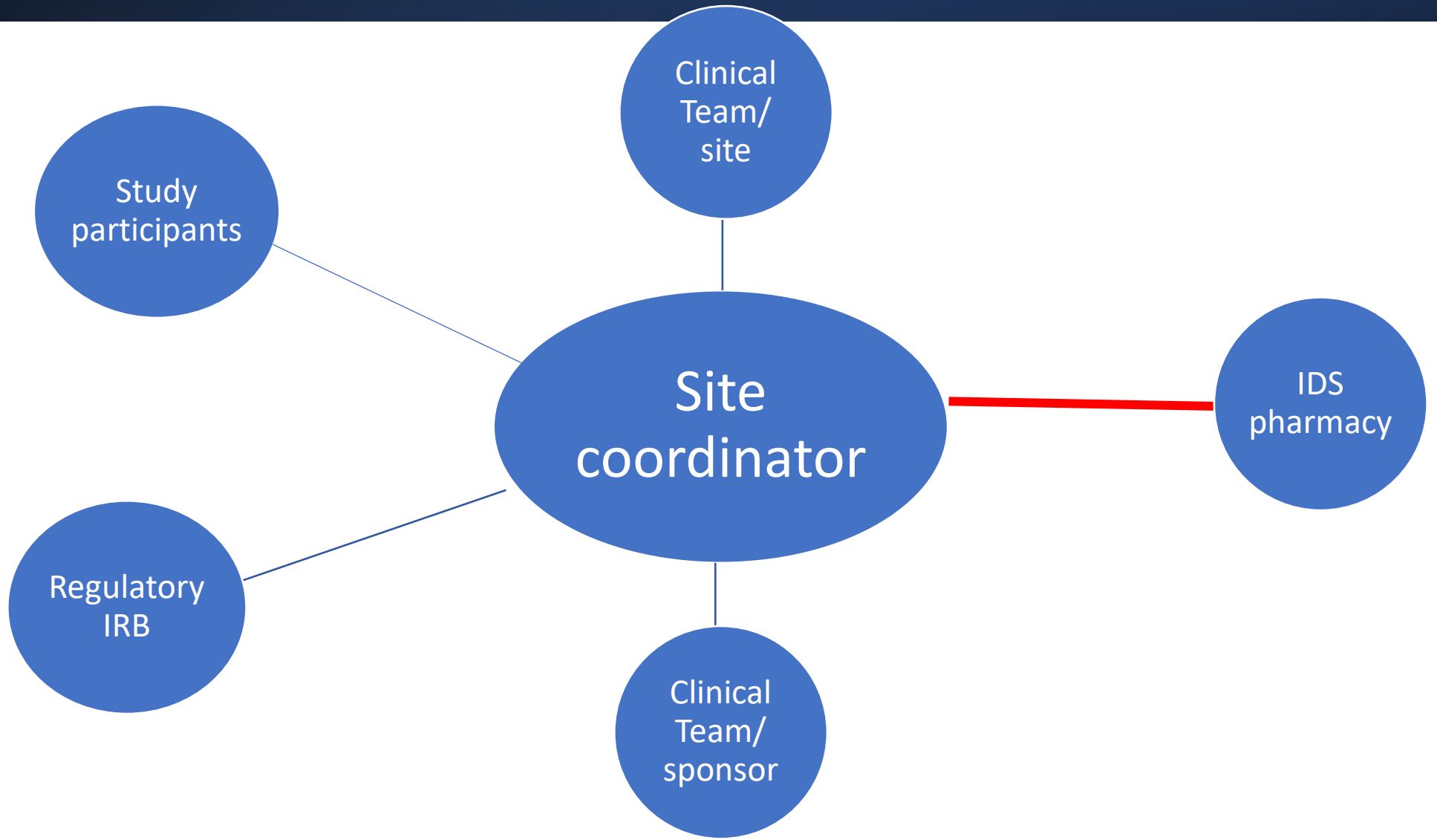
Modifiable vs non-Modifiable

<u>Strengths:</u>
Experience
Infrastructure
Compliance
Dedicated staff

Strength = Communication!!!



Collaborative efforts



Site-Pharmacy Role In clinical Trials

- Before Site Activation
- After Site Activation / Patient Enrollment

Pharmacy role
Before Site Activation

REVIEW FEASIBILITY QUESTIONER , PROTOCOL AND PHARMACY MANUAL

DETERMINE IF STUDY WILL PROVIDE ALL MEDICATIONS AND EQUIPMENT

PREPARE FOR SITE INITIATION VISIT / INTERNAL START-UP MEETING

(E.G MOCK ENROLLMENT)

EDUCATE RESEARCH STAFF ON NEW STUDY MEDICATIONS

SET UP PHARMACY DISPENSING DATABASE AND EPIC PRESCRIPTIONS

Pharmacy Role
After Site Activation / Patient Enrollment

Manage study drug (accountability)

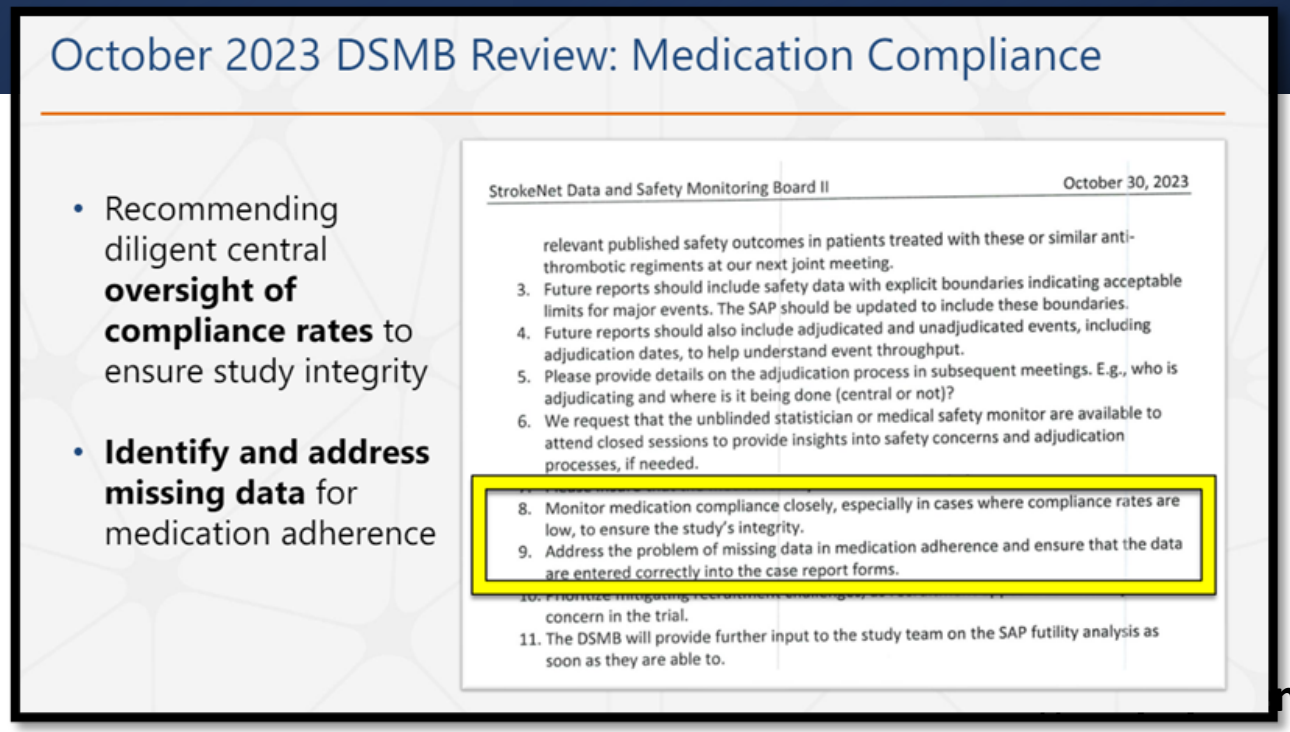
- Monthly inventory
- Temp excursion reporting
- Destroy or return if expired or unusable

Determine patient's treatment arm: medications to dispense (SISTER trial)

Request prescription to be signed by physician who is on FDA 1572 / DOA

Renew prescription as required by law

Pharmacy Workflow
After Site Activation / Patient Enrollment



Counsel patient about medication when dispensed

Ensure bottles are brought back at subsequent visits

nt

calibrations / certifications *Refrigerators, IV compounding hood*

Pharmacist Role to improve Medication Adherence

Impact
Remind
Outcom

Pharmaceutical Care & Health Syster

Research Article

Safe and Effective Use of Medicines for Ethr
Delivered Counseling Program That Improve

Pernille Dam*, Mira El-Souri, Hanne Herborg, Lotte Stig Nørgaard, Charlotte Rossing, Morten S

Danish College of Pharmacy Practice, Hillerød, Denmark

Abstract

ELSEVIER

Journal of the American Pharmacists Association

Volume 61, Issue 3, May–June 2021, Pages 340-350.e5

Association of pharmacist counseling with adherence, 30-day readmission, and mortality: A systematic review and meta-

CLINICAL STUDY

Role of pharmacist couns
improvement

Sanii, Yalda[1]; Torkamandi, Hassan[2]; Gholami, Kheir

Author Information

Journal of Research in Pharmacy Practice 5(2):p 132

Findings:

There were significant differences in medication adherence and satisf
time of second follow-up. Medication adherence in the study group is 42.9% more than the
group, also the treatment satisfaction determined to be 33.5% more than patients in contr
Furthermore, we found that, in intervention group, no one is readmitted while among the
control group eight people readmitted.

Conclusion:

CDC Centers for Disease Control and Preventio
CDC 24/7: Saving Lives, Protecting People™

Division for Heart Disease and Stroke P

CDC > DHDSP Home > Publications & Research > The Communi

DHDSP Home

About Us

Programs

Tailored
Improve

Multifaceted Intervention to Improve Medication Adherence and Secondary Prevention Measures After Acute Coronary Syndrome Hospital Discharge

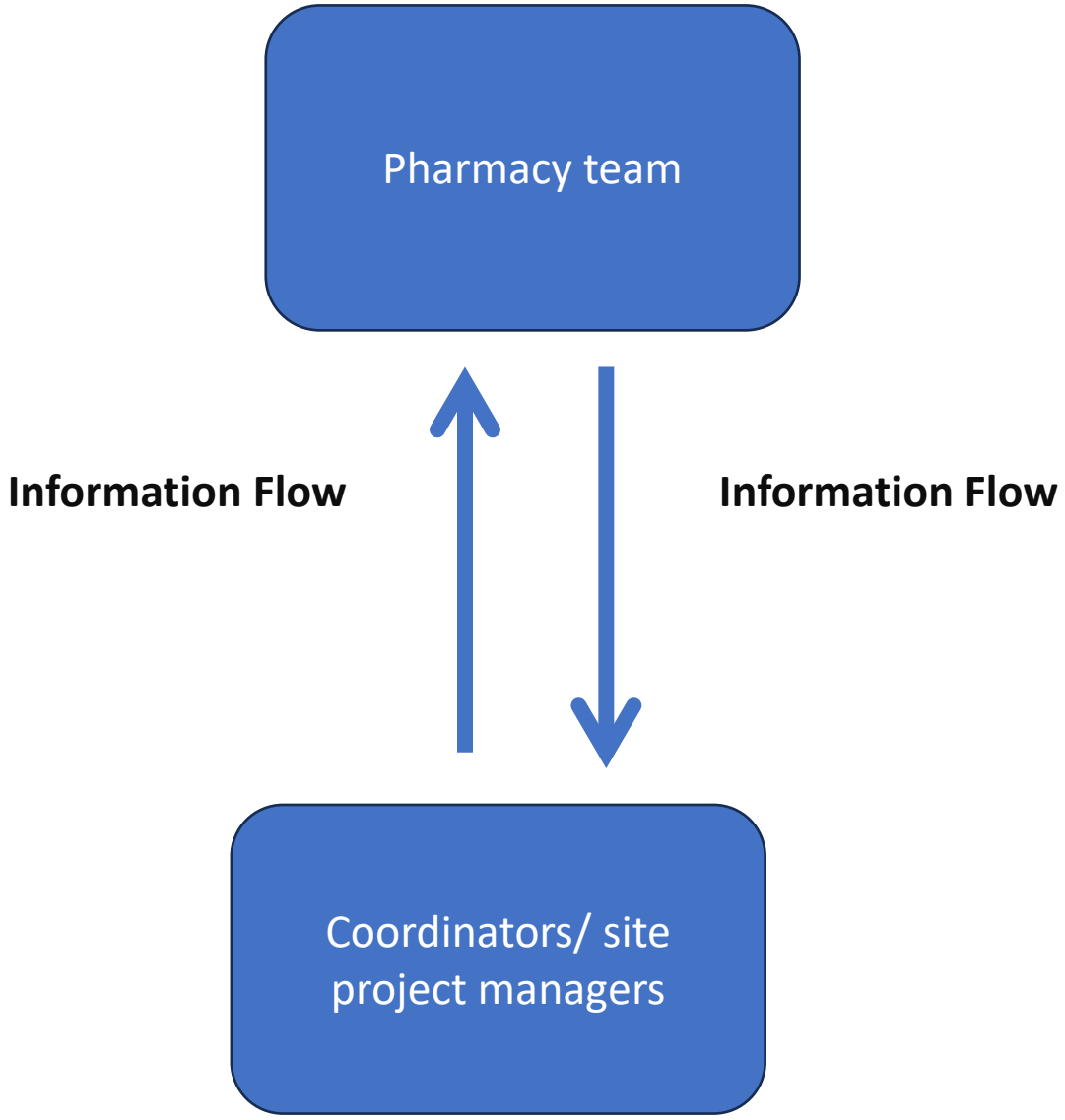
A Randomized Clinical Trial

Interventions The INT lasted for 1 year following discharge and comprised (1) pharmacist-led medication reconciliation and tailoring; (2) patient education; (3) collaborative care between pharmacist and a patient's primary care clinician and/or cardiologist; and (4) 2 types of voice messaging (educational and medication refill reminder calls).

Results Of 253 patients, 241 (95.3%) completed the study (122 in INT and 119 in UC). In the INT group, 89.3% of patients were adherent compared with 73.9% in the UC group ($P = .003$). Mean PDC was higher in the INT group (0.94 vs 0.87; $P < .001$). A greater proportion of intervention patients were adherent to clopidogrel (86.8% vs 70.7%; $P = .03$), statins (93.2% vs 71.3%; $P < .001$), and ACEI/ARB (93.1% vs 81.7%; $P = .03$) but not β-blockers (88.1% vs 84.8%; $P = .59$). There were no statistically significant differences in the proportion of patients who achieved BP and LDL-C level goals.

Examples of an effective team communication:

- Inform your pharmacy team upon identifying potential patients to allow them to review training materials and familiarize themselves with the procedures (e.g., in-patient pharmacy).
- Involve your team in reporting temperature excursions, as quarantined investigational products may temporarily halt enrollment at your site.
- If discrepancies are found during pill counts by some pharmacies, notify your coordinator for further action on non-adherence cases (subjects will require education and re-education).



Announcement

New

NIH StrokeNet Pharmacy Professional Committee (PPC)

Objective: Bring together pharmacists/ Pharmacy Technicians from different institutions involved in stroke care and research to collaborate, share best practices, and contribute to advancing stroke care.

A survey will be distributed soon, keep an eye out for an upcoming survey!

References

- *Elliott, W. J. (1998). Circadian variation in the timing of stroke onset: a meta-analysis. Stroke, 29(5), 992-996.*
- *Pasqualetti, P., Natali, G., Casale, R., & Colantonio, D. (1990). Epidemiological chronorisk of stroke. Acta neurologica scandinavica, 81(1), 71-74.*
- Ho, P. M., Lambert-Kerzner, A., Carey, E. P., Fahdi, I. E., Bryson, C. L., Melnyk, S. D., ... & Del Giacco, E. J. (2014). Multifaceted intervention to improve medication adherence and secondary prevention measures after acute coronary syndrome hospital discharge: a randomized clinical trial. *JAMA internal medicine*, *174*(2), 186-193.
- Kelly, W. N., Ho, M. J., Bullers, K., Klocksieben, F., & Kumar, A. (2021). Association of pharmacist counseling with adherence, 30-day readmission, and mortality: A systematic review and meta-analysis of randomized trials. *Journal of the American Pharmacists Association*, *61*(3), 340-350.
- Sanii, Y., Torkamandi, H., Gholami, K., Hadavand, N., & Javadi, M. (2016). Role of pharmacist counseling in pharmacotherapy quality improvement. *Journal of research in pharmacy practice*, *5*(2), 132-137.
- Dam, P., El-Souri, M., Herborg, H., Nørgaard, L. S., Rossing, C., Sodemann, M., & Thomsen, L. A. (2015). Safe and effective use of medicines for ethnic minorities–A pharmacist-delivered counseling program that improves adherence. *J Pharma Care Health Sys*, *2*(128), 2376-0419.
- Goruntla, N., Mallela, V., & Nayakanti, D. (2019). Impact of pharmacist-directed counseling and message reminder services on medication adherence and clinical outcomes in type 2 diabetes mellitus. *Journal of Pharmacy and Bioallied Sciences*, *11*(1), 69-76.