

Effective Time Management in Clinical Research

Elizabeth Ness, MS, BSN, RN

Deb Grady, MS, BSN, RN, CCRC

Objectives

- Identify common difficulties of time management
- Identify consequences of poor time management
- Describe techniques for improving time management

Polling Question

- What is your biggest time management challenge?

Disclosure for Nurses

- ***Criteria for Successful Completion:***
 - Attendance at 80% of the session and submission of an evaluation form.
 - There is no conflict of interest for anyone with the ability to control content for this activity.
 - National Cancer Institute is approved as a provider of nursing continuing professional development by the Ohio Nurses Association, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation. (OBN-001-091). The approved provider unit activity number is 2021001

Time Management

- Process of organizing and planning how to divide your time between specific activities.
- Good time management enables you to work smarter – not harder – so that you get more done in less time, even when time is tight and pressures are high.
- Failing to manage your time damages your effectiveness and causes stress.

Benefits of Time Management

- Gain time through organization
- Motivates to complete tasks
- Reduces avoidance of work to be done
- Reduces anxiety

Poor Time Management

- Stressed out
- Frustrated
- Pressured
- Over-worked
- Tired

Myth v. Fact #1

- **MYTH:** My time is completely controlled by external events.
- **FACT:** You can have control over many aspects of your time, and you alone are responsible for initiating that control.

Myth v. Fact #2

- MYTH: I should meet everyone's expectations.
- FACT: The needs and demands of others may be inappropriate for you. Know your role and your responsibilities. Clarify your role to others, when necessary. Become clear on your needs and expectations first; consider what others expect second.

Myth v. Fact #3

- MYTH: I should be able to do everything.
- FACT: We all have limits.... failure to acknowledge them may lead to perfectionism, which is nonproductive and a time management disaster.

Challenges in Clinical Research

- Nearly every activity must be thoroughly documented
- Many tasks cannot be easily delegated due to regulatory/licensure requirements or quality standards

Basic Principles

1. Spend time planning and organizing
2. Set Goals
3. Prioritize
4. Create a “To-Do” list
5. Be Flexible
6. Consider your biological peak time
7. Do the right thing and do it right the first time
7. Do Urgent Tasks 1st
8. Do not be a Perfectionist
9. Conquer Procrastination
10. Just say “NO”
11. Reward yourself

Tips for Good Time Management...

- Examine current habits and identify ways to change them
- Plan each day before it begins
- Develop and maintain a list of specific things to be done each day
- Concentrate on one thing at a time
- Set deadlines
- Ask for advice and utilize your resources
- Be an optimist whenever possible
- Move on after failures and learn from your mistakes

...Tips for Good Time Management

- Anticipate upcoming events or tasks
- Delegate responsibilities
- Have confidence in yourself and your ability to succeed
- Think on paper!!!
- Combine similar activities, or those that use the same resources



Getting Started & Maintaining Effective Time Management Skills

Getting Started...

- Establish a list of all job-related tasks, when and how often they occur, and how long they take to complete.
 - Take a week and write down all that you do every day. Then look at additional tasks that didn't occur in the assessment week (e.g., continuing reviews, event reporting, monitoring visit).
- Identify standing meetings and recurring events and add them into your task assessment.

...Getting Started...

- Use your outlook calendar and fill in all the things that you do on specific days of the week and month.
 - This will allow you to clearly see the blocks of time that are not dedicated to a required activity. ***This is time that you can control!***
- Think about how you work throughout the day and fill in this time with activities that are related to recurring events.
 - For example, if your clinic is Wednesday, you may want to block out several hours on Tuesday to prepare for clinic and Thursday for follow-up.

...Getting Started

- Account for your entire 40-hour week on your calendar or spreadsheet, including time blocks dedicated to unspecified tasks and issues.
 - You know that issues and needs will arise which will take you away from your expected task. However, once this issue is resolved, you can return to the task at hand.
- Develop process to best organize your emails.
 - Archiving
 - Inbox as “to do list”
 - Use of tags

Become a creature of habit

- Once you have established a workweek time plan that works, you will be able to attend to your responsibilities in a routine, relaxed manner.
- You know what to expect and can control the outcome.
- You can schedule other events or breaks in the plan with ease since you will be intimately familiar with your day and your week.

Get organized and stay that way

- Time management involves not only planning how you will use your time, but also making sure you have the supplies and resources you will need to perform your tasks.

Create a comfortable, useful, and personalized workspace

- Organize this space with the tools and supplies you use to do your job.
- Make a habit of clearing your desk/email at a designated time on a regular basis.
- Use your archived emails to store protocol specific emails

Make lists

- Making lists is essential for good time management.
 - Outlook, paper lists, or electronically generated lists. Most likely you will use a combination of lists.
 - Periodically update and modify the list, rearranging priorities and removing tasks completed.
 - It is amazing how pleasurable and satisfying it is to cross things off your “ to do” list!

Remember.....

- Allow time for the unexpected
- Handle things once
- Focus on one thing at a time
- Create realistic deadlines
- Eliminate or minimize distractions



Tools to Assist with Time Management in CR

Know your Protocol Portfolio

- Get them organized!

A	B	C	D	E	F	G
Protocol number	Brief Title	PI	Coordinator	Sponsor	Sponsor protocol number	Sponsor reporting timeframe for SAEs

H	I	J	K	L
Reviewing IRB / website	IRB reporting requirements	Monitor	Monitoring interval / next visit	Comments

Protocol Portfolio - example

A	B	C	D	E	F	G
Protocol number	Brief Title	PI	Coordinator	Sponsor	Sponsor protocol number	Sponsor reporting timeframe for SAEs
20C0032	Cure Me	L. Ness	Deb Grady	CTEP	9948	24 hr SAE AERS - table p 82
19C0125	Treat Me	L. Ness	Armine Tumasyan	CCR	n/a	24 hrs SAE
16C0003	Watch Me	L. Ness	Deb Grady	n/a	n/a	n/a

Protocol Portfolio – example cont’d

H	I	J	K	L	M
Reviewing IRB / website	IRB reporting requirements	Monitor	Monitoring interval / next visit	Comments	
CIRB	UPs, serious/continuing noncompliance AND policy 801	Theradex - Ashley Bathgate	Febraury 2021		
NCI IRB	Policy 801	OSRO - monitor name	January 16, 2021		
NCI IRB	Policy 801	n/a			

Reporting Requirements

IRB Reporting Requirements – Events Requiring Expedited Review

** Refer to website for current version of policy / SOP

NIH IRB: Policy [website](#)

Policy 801 *Reporting Research Events* (version date 7/1/2019)

- 24 hours: deaths possibly, probably or definitely related to study (drug, intervention or procedure)
- 7 calendar days:
 - Unanticipated problems
 - Major deviations
 - Noncompliance that is not a protocol deviation
 - New information that might impact participant willingness to continue participation
 - Any suspension or termination of research activities, including hold on new enrollment

IMPORTANT: The above also needs to be reported via REF to the Office of Human Subjects Research Protections (OHSRP) for studies that have an outside IRB for review

NCI Central IRB (CIRB): CIRB SOP [website](#)

National Cancer Institute Central Institutional Review Board Standard Operating Procedures (version date 10/29/2020), Section 10: Unanticipated Problems and Serious or Continuing Noncompliance

- 7 days for information related to local site serious adverse events that appears to meet the criteria of a UP
- 14 days for information related to other local site potential unanticipated problems
- Prompt reporting of local potential serious and/or continuing noncompliance to the CIRB to determine if the potential serious and/or continuing noncompliance requires immediate action to protect the safety, welfare, or rights of research participants

Protocol Status Management

- Use screening/enrollment log and add information
 - Enrollment goal
 - How many patients enrolled?
 - Status of enrolled patients

Status	Number of subjects enrolled
Screen failures	
Currently undergoing study interventions and/or procedures	
Completed study procedures and now in follow-up	
Completed follow-up/off study	
Withdrawn from study, no further follow-up	
Lost to follow-up	
Deaths (related to research)	
Deaths (unrelated to research)	

Other protocol information

- Amendment pending?
 - What is status?
- When is CR due?

- Consider using Outlook calendar to keep track of “to-do’s”

Other organizational tools

- Deviation log – for all protocols
- SAE log – for sponsored protocols and other intervention protocols

- Enter information in “real-time”
- Consider using Outlook calendar to keep track of when logs are due to be sent in

What Else Has Worked For You?

Takeaways

- Time management is a very useful tool to be successful
 - Understand the basic concepts of time management
 - Use a few tools appropriately
- Be aware of how you use your time and try to incorporate some of the ideas discussed today into your daily routine
- Be intentional about how you spend your time
- **Consistently practice the techniques and strategies**

Next Steps.....

- In what specific ways will you change your daily routine to achieve your goals?
- What are you already doing that you want to do more of?
- What behaviors do you want to change?

QUESTIONS



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