CMS's 3-hour rule: Strength of the evidence

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Medicare Benefit Policy Manual – 110.2.2

A primary distinction between the IRF environment and other rehabilitation settings is the intensity of rehabilitation therapy services provided in an IRF. For this reason, the information in the patient's IRF medical record (especially the required documentation described in section 110.1) must document a reasonable expectation that at the time of admission to the IRF the patient generally required the intensive rehabilitation therapy services that are uniquely provided in IRFs. Although the intensity of rehabilitation services can be reflected in various ways,

the generally-accepted standard by which the intensity of these services is typically demonstrated in IRFs is by the provision of intensive therapies at least **3 hours per day** at least **5 days per week**. However, this is not the only way that such intensity of services can be demonstrated (that is, CMS does not intend for this measure to be used as a "rule of thumb" for determining whether a particular IRF claim is reasonable and necessary). The intensity of therapy services provided in IRFs could also be demonstrated by the provision of **15 hours of therapy per week** (that is, in a 7-consecutive calendar day period starting from the date of admission).

For example, if a hypothetical IRF patient was admitted to an IRF for a hip fracture, but was also undergoing chemotherapy for an unrelated issue, the patient might not be able to tolerate therapy on a predictable basis due to the chemotherapy. Thus, this hypothetical patient might be more effectively served by the provision of 4 hours of therapy 3 days per week and 1 ½ hours of therapy on 2 (or more) other days per week in order to accommodate his or her chemotherapy schedule. Thus, IRFs may also demonstrate a patient's need for intensive rehabilitation therapy services by showing that the patient required and could reasonably be expected to benefit from at least 15 hours of therapy per week (defined as a 7-consecutve calendar day period starting from the date of admission), as long as the reasons for the patient's need for this program of intensive rehabilitation are well-documented in the patient's IRF medical record and the overall amount of therapy can reasonably be expected to benefit the patient. Many IRF patients will medically benefit from more than 3 hours of therapy per day or more than 15 hours of therapy per week, when all types of therapy are considered. However, the intensity of therapy provided must be reasonable and necessary under section 1862(a)(1)(A) of the Act and must never exceed the patient's level of need or tolerance,or compromise the patient's safety. See below for a brief exceptions policy for temporary and unexpected events. In accordance with 42 CFR § 412.622(a)(3)(ii), the required therapy treatments must begin within 36 hours from midnight of the day of admission to the IRF. Therapy evaluations are generally considered to constitute the beginning of the required therapy services. As such, they should generally be included in the total daily/weekly provision of therapies used to demonstrate the intensity of therapy services provided in an IRF. The standard of care for IRF patients is individualized (i.e., one-on-one) therapy. Group therapies serve as an adjunct to individual therapies. In those instances in which group therapy better meets the patient's needs on a limited basis, the situation/rationale that justifies group therapy should be specified in the patient's medical record at the IRF. Brief Exceptions Policy - While patients requiring an IRF stay are expected to need and receive an intensive rehabilitation therapy program, as described above, this may not be true for a limited number of days during a patient's IRF stay because patients' needs vary over time. For example, if an unexpected clinical event occurs during the course of a patient's IRF stay that limits the patient's ability to participate in the intensive therapy program for a brief period not to exceed 3 consecutive days (e.g., extensive diagnostic tests off premises, prolonged intravenous infusion of chemotherapy or blood products, bed rest due to signs of deep vein thrombosis, exhaustion due to recent ambulance transportation, surgical procedure, etc.), the specific reasons for the break in the provision of therapy services should generally be documented in the patient's IRF medical record. If these reasons are appropriately documented in the patient's IRF medical record, such a break in service (of limited duration) should generally not affect the determination of the medical necessity of the IRF admission. Thus, A/B MACs (A) may consider approving brief exceptions to the intensity of therapy requirement in these particular cases if they determine that the initial expectation of the patient's active participation in intensive therapy during the IRF stay was based on a diligent preadmission screening, postadmission physician evaluation, and overall plan of care that were based on reasonable conclusions.

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The Impact of the 3-Hour Rule

- Facilities may apply the Rule to all patients seeking IRF admission, regardless of:
  - age
  - diagnosis
  - comorbidities
  - functional status

- Explicit/Implicit assumptions:
  - 3 hours is necessary and sufficient
  - Limits/Eliminates consideration of modifiers and mediators that are supported by science

- Consequences include, but may not be limited to:
  - denial of admission to IRF (loss of WOO for recovery)
  - denial of payment for care received at an IRF (risk aversion)

Studies on 3-Hour Rule in Rehabilitation

Study	Design	Population	Results	Yes = Support No = No Support
Johnston & Miller, 1986	Retrospective Cohort Pre versus Post Rule implementation	US All Admissions N=927 (1°=Stroke) Ave age=69.8y	↑ cost/day ↑ total charges No significant change in mortality No significant change LOS No significant differences in functional outcomes No significant changes in dc placement	No

Studies on 3-Hour Rule in Rehabilitation – cont.

Study	Design	Population	Results	Yes = Support No = No Support
Wang et al, 2013	Retrospective Cohort ≥3.0h but <3.5h and ≥3.5h	US Stroke N=360 Ave age=64.8y	lower functional gains with < 3.0h compared to ≥3.0h No difference in gains with ≥3.0h but <3.5h and ≥3.5h Covariates: age, gender, race/ethnicity, employment, living status, marital status, ischemic v hemorrhagic; L v R stroke; CMG; co-morbidities; LOS; <30d admission Total Variance (R^2) = 0.23	(Yes)

Review Studies on Intensity in TBI/ABI Rehabilitation

Study	Design	TBI Studies	Intervention & Control	Methodological Quality Risk of Bias	Conclusions
Turner-Stokes et al, 2015	Cochrane Review 19 studies: • 12 good quality methodology • 7 low quality methodology 4 intensity (**3 included TBI)** ABI, N=3480 Adults, working age	Shiel et al, 2001: UK RCT Supplemental (h) 16-67 y/o Slade et al, 2002: UK - RCT (h) 16-65 y/o Zhu et al 2007: China – RCT (h) 12-65 y/o	Care as Usual (<3h/d on average) 6.5 v 4.9 h/d/w 4 h/d v 2 h/d	High High High	OVERALL REVIEW of Intensity: <u>STRONG evidence</u> moderate - severe injury: • early intervention • > intensive programs associated with earlier gains • balance between intensity and cost-effectiveness yet TBD
Konigs et al, 2018	Systematic Review Meta-Analysis 11 studies 6 Timing (1992-2016) 5 Intensity (2001-2007): **3 RCT's (subacute)** 2 CT's (postacute) 2 CT's in postacute: 1 on cog rehab in outpt; 1 in outpt in Finland msTBI, intervention	Canning et al, 2003: Australia-RCT Sit-to-Stand (5d/wk) 16-52 y/o Shiel et al, 2001: UK RCT Supplemental (h) 16-67 y/o Zhu et al 2007: China-RCT (h) 4h/day, 5d/wk 12-65 y/o	Care as Usual Care as Usual Care as Usual (2h/d, 5d/wk)	Low (Attrition, Missingness) Low (Pt Blinding) Low (Pt Blinding, Analysis)	**<u>OVERALL REVIEW</u>**: Early rehabilitation showed large positive effect compared to care as usual. Intensive rehabilitation compared to care as usual showed a medium positive effect.

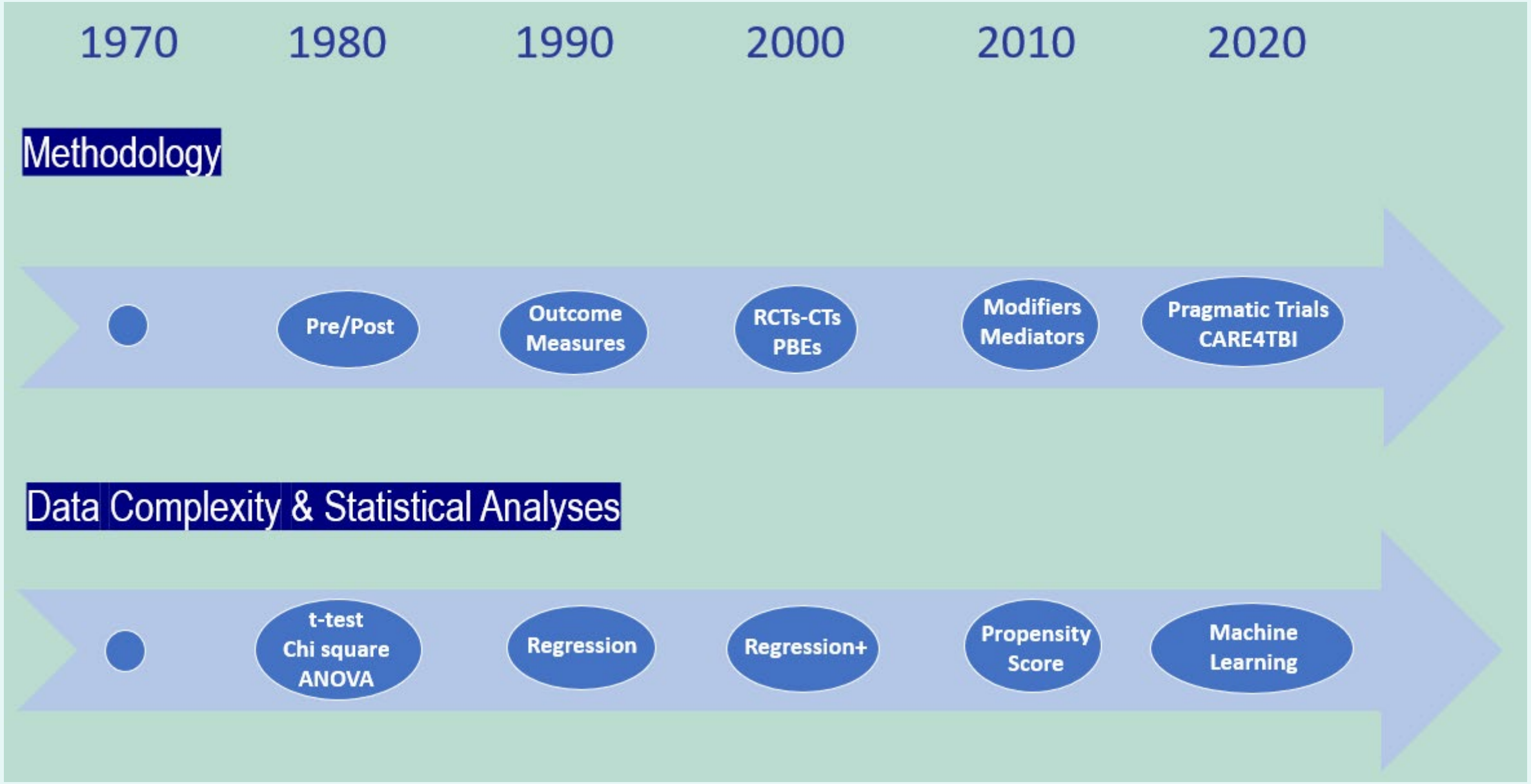
Recent Studies on 3-Hour Rule in Rehabilitation

Study	Design	Population	Results	Yes = Support No = No Support
Forrest et al, 2019	Retrospective Cohort	US All Admissions (1°=Stroke) N=581 Ave age=66y	3 hrs/day versus <3 hrs/day associated with n.s. difference in FIM improvement or FIM gain/day	No
Beaulieu et al, 2019	Prospective, longitudinal Naturalistic, observational (2° analysis)	US TBI N=1820 Ave age=44.5y	LOE not associated with 3-Hour Rule compliance controlling for LOE, compliance not associated with outcomes Significant interaction between compliance and effort for participants with less severe level of disability; i.e., matching intensity to patient wants/needs (not severity level) may optimize results	No

Most Recent Evidence on Intensity in Rehabilitation

Study	Design	Population	Results	Yes = Support No = No Support
Horn et al, 2015	Prospective, longitudinal Naturalistic, observational	US TBI ≥14 y/o N=2130	Better outcomes associated with > time spent in advanced, complex activities, use of specific medications, and greater perceived effort regardless of admission status Controlled for 70+ covariates	No
Bogner et al, 2019	Prospective, longitudinal Naturalistic, observational (2° analysis)	US TBI ≥14 y/o N=1843	Propensity score methods (statistical RCT) • Larger proportion of time in "contextualized" treatment associated with greater community participation during the year following dc (beneficial effect regardless of initial level of severity) • Larger proportion of "advanced" treatment associated with better cognition, self-care, mobility, productivity, and community participation • Family members attending at least 10% of treatment sessions associated with more community participation Controlled for 70+ covariates	No
Zarshenas et al, 2020	Prospective, longitudinal	Canada TBI ≥14 y/o N=149	Time in complex OT activities associated with dc FIM Motor No association with LOE or time in PT on outcomes Controlled for 25+ covariates	No
Cogan et al, 2024	Retrospective Cohort	US ABI Adult N=763	Time in ADL/IADL associated with greater self-care gain/day Time in bed mobility, therapeutic exercise associated with slower per day gain in mobility	No

Reasons for Discrepancies in the Evidence



Additional Reasons for Discrepancies

- Patient Selection:
  - Availability (limited sites)
  - Access (only those admitted can be included)
  - Selection (inclusion criteria differ, especially TBI v ABI)
  - Diagnostic groupings
- Facility Location:
  - Systems of care differ across countries (national/universal healthcare, affordability, none)
  - Practice standards may be interpreted and applied differently across sites
  - Productivity, case load, staffing ratios
  - Resource allocations differ across sites
- Outcome Selection:
  - Specific outcomes will likely be associated with different factors (see Appiah Balaji, et al 2023)

How to make sense about the impact of time on outcome?

1. Admission (time in rehabilitation) is necessary to benefit from rehabilitation:
   - Studies explicitly investigating the 3-Hour Rule do not find support.
   - Studies investigating time differ in defining hours/day (i.e., “intensity”).
   - Despite design, studies consistently find improvements in function from admission to discharge regardless of level of function or level of injury severity at admission.
   - Optimal “time” remains elusive (time may be a modifier or mediator).

2. It is critical to understand factors impacting outcome other than time:
   - Modifiers (strength and direction) and Mediators (process of relationship)
   - Critical factors backed by scientific evidence (so far):

     ✓ Timing (early > later…window of opportunity)
     ✓ Effort/Exertion
     ✓ Complexity of therapeutic activity (regardless of level of severity)
     ✓ Context/Content of therapy
     ✓ Family engagement

3. Specific outcomes will likely be associated with specific, different factors.

Thank You