

Frontline Support Work in Clinical Research and Special Education

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Abstract

Two workforces sit at the operational centre of two evidence-driven fields and are theorised in neither. Clinical research coordinators translate protocols into enrolled participants, extracted variables, and regulatory records. Instructional assistants translate individualised education plans into daily instruction, communication, and behavioural support. The two roles have developed in separate professional worlds with separate literatures, separate credentialing pathways, and no shared vocabulary. This conceptual paper argues that they occupy the same structural position and generate the same category of risk and the same category of opportunity. In both fields, the person with the least formal preparation exercises the highest density of consequential discretion over the people with the greatest vulnerability, and the aggregate of that discretion determines what the field can subsequently claim to know or to have achieved. The paper develops a six-domain comparative framework covering structural position, discretion under incomplete instruction, documentation as practice, access and the construction of who counts, calibrated support and the discipline of fading, and vigilance with ethical escalation. Each domain is examined in both fields, and each yields a transfer proposition in which one field's accumulated solution addresses the other's unresolved problem. Special education's scholarship on proximity, dependence, and deliberate fading offers clinical research a language for over-assistance it currently lacks. Clinical research's architecture of protocol specification, provenance documentation, and structured safety escalation offers special education a discipline of traceability it has never systematically applied. The paper concludes with implications for training design, supervision, role definition, and workforce policy, and specifies testable propositions for empirical investigation.

Keywords: clinical, instructional, assistants, paraprofessionals, frontline, discretion, inclusive, education, implementation fidelity, workforce policy

1. Introduction

Consider two people at work on the same afternoon. The first is a clinical research assistant in a hospital in the American Midwest. She has spent the morning screening an oncology clinic list for a study of symptom burden and goals-of-care communication in advanced lung cancer. She has approached four patients, enrolled one, been declined by two, and decided not to approach a fourth because the patient's daughter was crying in the corridor. She extracted medication and encounter data from the electronic medical record for eleven enrolled participants, flagged three discrepancies between the chart and the participant's account, conducted a semi-structured interview, coded two transcripts, and noticed that a participant she had followed for four months seemed more disoriented than usual. She is now deciding whether that observation constitutes an adverse event, a symptom of disease progression, or nothing worth raising.

The second is an instructional assistant in an autism-focused school in Doha. He has supported one student through four lesson transitions, delivered two small-group sessions reinforcing a literacy objective, adapted a worksheet on the spot when the original proved inaccessible, prompted three exchanges on a picture-based communication system, judged twice whether to intervene in a peer interaction that was going badly, supported a toileting routine, implemented a de-escalation sequence when a student became distressed during a fire alarm, and noticed that a strategy prescribed in the student's behaviour plan has stopped working. He is now deciding whether to mention this at the end of the day, when the teacher will be rushing to a meeting, or to wait for the review that is scheduled in six weeks. These two people have never met, work in different sectors, hold different qualifications, and would not recognise one another as colleagues. Neither field's literature describes the other's role. Yet they occupy the same structural position, and this paper argues that recognising this fact produces analytic and practical returns neither field can generate alone. The position is defined by the conjunction of four features, and it is the conjunction rather than any single feature that does the analytic work. In both fields, the frontline worker holds more sustained, individualised contact with the vulnerable person than any other member of the team, while holding the least formal preparation for the judgements that contact requires. Governing documents are systematically incomplete relative to the situations they govern, so the resulting gap is resolved in real time, repeatedly, by that same person. And because those resolutions are rarely recorded as decisions, their effects accumulate invisibly into properties of the result: the composition of a sample, the provenance of a dataset, the quality of a child's access to the curriculum, and the extent to which a vulnerable person's own perspective enters the record at all. Each of these features is separately documented in one field or the other, and the documentation is more recent and more extensive than the fields' mutual silence would suggest. In education, the assistant workforce has become a substantial and permanent part of the school system across many jurisdictions, with roles, titles, and conditions varying so widely that international comparison has itself become a research problem (Webster & de Boer, 2023; Zhao et al., 2021). Giangreco (2021) has argued that the field's reliance on assistant support now functions as a default solution applied irrespective of fit, and Suter et al. (2020) demonstrated that the organisational arrangements surrounding these staff, including absence and cover, materially shape what students actually receive. Reviews of intervention research find that assistants can deliver structured programmes effectively when trained and supervised, and that training combining explanation, modelling, and performance feedback reliably changes what they do (Walker et al., 2021; Damiani et al., 2023). The difficulty identified across this literature is therefore not the workforce but the conditions of its deployment, a distinction the field has made carefully and one this paper adopts throughout.

In clinical research, the equivalent workforce has attracted attention chiefly through the problems its instability creates. Coordinators carry heavy and heterogeneous workloads, and studies of the role describe a position defined less by delegated tasks than by the continuous management of contingencies that no protocol anticipates (Kengne Talla et al., 2023; Showalter et al., 2022). Where coordinators have been asked directly about recruitment, they describe organisational conditions, competing demands, and the absence of systems as the binding constraints on who ends up in a trial (Yousafi et al., 2024). Reviews of participation barriers among under-represented populations find obstacles distributed across awareness, opportunity, and acceptance, with many operating well before formal eligibility is assessed (Ford et al., 2008; Alarcón Garavito et al., 2025). These are descriptions of frontline discretion, but the field has not named them as such and has not developed the conceptual apparatus that would allow their effects on the resulting evidence to be traced. That asymmetry is the paper's point of departure. Special education has produced the more mature critical literature on frontline support. Giangreco et al. (1997) documented eight consequences of instructional assistant proximity, including separation from classmates, dependence on adults, and reduced access to competent instruction, and successive reviews confirmed and extended the pattern (Giangreco et al., 2001; Giangreco & Broer, 2005; Giangreco et al., 2010). Blatchford et al. (2012) and Webster et al. (2010) established in large-scale British data that pupils receiving the most assistant support progressed less than comparable peers receiving less, a finding the authors attribute to deployment rather than to the people deployed. Sharma and Salend (2016) found the same configuration of role ambiguity, limited training, and minimal collaboration time across international evidence. Radford et al. (2014, 2015) supplied a corrective grounded in scaffolding theory, drawing on a longer tradition of research into how adult support is calibrated and withdrawn in instructional interaction (Van de Pol et al., 2010). The field therefore possesses both a diagnosis of how well-intentioned support produces harm and a vocabulary for the mechanism. What it lacks is the traceability architecture that clinical research has built. Good clinical practice guidance specifies documentation, monitoring, and reporting obligations in detail (International Council for Harmonisation, 2016); reporting standards govern the presentation of trial conduct (Schulz et al., 2010), intervention description (Hoffmann et al., 2014), and evidence synthesis (Page et al., 2021); data quality frameworks address the reuse of clinical records for research (Weiskopf & Weng, 2013; Kahn et al., 2016); provenance metadata has been developed to transform routine data traceable (Gierend et al., 2023); and the reusability of the algorithms that define research populations has itself become a subject of formal evaluation (Wiley et al., 2026). What clinical research lacks is any equivalent of the proximity literature, meaning a body of work examining how coordinator discretion shapes the evidence produced. Fisher (2009) provided an important sociological account and Timmermans and Berg (2003) established the general principle that standards are locally accomplished rather than simply applied, but neither has generated a practice-facing corrective comparable to the scaffolding literature. The deficits are therefore complementary rather than merely different: special education has the critique and lacks the architecture, clinical research has the architecture and lacks the critique, and the central claim of this paper is that each field holds the solution the other needs. The claim is developed through six domains. Each describes the phenomenon in clinical research, describes it in special education, identifies the common mechanism, and specifies a transfer proposition. The domains are the structural position itself; discretion under incomplete instruction; documentation as practice; access, approach, and the construction of who counts; calibrated support and the discipline of fading; and vigilance with ethical escalation. The consistency of the

pattern across six independently developed domains is itself part of the argument, since a superficial analogy would hold in one or two of them and fail in the rest.

This is a conceptual paper. It synthesises existing theory and evidence into an organising framework, advances propositions, and derives implications, and it reports no new data, so its propositions are offered as testable claims rather than as established findings. It does not claim that the two roles are identical. Clinical research generates knowledge for future populations while special education develops capability in present individuals, and the purposes, accountability structures, and regulatory environments differ profoundly. What is shared is the structural position of the frontline worker and the mechanisms by which that position converts discretion into outcome. Illustrative attention falls on populations where both fields' challenges intensify: adults with dementia and advanced illness in the clinical case, children with autism and complex communication needs in the educational case. These populations share a decisive feature, which is that their capacity to correct a frontline worker's misinterpretation is limited, so the worker's interpretation stands with unusual finality.

2. Two Fields and One Structural Position

The first domain establishes the comparison itself, because the argument depends on the claim that the similarity is structural rather than superficial.

2.1 Executory framing and the incompleteness of governing documents

Both roles are framed as executory, and the job descriptions in both fields enumerate tasks to be performed under direction. Clinical research coordinator descriptions specify scheduling, consent administration, data entry, documentation maintenance, and regulatory tracking, while instructional assistant descriptions specify supporting the teacher, reinforcing instruction, assisting with personal care, and supervising activities. Both formulations position the worker as implementing decisions made elsewhere by someone better qualified, and both share a characteristic silence in that neither describes judgement, neither specifies which decisions belong to the worker, which must be escalated, and on what basis the distinction is drawn. Sharma and Salend (2016) identified role ambiguity as the most consistent international finding in the assistant literature, and subsequent international mapping of the role has found that ambiguity reproduced across systems which otherwise share very little (Webster & de Boer, 2023; Zhao et al., 2021). The same ambiguity exists in clinical research and has attracted less attention, because the regulatory environment creates an impression of specification. Good clinical practice guidance specifies what must be documented; it does not specify how to decide whether an ambiguous clinical event is an adverse event, and no document can. The protocol and the individualised education plan are functionally analogous in a way that makes this silence consequential. Each is an authoritative document produced by qualified professionals, subject to formal approval, intended to govern practice, and enacted by someone who did not write it. Each specifies objectives, procedures, and measurement, and each is necessarily incomplete for the same reason, which is that both describe a general case while the people they govern are specific. A protocol specifying enrolment of adults with stage IV non-small-cell lung cancer cannot specify whether to approach a patient whose family is visibly distressed, and an education plan specifying a visual schedule to support transitions cannot specify what to do when the schedule is left at home, when the routine is disrupted by an unannounced assembly, or when the student who used it successfully for six months suddenly refuses it. Timmermans and Berg (2003) named the labour that closes this gap articulation work, meaning the local effort required to make a standard function in a particular setting, and their central insight is that articulation work is not a deviation from the standard but

the condition of the standard's operation. A protocol that required no articulation would be a protocol that could not be run. Implementation research has since converged on the same conclusion from the opposite direction, distinguishing the core functions of an intervention from the forms through which they are delivered and arguing that forms must vary if functions are to be preserved (Perez Jolles et al., 2019; Pérez et al., 2016). The frontline worker is therefore not a potential source of noise in an otherwise specified system, but the mechanism through which specification becomes practice, and the failure of both fields to describe this work is a failure to describe how either of them actually operates.

2.2 Interpretation, invisibility and the fate of undocumented knowledge

Three properties follow from that position, and they are connected rather than merely coincident: the worker interprets, the interpretation is invisible, and what the worker learns in the course of interpreting is never written down. The first is a matter of translation between vocabularies. The coordinator moves between clinical language, regulatory language, data system language, and the ordinary language of participants and families, and the assistant moves between curriculum language, specialist plan language, the communicative repertoire of the student, and, in internationally staffed schools, between languages proper. Every such translation involves selection, and selection is interpretation. A participant describes fatigue that comes in waves and makes everything feel distant, and that description may become a numeric score, a qualitative code, a clinical note, or nothing at all, depending on what the coordinator hears and where the instruments permit it to go. A student pushes a worksheet away, and that action may become a recorded refusal, an inferred request for a break, evidence of task difficulty, or a behavioural incident, depending on the assistant's reading of it. In both cases, the record that survives is the interpretation rather than the event, which means that the analyst working with the data downstream is working with the product of a judgement they cannot see.

That invisibility is the second property, and it is a feature of infrastructural work generally rather than a peculiarity of these two roles. Star (1999) observed that infrastructure becomes apparent chiefly upon breakdown, and Bowker and Star (1999) demonstrated how classification work, once embedded in routine, disappears from view while continuing to shape what can be known. Both roles exhibit the pattern with unusual clarity. A study that enrolls on schedule, produces clean data, and passes audit generates no attention to the coordination that made this possible, and a student who has a settled day generates no attention to the hundreds of micro-adjustments that produced it. Attention arrives only with an audit finding, a recruitment shortfall, a data discrepancy, a behavioural crisis, or a safeguarding concern, so the work is noticed only in its failures and is therefore understood almost exclusively through them. The consequence is a systematic bias in how both fields conceive the role, since a body of knowledge assembled entirely from breakdowns will describe the worker as a source of risk rather than as a source of the result.

The third property is that the knowledge generated by this work accumulates only in the worker. The coordinator knows which clinic days produce eligible patients, which extraction rules were adopted for ambiguous chart entries, and which participants require a call the day before a visit. The assistant knows which sensory environments precede difficult afternoons, which peer will respond well to a facilitated interaction, and which prompt this student accepts and which provokes refusal. Hargreaves and Fullan (2012) argued that professional capital combines human capital in the form of individual skill, social capital in the form of relationships and collaboration, and decisional capital in the form of judgement developed through experience and feedback. Frontline workers in both fields accumulate the third in quantity while being supported in none of the three,

and because none of it is recorded, turnover removes it completely. Turnover is high in both fields, and in education, even routine absence has measurable consequences for what students receive (Suter et al., 2020), which indicates that the vulnerability created by undocumented knowledge is not confined to the moment of departure.

2.3 Transfer proposition one

Each field should adopt the other's framing of the role. Special education should recognise, as clinical research formally does, that the frontline worker operates within a governance structure with documentary obligations and specified escalation routes. Clinical research should recognise, as special education increasingly does, that the frontline worker's relational and interpretive practice is a legitimate object of scholarly attention rather than an operational detail.

3. Discretion Under Incomplete Instruction

The second domain examines what the frontline worker actually does in the space that the governing document leaves open.

3.1 The anatomy of a frontline decision and the pull of defaults

Frontline decisions in both fields share a common structure, in that they are made under time pressure, without consultation, on the basis of incomplete information, with consequences that are individually modest and cumulatively substantial, and they are usually unrecorded. A coordinator deciding whether to approach a patient today is weighing eligibility, apparent clinical stability, family presence, clinic schedule, the study's recruitment position, and an intuitive read of receptiveness. An assistant deciding whether to intervene in a faltering peer interaction is weighing the student's distress, the peer's patience, the learning objective, the risk of escalation, and the developmental value of letting the interaction fail. Neither decision appears in any record, and both shape outcomes. Under conditions of pressure and low preparation, workers adopt default strategies, and defaults are not random. They are shaped by what is fastest, what is most visibly competent, and what produces fewest immediate difficulties, which makes default-driven error systematic rather than idiosyncratic, and systematic error is the kind that biases evidence. In clinical research, the fastest approach is to the patient who is alone, alert, fluent in the language of the study materials, and unaccompanied by complicating family dynamics. No individual choice is unreasonable, and the aggregate produces a sample whose composition reflects workflow rather than sampling logic. The recruitment literature supports this reading. Ford et al. (2008) found barriers distributed across awareness, opportunity, and acceptance, and a recent systematic review of participation among minority ethnic groups reached a structurally similar conclusion, locating much of the shortfall in processes that precede eligibility assessment (Alarcón Garavito et al., 2025). Coordinators themselves, when asked, describe the constraint as organisational rather than attitudinal: insufficient time, no system for tracking approach decisions, and no expectation that the pattern of approaches will ever be examined (Yousafi et al., 2024).

In special education, the fastest support strategy is to supply the answer, complete the step, and remain close. Giangreco et al. (1997) documented the consequences, and Radford et al. (2014, 2015) explained the mechanism, noting that untrained assistant's default to the most intrusive form of support because it produces the fastest visible task completion. It is the strategy that most resembles good help and does the least developmental work. The parallel with recruitment is exact, since in both fields the default optimises for the immediate and visible at the expense of the aggregate and invisible, and in both fields the worker who follows it is doing what the setting

rewards. This is why the problem does not respond to appeals to conscientiousness. A conscientious worker under the same conditions produces the same aggregate, because the conditions rather than the disposition select the strategy.

3.2 The competence paradox

Both roles exhibit what may be called a competence paradox, in which the behaviours that appear most competent to an observer are frequently the behaviours that do most harm. An assistant who keeps a student on task, error-free, and quiet appears highly effective and may be producing dependence, isolation, and reduced access to instruction. A coordinator who enrolls quickly, produces complete data with no missing fields, and reports few adverse events appears highly effective and may be producing a narrow sample, over-prompted responses, and under-ascertained safety signals. In each case, the indicator that is easiest to observe is the one the harmful strategy maximises. The paradox has a common source in the misalignment between observable short-term indicators and unobservable long-term ones, combined with supervision that attends, where it exists at all, to the observable. Broer et al. (2005), gathering the perspectives of students with intellectual disabilities on their assistants, found descriptions ranging from mother figure to friend to protector, characterisations that reveal how thoroughly the relationship exceeds its official specification and how easily protective competence shades into constraint. Giangreco (2021) makes the further point that a support strategy which is visibly reassuring to parents, teachers, and administrators acquires a constituency independent of its effects, which is part of why evidence of harm has changed practice so slowly. The implication for both fields is uncomfortable. Neither can improve frontline practice by attending more closely to the indicators it already watches, because those indicators are precisely what the harmful strategy optimises, and any intervention that leaves the indicator set unchanged will be absorbed without effect.

3.3 Discretion is not eliminable

A tempting response is to specify more, writing longer protocols, more detailed plans, and more granular procedures, and this response fails for a reason both fields have learned independently. Specification cannot outrun situational variety, because each additional specification addresses one anticipated case and leaves the unanticipated ones untouched while adding to a document that the frontline worker becomes progressively less likely to read in full. Beyond a threshold, specification reduces rather than increases fidelity, since it converts a usable guide into an unusable reference. The alternative is to accept discretion and address its quality, which means preparing workers to exercise judgement rather than only to follow procedure, and that in turn requires teaching the reasoning behind provisions and not only the provisions themselves. Cook and Odom (2013) emphasised that adaptation in special education is routine and that the useful question concerns which adaptations preserve the active ingredients of an intervention. Hawe et al. (2004) made a structurally identical argument for complex interventions in health, proposing that standardisation should apply to function rather than to form, and subsequent implementation scholarship has built the machinery that argument requires, including taxonomies for reporting what was modified, by whom, and why (Wiltsey Stirman et al., 2019), models for anticipating the impact of a given adaptation on outcomes (Kirk et al., 2020), and decision procedures for balancing adaptation against fidelity in the moment (Miller et al., 2020). Fixsen et al. (2005) made the parallel argument at the level of programmes, treating implementation as a set of practices requiring competence, coaching, and organisational support rather than as an automatic consequence of specification.

The significance of this body of work for the present argument is that it has already solved, at the level of interventions, the problem both fields face at the level of individuals. It establishes that adaptation is expected, that its acceptability depends on whether core functions are preserved, and that the judgement involved can be made explicit and recorded. What neither field has done is extend the apparatus to the frontline worker, who performs the same reasoning many times a day without the vocabulary, the authority, or the documentary infrastructure that the intervention-level literature takes for granted.

3.4 Transfer proposition two

Both fields should reframe frontline preparation from procedural compliance to reasoned judgement, and both should adopt function-level rather than form-level standardisation as the governing principle. The practical test is whether a worker can explain why a provision exists and can therefore adapt it when circumstances change without abandoning its purpose.

4. Documentation as Practice Rather Than Paperwork

The third domain concerns the record. Both fields generate substantial documentation, both treat it as an administrative burden, and both lose critical information as a result.

4.1 What the record captures and what it omits

In clinical research, the record is extensive, with case report forms, source documents, consent forms, monitoring logs, deviation reports, and regulatory correspondence accumulating across a study, and electronic data capture systems recording timestamps and audit trails (Harris et al., 2009; Harris et al., 2019). Yet a specific and consequential category of information is systematically absent, which is the reasoning that produced the recorded values. Which extraction rule was applied when a chart entry was ambiguous, how a borderline eligibility case was adjudicated, and when the team refined a definition mid-study and why are questions the record cannot usually answer. The data quality literature has approached this obliquely and has been moving towards it. Weiskopf and Weng (2013) identified completeness, correctness, concordance, plausibility, and currency as dimensions of data quality in record reuse and noted inconsistent assessment, and Kahn et al. (2016) proposed harmonised terminology precisely because teams were using incompatible language for the same problems. More recent work has made the underlying issue explicit by treating provenance as a first-class requirement, developing metadata structures that record what was transformed, when, and by which rule, so that a data element carries its own history (Gierend et al., 2023), and by subjecting the algorithms that define study populations to formal assessment of whether they can be reused in another setting at all (Wiley et al., 2026). The trajectory of this literature supports the argument advanced here, but it remains a literature about systems rather than about people, and the decisions it seeks to capture are still made by an individual whose reasoning is not solicited.

In special education, the record is thinner and the omission broader. Plans are written and reviewed, progress is recorded against goals, and incidents are logged, but the daily texture of implementation, including which adaptations were made, which prompts succeeded, and which strategies had ceased to work, exists largely in the assistant's memory and in informal conversation. The two fields therefore lose the same category of information by opposite routes, one by omitting the reasoning behind a detailed record and the other by not keeping the record at all, and in both cases what is lost is the only evidence that would allow the delivered intervention to be distinguished from the intended one.

4.2 Documentary integrity and the implementation gap

It is worth being precise about what kind of failure this is, because the three ways a record can fail are routinely conflated and they call for different remedies. A record can fail technically, in that required fields are incomplete, values fall outside plausible ranges, discrepancies go unresolved, or audit trails do not function, and this is the failure mode clinical research addresses well, and special education addresses inconsistently. It can fail representationally, in that the record is internally impeccable and does not correspond to the reality it purports to describe, so that a dataset can be technically flawless and representationally hollow, just as a progress record can show goal attainment that reflects prompt dependence rather than capability. And it can fail procedurally, in that the decisions which produced the record cannot be traced. The third is the failure both fields most consistently neglect, and it is the one most dependent on frontline practice, because the decisions in question are made by the frontline worker and by no one else. The distinction matters because investment in technical integrity, which is where both fields concentrate their effort, does nothing for the other two and can obscure them, since a record whose surface quality is high invites a confidence that its provenance does not support. Special education has named a version of the procedural failure directly. The individualised education plan is written by qualified professionals and enacted substantially by assistants who may not have attended the meeting, may not have read the document in full, and may have received its content as a verbal summary, and the distance between plan as written and plan as enacted is the implementation gap. Its causes are structural rather than dispositional. Assistants receive provisions without rationale, and rationale is what permits intelligent adaptation, as the training literature demonstrates when it shows that explanation combined with modelling and feedback changes practice in ways that instruction alone does not (Walker et al., 2021; Damiani et al., 2023). Plan goals are written at a level of abstraction that cannot be directly enacted, so their conversion into hundreds of specific daily decisions is interpretive professional work performed without professional recognition. And assistants observe the plan's effects more continuously than anyone else, yet structured routes for returning those observations to plan review are uncommon, which means the person best placed to detect that a provision has stopped working has no reliable way of saying so. Clinical research has the same gap under a different name. Protocol deviations are recorded, and protocol interpretation is not, and the distinction matters because interpretation that never crosses the threshold into deviation is invisible by definition while still shaping the dataset systematically. A study can therefore report full protocol compliance and contain a dataset whose variables were constructed through a sequence of undocumented judgements, which is the clinical equivalent of a plan delivered faithfully in name and substantially adapted in practice. In both fields, the appearance of fidelity is produced by the same mechanism, namely that the only departures visible to the system are the ones the system has a category for.

4.3 What each field can lend

Clinical research has developed machinery that special education lacks, including version control on governing documents, formal amendment processes, audit trails, structured deviation reporting, and independent monitoring. None of this is exotic, and all of it is absent from most special education settings, where a plan may be revised informally, where practice may drift from the plan without anyone recording that it has, and where no mechanism exists to reconstruct what was actually delivered to a particular child over a particular year.

Special education has developed something clinical research lacks, namely a sustained critical literature on how frontline practice distorts outcomes together with a vocabulary for naming the

distortion. Clinical research has no equivalent of the proximity literature, no established concept of coordinator-induced dependence, and no practice-facing framework for calibrated assistance, which means that the phenomena the proximity literature describes may be occurring in trials without anyone possessing the language to identify them. The exchange is therefore not a matter of one field being more advanced than the other. Each has built what its own accountability structure demanded and has neglected what that structure never asked for.

4.4 Transfer proposition three

Both fields should adopt a provenance record as a first-class study or plan document, standing alongside the protocol or education plan and recording interpretive decisions, adaptations, adjudication rules, and the dates on which each was adopted. In clinical research, this would document extraction definitions and discrepancy resolutions, extending to human judgement the provenance logic already being applied to automated data transformation (Gierend et al., 2023). In special education, it would document which adaptations were made to a plan provision, why, and with what observed effect, using categories of the kind implementation research has already developed for reporting modifications to interventions (Wiltsey Stirman et al., 2019). In both, the frontline worker is the natural author, because they are the only person with sustained visibility across the relevant decisions. Two further recommendations follow. Special education should adopt version control and structured amendment for education and behaviour plans, so that the document governing a child's support has a traceable history rather than an assumed continuity. Clinical research should adopt structured routes for returning coordinator observation into protocol review, on the model that special education's better practice has developed for plan review.

5. Access, Approach and the Construction of Who Counts

The fourth domain concerns selection: who enters a study, who participates in a classroom, and the frontline work that determines both.

5.1 The visible and invisible portions of selection

Clinical research has a canonical representation of selection in the CONSORT flow diagram, which tracks assessment for eligibility, exclusion, allocation, follow-up, and analysis (Schulz et al., 2010). Its value is that it makes attrition and exclusion visible, and its limitation is that it begins at assessment for eligibility and cannot represent the work determining who was assessed at all. That prior work, which this paper calls access work, includes deciding which clinic lists to screen, which days to attend, how to approach a family, whether to attempt a conversation with someone who appears exhausted, how many contact attempts to make before recording non-response, and how to phrase recruitment materials. It is entirely frontline and entirely undocumented, and the reporting architecture has no place to put it. Special education has a structurally identical problem with no canonical representation at all. A student may be formally included in a mainstream classroom while being functionally excluded from its social and instructional life, and the distinction is not recorded anywhere that a researcher or an inspector would find it. Feldman et al. (2016), examining adolescents with severe disabilities in general education classrooms, distinguished presence from proximity from peer interaction and demonstrated that physical placement predicts social participation poorly. The assistant's positioning, prompting, and withdrawal decisions determine which of the three a student experiences on any given day, and the intervention literature confirms that these decisions are modifiable, since paraeducator-facilitated peer support produces measurable changes in both interaction and access when the adult is trained to withdraw (Walker et al., 2021).

In both cases, therefore, the field possesses a well-developed account of the part of selection that occurs after the consequential decisions have already been made. The screened population and the placed student are treated as given, when both are products of frontline judgement operating without record, criteria, or review. The consequence is not only that inequity goes undetected but that neither field can distinguish a sample or a placement reflecting considered judgement from one reflecting the path of least resistance, because the two are documented identically.

5.2 Fair selection, participation equity and compounding vulnerability

Emanuel et al. (2000) identified fair subject selection as a requirement of ethical research distinct from consent and risk-benefit assessment, and fair selection is not achieved by writing inclusive eligibility criteria but is achieved or defeated at the point of approach. The educational analogue is participation equity. Inclusive policy is established at system level through instruments such as the Salamanca Statement (UNESCO, 1994) and the Convention on the Rights of Persons with Disabilities (United Nations, 2006), and has been reaffirmed as a whole-system obligation rather than a specialist provision (UNESCO, 2020), while Ainscow (2005) and Booth and Ainscow (2011) translated these commitments into school development processes. But policy establishes entitlement and does not deliver participation, which is delivered or withheld in the moment when an adult decides whether to facilitate a peer interaction or to fill the gap themselves. In both fields, an equity commitment articulated at the level of policy is operationalised at the level of frontline discretion, and the gap between the two is unmeasured. Both fields also encounter the same compounding pattern, in which the people most likely to be excluded by frontline default are those whose participation requires the most frontline effort. In clinical research, this includes participants requiring interpretation, participants with limited caregiver support, participants whose cognitive impairment requires a slower consent process, and participants whose transport or scheduling constraints require accommodation. Casarett and Karlawish (2000) argued that standard ethical principles apply to palliative care research but that their application demands heightened attention to vulnerability and burden, which is precisely the attention that schedule pressure removes. The recent evidence on under-representation is consistent with this account, locating much of the shortfall in the interaction between participant circumstances and site capacity rather than in participant unwillingness (Alarcón Garavito et al., 2025; Yousafi et al., 2024). In special education, the pattern repeats with students whose communication requires patient partner behaviour, whose behaviour requires skilled regulation, and whose personal care requires time. Each is more likely to receive the containment-oriented support that produces the poorest outcomes, precisely because containment is what an under-prepared adult can deliver, and the students concerned are also those for whom the assistant is most likely to be the primary and sometimes the only consistent adult (Giangreco, 2021). The compounding is therefore not a matter of individual bias but of the interaction between need and capacity, which is why it responds to preparation, deployment design, and documentation rather than to exhortation.

5.3 Peer facilitation as the neglected alternative

Special education has developed an alternative for which clinical research has no analogue and may not need one, but which illuminates the general principle. Carter et al. (2005) demonstrated that peer support interventions can improve both curricular access and social interaction for students with severe disabilities, redistributing support from the adult to the peer group, and subsequent synthesis of paraeducator-delivered interventions found peer-mediated approaches to be among the most consistently effective uses of the role (Walker et al., 2021). The significance is

conceptual as well as practical, since it shows that the frontline worker's function can be reconceived from providing support to engineering the conditions in which support comes from elsewhere. The clinical research analogue would be a reconception of the coordinator's recruitment function from approaching individuals to building the clinical relationships, materials, and workflows through which eligible patients learn about studies from their own care teams. Both moves shift the worker from direct provision to system design, both reduce the dependence of the outcome on a single person's moment-to-moment judgement, and both require a role definition that permits the worker to spend time on something other than immediate delivery. Neither is likely to survive in a setting that measures the worker by units of direct contact, which is how both fields currently measure them.

5.4 Transfer proposition four

Both fields should extend documentation of selection upstream. Clinical research should adopt access transparency, systematically recording the population screened, the subset approached, the basis for approach decisions, and reasons for non-approach, extending the CONSORT logic to the stage that currently precedes it. Special education should adopt a participation record distinguishing presence, proximity, and interaction, on the model Feldman et al. (2016) supplied, so that placement is not mistaken for inclusion.

6. Calibrated Support and the Discipline of Fading

The fifth domain contains this paper's clearest transfer, because special education has developed a theory of support calibration that clinical research has never articulated and demonstrably needs.

6.1 The scaffolding account and its developmental rationale

Vygotsky (1978) described the zone of proximal development as the distance between independent performance and performance with support from a more capable other, and Wood et al. (1976) specified the adult behaviours that constitute scaffolding, including recruiting interest, reducing degrees of freedom, maintaining direction, marking critical features, controlling frustration, and demonstrating solutions. The defining feature of scaffolding is that it is temporary by design, since a scaffold that is never removed is not a scaffold but a permanent structure, and what it surrounds never learns to stand. A substantial body of subsequent research has examined how contingency, fading, and the transfer of responsibility operate in real instructional interaction, and has established that the withdrawal of support is the element practitioners find hardest and implement least consistently (Van de Pol et al., 2010). Radford et al. (2014, 2015) applied this to teaching assistants and proposed three functional roles which differ in intrusiveness. The support role involves the most intrusive assistance and is appropriate when a task would otherwise be inaccessible. The repair role responds to breakdowns by re-establishing the trouble source rather than supplying the answer. The heuristic role is the least intrusive and the most developmental, prompting towards a strategy the learner can generalise. The resulting discipline is straightforward to state and difficult to practise: default to the least intrusive intervention likely to succeed, escalate only as required, and de-escalate as soon as possible. Untrained assistance operates in permanent support mode, because support mode produces the fastest completion and the fewest visible difficulties. The developmental stakes are substantial. Ryan and Deci (2000) identified autonomy, competence, and relatedness as basic psychological needs underpinning motivation and wellbeing, and support that removes choice undermines autonomy, support that completes tasks undermines competence, and support that isolates from peers undermines relatedness. Shogren et al. (2015)

extended this reasoning through causal agency theory, emphasising the development of the learner's capacity to act as the causal agent in their own life, and intervention research has since shown that instruction explicitly directed at self-determination produces measurable gains in inclusive secondary classrooms (Raley et al., 2021). Persistent maximal assistance is therefore not a neutral inefficiency but works directly against the developmental purpose that inclusive education exists to serve, and the evidence that the alternative is teachable removes the last defence for leaving the calibration of support to improvisation.

6.2 The unnamed clinical analogue

Clinical research has no vocabulary for over-assistance, and the absence is costly because the phenomenon occurs constantly and in settings where its effects bear directly on the evidence produced. Consent is the clearest case. A coordinator working through a lengthy form under time pressure may summarise, emphasise, and reassure in ways that produce agreement rather than understanding, and the empirical picture suggests this is not a marginal risk, since reviews of participant comprehension find that substantial proportions of enrolled participants do not understand core elements of what they agreed to, including randomisation, voluntariness, and the distinction between research and care (Grady, 2015; Pietrzykowski & Smilowska, 2021). What the scaffolding literature adds to this familiar finding is a diagnosis of mechanism rather than a further description of the deficit. The coordinator is operating in permanent support mode, doing the cognitive work of comprehension on the participant's behalf because that is faster and looks more helpful than tolerating the participant's struggle with a genuinely difficult document, and the resulting agreement is an artefact of the assistance rather than evidence of understanding.

The same dynamic operates wherever a response is elicited. Administering a patient-reported outcome measure to a participant with cognitive impairment involves continuous judgement about clarification, rephrasing, and prompting, and each accommodation improves completion while potentially degrading validity, so the scaffolding frame reframes this as a calibration problem with a principled answer, which is the least assistance that permits a valid response rather than the most assistance that permits any response. In qualitative work, an interviewer who fills silences, offers candidate formulations, and confirms hypotheses produces transcripts that reflect the interviewer's framing, and while Braun and Clarke (2006) and Nowell et al. (2017) addressed analytic rigour in thematic work and Lincoln and Guba (1985) established trustworthiness criteria including credibility, dependability, confirmability, and transferability, all of these operate downstream, and none can repair over-prompting in collection. Retention presents the same problem in the form the field is least inclined to examine, since a coordinator who reminds, arranges, and smooths every barrier may maintain a participant in a study who would otherwise have withdrawn, which is valuable for completeness and raises questions about voluntariness that are rarely asked.

What unifies these settings is that the coordinator is doing precisely what an untrained assistant does at a desk beside a struggling student, and that neither field's training addresses the judgement involved. The clinical literature treats the resulting variation as interviewer effect, a source of error to be minimised through standardisation, which is unhelpful in populations where some assistance is the enabling condition of any response at all. The educational literature holds the concept the clinical field needs, and the clinical field holds the measurement apparatus that would allow the concept to be tested. Neither has noticed the other.

6.3 Tolerated difficulty as the shared skill

The common principle is that some difficulty is generative and should be tolerated. A learner prevented from all error is prevented from the productive difficulty through which learning consolidates, and a participant whose comprehension struggle is smoothed away is a participant whose consent has not been tested. In both cases, the skill is calibration, meaning the ability to distinguish struggle that is developmentally or epistemically useful from distress that is not and to respond differently to each. The distinction cannot be specified in advance, which is exactly why it belongs to the frontline worker and why it cannot be delegated to a protocol.

This is the judgement that training rarely addresses and that supervision rarely observes in either field, and its absence is not explained by difficulty. Fading is an observable behaviour rather than a disposition, since the decision to wait, to prompt minimally, or to supply the answer is visible to anyone watching the interaction, and the training literature demonstrates that observable behaviours of exactly this kind respond to modelling and performance feedback (Walker et al., 2021). Its absence from preparation in both fields is therefore a choice about what is worth training rather than a limit on what can be trained, and the choice follows from the framing of the role examined in section 2, since a worker understood as executing instructions has no evident need of calibration. Calibration is what one does when the instruction runs out, and neither field's account of the role admits that this happens.

6.4 Transfer proposition five

Clinical research should adopt the scaffolding framework and its three functional roles as an explicit model for coordinator assistance in consent, data collection, and interviewing, and should treat fading discipline as a trainable and observable competency. Special education should reciprocally adopt clinical research's practice of specifying assistance parameters in advance, so that the permissible range of prompting is defined before the interaction rather than improvised within it.

7. Vigilance, Escalation and Ethical Voice

The sixth domain concerns what happens when the frontline worker notices something wrong.

7.1 Noticing precedes reporting

Regulatory frameworks in clinical research specify what must be reported, to whom, and within what timeframe (International Council for Harmonisation, 2016), and safeguarding frameworks in education specify equivalent obligations. Neither can specify the prior and harder act of noticing, which is judgement under ambiguity and which no framework has ever successfully proceduralised. In both fields the ambiguity is structural rather than incidental. A participant with metastatic disease and multiple comorbidities generates a continuous stream of clinical events, and distinguishing expected trajectory from study-related harm requires clinical knowledge, longitudinal familiarity, and the confidence to raise a concern that may prove unfounded. A student with communication differences and sensory sensitivities generates a continuous stream of behavioural signals, and distinguishing ordinary variation from distress requiring escalation requires the same three things. The distribution of those three requirements is what makes the position difficult. In both fields, the frontline worker is the person most likely to hold the longitudinal familiarity that rotating professionals lack, and least likely to hold the epistemic authority to act on it. The observation that matters most is therefore held by the person least positioned to have it heard, and neither field has an account of what becomes of such observations when they are not raised, because an unraised observation leaves no trace of any kind.

7.2 From individual vigilance to escalation capacity

Whether an observation travels depends on three things that are usually treated separately and are better understood as aspects of a single team property. The first is epistemic authority, in that the worker must believe their observation counts as evidence, and where team culture treats frontline observation as anecdote pending professional validation, borderline concerns go unreported. The second is the perceived cost of raising a concern, which includes delay, documentation, implied criticism of a senior colleague, and friction with someone invested in timelines or in a plan they authored. The health services literature has examined this at length under the heading of psychological safety and voice, finding that silence is patterned by hierarchy, seniority, and anticipated futility rather than by the seriousness of the concern, and that staff who withhold a concern commonly do so having judged that raising it would change nothing (O'Donovan et al., 2021; Lainidi et al., 2023; Carrillo et al., 2024). The third is structural opportunity, meaning the existence of a channel through which an observation can enter the formal record, whether a data and safety monitoring meeting, a team huddle, a structured debrief, or a plan review. Where these are absent or perfunctory, vigilance has nowhere to go, and interventions addressing only the individual's willingness to speak while leaving the channel unchanged have limited and poorly sustained effects (Jones et al., 2021). Taken together, these conditions constitute what this paper calls escalation capacity, meaning the extent to which a frontline worker's uncertain observation can reach the formal record without being filtered by hierarchy, time pressure, or anticipated disapproval. Stating it as a single team property rather than as three separate problems has an analytic purpose, since the three are not independent: a worker who believes their observation is not evidence will never test whether the channel works, and a channel that exists but is never used will be judged unnecessary and removed. Escalation capacity is also distinct from compliance in a way both fields systematically miss. A study can satisfy every reporting requirement while possessing low escalation capacity, because compliance is measured on events that entered the system and not on events that never did, and a school can satisfy every safeguarding requirement in the same way. Weiner (2009) argued that shared commitment and shared efficacy determine whether intended practices are actually enacted; Damschroder et al. (2009) located such dynamics in the inner setting of an organisation, and Proctor et al. (2011) distinguished implementation outcomes such as fidelity and penetration from service and client outcomes, a distinction that clarifies why monitoring can be nominally compliant and functionally weak.

The concept clarifies a common misreading in both fields. Ethical conduct is frequently treated as an attribute of documents and approvals, and on the account offered here it is substantially an attribute of team communication structures, within which frontline workers are simultaneously the most exposed and the least empowered participants. This also explains why neither field can improve its safety or safeguarding performance by strengthening reporting requirements alone, since requirements act only on observations that have already been raised, and the failure described here occurs earlier than that.

7.3 The regulatory capacity of the supporting adult

A further consideration applies with particular force in education and applies in clinical research more than is acknowledged, which is that the worker's own state is an active variable rather than a background condition. A dysregulated student borrows the regulatory capacity of a calm adult before developing their own, and the frameworks that govern behaviour support presuppose exactly this. Positive behaviour support frames behaviour functionally, seeking to teach more effective means of achieving a purpose while altering the conditions that made the original

response necessary (Carr et al., 2002; Horner & Sugai, 2015), and Dunn (1997) provided a model relating sensory processing patterns to behavioural responses. Both presuppose an adult with the capacity to remain regulated under pressure.

That capacity is itself unsupported in both fields. Assistants absorb significant emotional load, often including physical risk, typically with minimal debriefing. Coordinators working in oncology, dementia, and palliative care absorb a comparable load of a different kind, forming sustained relationships with participants who deteriorate and die, and the research nursing literature has begun to describe the resulting strain as moral distress rather than as ordinary occupational stress, locating its source in situations where the worker can see what a participant needs and is not positioned to provide it (Showalter et al., 2022). An unsupported worker cannot reliably supply capacity they do not have, which means that the emotional sustainability of the frontline worker is a condition of practice quality rather than a matter of staff welfare.

This reframing matters for how both fields interpret variation in frontline performance. A worker whose judgement deteriorates across a term or across a difficult study period is frequently read as a training or motivation problem, when the more parsimonious explanation is cumulative load without recovery, and the workforce evidence in both sectors makes the alternative reading plausible given documented rates of turnover and the organisational disruption that follows from them (Suter et al., 2020; Kengne Talla et al., 2023). Neither field currently collects the information that would distinguish the two explanations, and in the absence of that information the individualising interpretation prevails by default.

7.4 Transfer proposition six

Both fields should treat escalation capacity as a measurable and improvable team property, assessed independently of compliance. Both should institute structured debriefing following significant events, and both should recognise the frontline worker's own emotional and regulatory sustainability as a condition of practice quality rather than a welfare afterthought.

8. Conclusion

This paper has argued that clinical research coordinators and instructional assistants occupy the same structural position and that examining them together yields insight neither field generates alone. The position has four properties. The frontline worker holds more sustained contact with the vulnerable person than anyone else in the system, holds the least formal preparation, resolves the incompleteness of protocols and plans hundreds of times daily without observation or record, and produces in aggregate the sample composition, data provenance, curricular access, and participation that each field subsequently reports as a result. Six domains were developed on that basis: structural position, discretion under incomplete instruction, documentation as practice, access and the construction of who counts, calibrated support and the discipline of fading, and vigilance with ethical escalation. The pattern recurs in all six, which is the principal evidence that the similarity is structural rather than superficial, since a loose analogy would hold in one or two domains and fail in the rest. The two fields hold complementary deficits. Special education possesses the critique, having produced three decades of research on proximity, dependence, and deployment together with a theoretically grounded corrective in the scaffolding literature, but it cannot reconstruct, for any individual child, what support was actually delivered. Clinical research possesses the traceability architecture of version control, structured amendment, provenance documentation, and independent monitoring, but it has no equivalent of the proximity literature and no practice-facing account of how coordinator discretion shapes the evidence produced. The

asymmetry is historical. One field built its architecture under regulatory pressure that framed the frontline worker as a compliance risk; the other built its critique under an inclusion agenda that never generated a documentary obligation. Neither deficit is therefore likely to correct itself from within, which is why the paper proposes transfer: special education should adopt provenance documentation, version control, and specified assistance parameters, while clinical research should adopt the scaffolding framework, fading discipline as a trainable competency, and the recognition that frontline interpretive practice is a legitimate object of study rather than an operational detail. The practical implications are modest individually and consequential together. Both fields should specify decision rights rather than tasks alone, since ambiguity does not eliminate judgement but removes it from oversight. Both should shift preparation from compliance content towards reasoned judgement, calibrated assistance, interpretive documentation, and structured escalation, all of which are observable behaviours and therefore teachable. Both should establish named supervision, joint planning time, and structured debriefing, without which training does not reliably change practice. Both should extend documentation upstream to record who was approached and on what basis, and downstream to distinguish presence from participation. And both should treat turnover and constrained authority in these roles as threats to evidence quality rather than as human resource problems, since tacit knowledge departs with the person holding it. These claims are advanced as propositions rather than findings. This is a conceptual paper reporting no new data; the educational evidence it draws on is correlational and contested in its interpretation; the roles are structurally rather than functionally alike so that transfers require adaptation rather than import; and documentation proposed for an already overloaded workforce will fail unless it replaces reconstruction effort rather than adding to it. The framework is testable, and the most direct test is a parallel observational study of the two workforces using a common coding scheme, which would falsify the central claim cleanly if their discretion patterns diverge. Both fields have arranged themselves so that the most consequential interpretive work is performed by the least prepared people and is then rendered invisible in the record. Both have subsequently discovered problems, in reproducibility and in educational outcomes respectively, whose sources they have sought in design and analysis. Design and analysis matter. But a proportion of the problem lies further upstream, in the moment when an under-prepared person makes a reasonable decision under pressure and no one records that a decision was made at all. The two workers described at the opening of this paper will make several hundred such decisions before the end of the week. Almost all will be reasonable. A few will determine what a study can claim or what a child can reach. None will be written down as decisions. Making that layer visible is not an administrative reform. It is a condition of knowing what either field actually achieves.

References

- Ainscow, M. (2005). Developing inclusive education systems: What are the levers for change? *Journal of Educational Change*, 6(2), 109–124. <https://doi.org/10.1007/s10833-005-1298-4>
- Alarcón Garavito, G. A., Gilchrist, K., Ciurtin, C., Khanna, S., Chambers, P., McNally, N., Merivale, E., Carr, E., Yu, R., & Vindrola-Padros, C. (2025). Enablers and barriers of clinical trial participation in adult patients from minority ethnic groups: A systematic review. *Trials*, 26. <https://doi.org/10.1186/s13063-025-08769-y>
- Blatchford, P., Russell, A., & Webster, R. (2012). *Reassessing the impact of teaching assistants: How research challenges practice and policy*. Routledge.
- Booth, T., & Ainscow, M. (2011). *Index for inclusion: Developing learning and participation in schools* (3rd ed.). Centre for Studies on Inclusive Education.
- Bowker, G. C., & Star, S. L. (1999). *Sorting things out: Classification and its consequences*. MIT Press.
- Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, 3(2), 77–101. <https://doi.org/10.1191/1478088706qp063oa>
- Broer, S. M., Doyle, M. B., & Giangreco, M. F. (2005). Perspectives of students with intellectual disabilities about their experiences with paraprofessional support. *Exceptional Children*, 71(4), 415–430. <https://doi.org/10.1177/001440290507100402>
- Carr, E. G., Dunlap, G., Horner, R. H., Koegel, R. L., Turnbull, A. P., Sailor, W., Anderson, J. L., Albin, R. W., Koegel, L. K., & Fox, L. (2002). Positive behavior support: Evolution of an applied science. *Journal of Positive Behavior Interventions*, 4(1), 4–16. <https://doi.org/10.1177/109830070200400102>
- Carrillo, I., Serpa, P., Landa-Ramírez, E., Guilabert, M., Gómez-Ayala, Y., López-Pineda, A., & Mira, J. J. (2024). Speaking up about patient safety, withholding voice and safety climate in clinical settings: A cross-sectional study among Ibero-American healthcare students. *International Journal of Public Health*, 69, 1607406. <https://doi.org/10.3389/ijph.2024.1607406>
- Carter, E. W., Cushing, L. S., Clark, N. M., & Kennedy, C. H. (2005). Effects of peer support interventions on students' access to the general curriculum and social interactions. *Research and Practice for Persons with Severe Disabilities*, 30(1), 15–25. <https://doi.org/10.2511/rpsd.30.1.15>
- Casarett, D. J., & Karlawish, J. H. T. (2000). Are special ethical guidelines needed for palliative care research? *Journal of Pain and Symptom Management*, 20(2), 130–139. [https://doi.org/10.1016/S0885-3924\(00\)00164-0](https://doi.org/10.1016/S0885-3924(00)00164-0)
- Cook, B. G., & Odom, S. L. (2013). Evidence-based practices and implementation science in special education. *Exceptional Children*, 79(2), 135–144. <https://doi.org/10.1177/001440291307900201>
- Damiani, M. L., Woodfield, C., Elder, B. C., & Freedman, J. E. (2023). Professional development for paraprofessionals on inclusive practices using disability studies in education. *Journal of Special Education Preparation*.
- Damschroder, L. J., Aron, D. C., Keith, R. E., Kirsh, S. R., Alexander, J. A., & Lowery, J. C. (2009). Fostering implementation of health services research findings into practice: A consolidated framework for advancing implementation science. *Implementation Science*, 4, 50. <https://doi.org/10.1186/1748-5908-4-50>

- Dunn, W. (1997). The impact of sensory processing abilities on the daily lives of young children and their families: A conceptual model. *Infants & Young Children*, 9(4), 23–35.
- Emanuel, E. J., Wendler, D., & Grady, C. (2000). What makes clinical research ethical? *JAMA*, 283(20), 2701–2711. <https://doi.org/10.1001/jama.283.20.2701>
- Feldman, R., Carter, E. W., Asmus, J., & Brock, M. E. (2016). Presence, proximity, and peer interactions of adolescents with severe disabilities in general education classrooms. *Exceptional Children*, 82(2), 192–208. <https://doi.org/10.1177/0014402915585481>
- Fisher, J. A. (2009). *Medical research for hire: The political economy of pharmaceutical clinical trials*. Rutgers University Press.
- Fixsen, D. L., Naoom, S. F., Blase, K. A., Friedman, R. M., & Wallace, F. (2005). *Implementation research: A synthesis of the literature*. University of South Florida, Louis de la Parte Florida Mental Health Institute.
- Ford, J. G., Howerton, M. W., Lai, G. Y., Gary, T. L., Bolen, S., Gibbons, M. C., Tilburt, J., Baffi, C., Tanpitukpongse, T. P., Wilson, R. F., Powe, N. R., & Bass, E. B. (2008). Barriers to recruiting underrepresented populations to cancer clinical trials: A systematic review. *Cancer*, 112(2), 228–242. <https://doi.org/10.1002/cncr.23157>
- Giangreco, M. F. (2021). Maslow's hammer: Teacher assistant research and inclusive practices at a crossroads. *European Journal of Special Needs Education*, 36(2), 278–293. <https://doi.org/10.1080/08856257.2021.1901377>
- Giangreco, M. F., & Broer, S. M. (2005). Questionable utilization of paraprofessionals in inclusive schools: Are we addressing symptoms or causes? *Focus on Autism and Other Developmental Disabilities*, 20(1), 10–26. <https://doi.org/10.1177/10883576050200010201>
- Giangreco, M. F., Edelman, S. W., Broer, S. M., & Doyle, M. B. (2001). Paraprofessional support of students with disabilities: Literature from the past decade. *Exceptional Children*, 68(1), 45–63. <https://doi.org/10.1177/001440290106800103>
- Giangreco, M. F., Edelman, S. W., Luiselli, T. E., & MacFarland, S. Z. C. (1997). Helping or hovering? Effects of instructional assistant proximity on students with disabilities. *Exceptional Children*, 64(1), 7–18. <https://doi.org/10.1177/001440299706400101>
- Giangreco, M. F., Suter, J. C., & Doyle, M. B. (2010). Paraprofessionals in inclusive schools: A review of recent research. *Journal of Educational and Psychological Consultation*, 20(1), 41–57. <https://doi.org/10.1080/10474410903535356>
- Gierend, K., Waltemath, D., Ganslandt, T., & Siegel, F. (2023). Traceable research data sharing in a German medical data integration center with FAIR-gearred provenance implementation: Proof-of-concept study. *JMIR Formative Research*, 7, e50027. <https://doi.org/10.2196/50027>
- Grady, C. (2015). Enduring and emerging challenges of informed consent. *New England Journal of Medicine*, 372(9), 855–862. <https://doi.org/10.1056/NEJMr1411250>
- Hargreaves, A., & Fullan, M. (2012). *Professional capital: Transforming teaching in every school*. Teachers College Press.
- Harris, P. A., Taylor, R., Minor, B. L., Elliott, V., Fernandez, M., O'Neal, L., McLeod, L., Delacqua, G., Delacqua, F., Kirby, J., & Duda, S. N. (2019). The REDCap consortium: Building an international community of software platform partners. *Journal of Biomedical Informatics*, 95, 103208. <https://doi.org/10.1016/j.jbi.2019.103208>
- Harris, P. A., Taylor, R., Thielke, R., Payne, J., Gonzalez, N., & Conde, J. G. (2009). Research electronic data capture (REDCap): A metadata-driven methodology and workflow process

- for providing translational research informatics support. *Journal of Biomedical Informatics*, 42(2), 377–381. <https://doi.org/10.1016/j.jbi.2008.08.010>
- Hawe, P., Shiell, A., & Riley, T. (2004). Complex interventions: How far out of control can a randomised controlled trial be? *BMJ*, 328(7455), 1561–1563. <https://doi.org/10.1136/bmj.328.7455.1561>
- Hoffmann, T. C., Glasziou, P. P., Boutron, I., Milne, R., Perera, R., Moher, D., Altman, D. G., Barbour, V., Macdonald, H., Johnston, M., Lamb, S. E., Dixon-Woods, M., McCulloch, P., Wyatt, J. C., Chan, A.-W., & Michie, S. (2014). Better reporting of interventions: Template for intervention description and replication (TIDieR) checklist and guide. *BMJ*, 348, g1687. <https://doi.org/10.1136/bmj.g1687>
- Horner, R. H., & Sugai, G. (2015). School-wide PBIS: An example of applied behavior analysis implemented at a scale of social importance. *Behavior Analysis in Practice*, 8(1), 80–85. <https://doi.org/10.1007/s40617-015-0045-4>
- International Council for Harmonisation. (2016). Integrated addendum to ICH E6(R1): Guideline for good clinical practice E6(R2). ICH.
- Jones, A., Blake, J., Adams, M., Kelly, D., Mannion, R., & Maben, J. (2021). Interventions promoting employee “speaking-up” within healthcare workplaces: A systematic narrative review of the international literature. *Health Policy*, 125(3), 375–384.
- Kahn, M. G., Callahan, T. J., Barnard, J., Bauck, A. E., Brown, J., Davidson, B. N., Estiri, H., Goerg, C., Holve, E., Johnson, S. G., Liaw, S.-T., Hamilton-Lopez, M., Meeker, D., Ong, T. C., Ryan, P., Shang, N., Weiskopf, N. G., Weng, C., Zozus, M. N., & Schilling, L. (2016). A harmonized data quality assessment terminology and framework for the secondary use of electronic health record data. *eGEMs*, 4(1), 1244. <https://doi.org/10.13063/2327-9214.1244>
- Kengne Talla, P., Robillard, C., Ahmed, S., Guindon, A., Houtekier, C., & Thomas, A. (2023). Clinical research coordinators’ role in knowledge translation activities in rehabilitation: A mixed methods study. *BMC Health Services Research*, 23, 124. <https://doi.org/10.1186/s12913-023-09027-0>
- Kirk, M. A., Moore, J. E., Wiltsey Stirman, S., & Birken, S. A. (2020). Towards a comprehensive model for understanding adaptations’ impact: The model for adaptation design and impact (MADI). *Implementation Science*, 15(1), 56. <https://doi.org/10.1186/s13012-020-01021-y>
- Lainidi, O., Jendeby, M. K., Montgomery, A., Mouratidis, C., Paitaridou, K., Cook, C., Johnson, J., & Karakasidou, E. (2023). An integrative systematic review of employee silence and voice in healthcare: What are we really measuring? *Frontiers in Psychiatry*, 14, 1111579. <https://doi.org/10.3389/fpsy.2023.1111579>
- Lincoln, Y. S., & Guba, E. G. (1985). *Naturalistic inquiry*. SAGE.
- Miller, C. J., Wiltsey Stirman, S., & Baumann, A. A. (2020). Iterative decision-making for evaluation of adaptations (IDEA): A decision tree for balancing adaptation, fidelity, and intervention impact. *Journal of Community Psychology*, 48(4), 1163–1177. <https://doi.org/10.1002/jcop.22279>
- Nowell, L. S., Norris, J. M., White, D. E., & Moules, N. J. (2017). Thematic analysis: Striving to meet the trustworthiness criteria. *International Journal of Qualitative Methods*, 16(1), 1–13. <https://doi.org/10.1177/1609406917733847>
- O’Donovan, R., De Brún, A., & McAuliffe, E. (2021). Healthcare professionals' experience of psychological safety, voice, and silence. *Frontiers in Psychology*, 12, 626689. <https://doi.org/10.3389/fpsyg.2021.626689>

- Page, M. J., McKenzie, J. E., Bossuyt, P. M., Boutron, I., Hoffmann, T. C., Mulrow, C. D., Shamseer, L., Tetzlaff, J. M., Akl, E. A., Brennan, S. E., Chou, R., Glanville, J., Grimshaw, J. M., Hróbjartsson, A., Lalu, M. M., Li, T., Loder, E. W., Mayo-Wilson, E., McDonald, S., ... Moher, D. (2021). The PRISMA 2020 statement: An updated guideline for reporting systematic reviews. *BMJ*, 372, n71. <https://doi.org/10.1136/bmj.n71>
- Pérez, D., Van der Stuyft, P., Zabala, M. C., Castro, M., & Lefèvre, P. (2016). A modified theoretical framework to assess implementation fidelity of adaptive public health interventions. *Implementation Science*, 11. <https://doi.org/10.1186/s13012-016-0457-8>
- Perez Jolles, M., Lengnick-Hall, R., & Mittman, B. S. (2019). Core functions and forms of complex health interventions: A patient-centered medical home illustration. *Journal of General Internal Medicine*, 34(6), 1032–1038. <https://doi.org/10.1007/s11606-018-4818-7>
- Pietrzykowski, T., & Smilowska, K. (2021). The reality of informed consent: Empirical studies on patient comprehension — systematic review. *Trials*, 22, 57. <https://doi.org/10.1186/s13063-020-04969-w>
- Proctor, E., Silmere, H., Raghavan, R., Hovmand, P., Aarons, G., Bunger, A., Griffey, R., & Hensley, M. (2011). Outcomes for implementation research: Conceptual distinctions, measurement challenges, and research agenda. *Administration and Policy in Mental Health and Mental Health Services Research*, 38(2), 65–76. <https://doi.org/10.1007/s10488-010-0319-7>
- Radford, J., Bosanquet, P., Webster, R., & Blatchford, P. (2015). Scaffolding learning for independence: Clarifying teacher and teaching assistant roles for children with special educational needs. *Learning and Instruction*, 36, 1–10. <https://doi.org/10.1016/j.learninstruc.2014.10.005>
- Radford, J., Bosanquet, P., Webster, R., Blatchford, P., & Rubie-Davies, C. (2014). Fostering learner independence through heuristic scaffolding: A valuable role for teaching assistants. *International Journal of Educational Research*, 63, 116–126. <https://doi.org/10.1016/j.ijer.2013.02.010>
- Raley, S. K., Shogren, K. A., Rifenbark, G. G., Lane, K. L., & Pace, J. R. (2021). The impact of the Self-Determined Learning Model of Instruction on student self-determination in inclusive, secondary classrooms. *Remedial and Special Education*, 42(6), 363–373.
- Ryan, R. M., & Deci, E. L. (2000). Self-determination theory and the facilitation of intrinsic motivation, social development, and well-being. *American Psychologist*, 55(1), 68–78. <https://doi.org/10.1037/0003-066X.55.1.68>
- Schulz, K. F., Altman, D. G., & Moher, D. (2010). CONSORT 2010 statement: Updated guidelines for reporting parallel group randomised trials. *BMJ*, 340, c332. <https://doi.org/10.1136/bmj.c332>
- Sharma, U., & Salend, S. J. (2016). Teaching assistants in inclusive classrooms: A systematic analysis of the international research. *Australian Journal of Teacher Education*, 41(8), 118–134. <https://doi.org/10.14221/ajte.2016v41n8.7>
- Shogren, K. A., Wehmeyer, M. L., Palmer, S. B., Forber-Pratt, A. J., Little, T. J., & Lopez, S. (2015). Causal agency theory: Reconceptualizing a functional model of self-determination. *Education and Training in Autism and Developmental Disabilities*, 50(3), 251–263.
- Showalter, B. L., Malecha, A., Cesario, S., & Clutter, P. (2022). Moral distress in clinical research nurses. *Nursing Ethics*, 29(7–8), 1697–1708. <https://doi.org/10.1177/09697330221090613>
- Star, S. L. (1999). The ethnography of infrastructure. *American Behavioral Scientist*, 43(3), 377–391. <https://doi.org/10.1177/00027649921955326>

- Suter, J. C., Giangreco, M. F., & Bruhl, S. A. D. (2020). Special education personnel absences in inclusion-oriented schools: Implications for building effective service delivery models. *Remedial and Special Education*, 41(6), 341–351. <https://doi.org/10.1177/0741932519865617>
- Timmermans, S., & Berg, M. (2003). *The gold standard: The challenge of evidence-based medicine and standardization in health care*. Temple University Press.
- UNESCO. (1994). *The Salamanca Statement and Framework for Action on Special Needs Education*. UNESCO.
- UNESCO. (2020). *Global education monitoring report 2020: Inclusion and education: All means all*. UNESCO.
- United Nations. (2006). *Convention on the Rights of Persons with Disabilities*. United Nations.
- Van de Pol, J., Volman, M., & Beishuizen, J. (2010). Scaffolding in teacher–student interaction: A decade of research. *Educational Psychology Review*, 22(3), 271–296. <https://doi.org/10.1007/s10648-010-9124-7>
- Vygotsky, L. S. (1978). *Mind in society: The development of higher psychological processes*. Harvard University Press.
- Walker, V. L., Kurth, J., Carpenter, M. E., Tapp, M. C., Clausen, A., & Lockman Turner, E. (2021). Paraeducator-delivered interventions for students with extensive support needs in inclusive school settings: A systematic review. *Research and Practice for Persons with Severe Disabilities*, 46(4), 278–295. <https://doi.org/10.1177/15407969211055127>
- Webster, R., & de Boer, A. A. (Eds.). (2023). *Teaching assistants, inclusion and special educational needs: International perspectives on the role of paraprofessionals in schools*. Routledge.
- Webster, R., Blatchford, P., Bassett, P., Brown, P., Martin, C., & Russell, A. (2010). Double standards and first principles: Framing teaching assistant support for pupils with special educational needs. *European Journal of Special Needs Education*, 25(4), 319–336. <https://doi.org/10.1080/08856257.2010.513533>
- Weiner, B. J. (2009). A theory of organizational readiness for change. *Implementation Science*, 4, 67. <https://doi.org/10.1186/1748-5908-4-67>
- Weiskopf, N. G., & Weng, C. (2013). Methods and dimensions of electronic health record data quality assessment: Enabling reuse for clinical research. *Journal of the American Medical Informatics Association*, 20(1), 144–151. <https://doi.org/10.1136/amiajnl-2011-000681>
- Wiley, L. K., Rasmussen, L. V., Levinson, R. T., Malinowski, J., Manemann, S. M., Wilson, M. P., Chapman, M., Pacheco, J. A., Walunas, T. L., Starren, J. B., Bielinski, S. J., & Richesson, R. L. (2026). PhenoFit: A framework for determining computable phenotyping algorithm fitness for purpose and reuse. *Journal of the American Medical Informatics Association*, 33(2), 536–542. <https://doi.org/10.1093/jamia/ocaf195>
- Wiltsey Stirman, S., Baumann, A. A., & Miller, C. J. (2019). The FRAME: An expanded framework for reporting adaptations and modifications to evidence-based interventions. *Implementation Science*, 14, 58. <https://doi.org/10.1186/s13012-019-0898-y>
- Wood, D., Bruner, J. S., & Ross, G. (1976). The role of tutoring in problem solving. *Journal of Child Psychology and Psychiatry*, 17(2), 89–100. <https://doi.org/10.1111/j.1469-7610.1976.tb00381.x>
- Yousafi, S., Rangachari, P., & Holland, M. L. (2024). Barriers to recruitment and retention among underrepresented populations in cancer clinical trials: A qualitative study of the

perspectives of clinical trial research coordinating staff at a cancer center. *Journal of Healthcare Leadership*, 16, 427–441. <https://doi.org/10.2147/JHL.S488426>

Zhao, Y., Rose, R., & Shevlin, M. (2021). Paraprofessional support in Irish schools: From special needs assistants to inclusion support assistants. *European Journal of Special Needs Education*.