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*Clin Rehabil* 2009; 23; 387

DOI: 10.1177/0269215509104072

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## Editorial

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### **Adverse effects of rehabilitation – an opportunity to increase quality and effectiveness of rehabilitation**

Rehabilitation is a problem-solving process focused on activities and aiming to optimize social participation. Until recently, studies have rarely considered adverse effects arising from rehabilitation. Consideration of adverse effects is ethically necessary; one should not act in a way that may cause net harm. Several types of adverse effect exist. Societal adverse effects arise when resources are used that deliver less benefit than an alternative use of the same resource; this applies in all health care systems, albeit more apparently in those providing more-or-less universal coverage. Patient adverse effects may be transient or permanent, and may be inevitable, or arise by change, or arise predictably in a proportion of people. All are discussed in this Editorial. One significant potential adverse event is stressed: the maintenance of the patient in the sick role and, associated with this, maintenance of unattainable expectations. There is minimal evidence available concerning the actual frequency and severity of adverse events. Two recommendations arise. First, systematic recording of adverse outcomes should become routine, with the goal of improving service quality. Second, rehabilitation services should always focus on helping patients to find satisfying, sustainable activities and roles to replace the role of being a patient.

### **Introduction**

The use of simple checklists to reduce adverse events during surgery may reduce mortality and morbidity by about one-third.<sup>1</sup> The explanation given is that surgery is a complex activity requiring coordinated actions from a team of people. Rehabilitation has similar characteristics, being arguably more complex and involving

more people. Rehabilitation may not involve an immediate major risk of death or severe harm but it may well involve risk and harm. A focus on preventing harm might improve rehabilitation – if there is harm.

The potential risk and harm associated with rehabilitation is not trivial, although many people assume it is. For example, researchers reporting a study of a new treatment may state, ‘It would have been unethical to randomize patients’. This excuse is commonly used to justify a non-randomized, often uncontrolled design that only allows very weak conclusions to be drawn, if any. Two assumptions underlie this statement: the new treatment must have a greater beneficial effect than the alternative, and the new treatment cannot cause more harm than the alternative. Both are false.

A critical reader could respond ‘What evidence is there of harm associated with rehabilitation?’ This is a reasonable question. The evidence is limited, not because people have looked and found no harm but because most people do not consider or record harm, systematically or otherwise. However the high rate of iatrogenic illness might urge caution.<sup>2</sup>

Thus it is important to consider how rehabilitation might cause harm. This will allow both practising clinicians and researchers to collect data in a systematic way. It might also encourage a more critical approach towards current practices. Ultimately, like the surgical checklist, it may be the most effective way to improve quality.

Currently the majority of all health care decisions, including those in rehabilitation, are made on the basis of belief rather than evidence. This is inevitable. Most health care actions have not been researched. And even when there is some research available, it is not easy to translate research into a definitive factor determining a decision.

This Editorial aims to review how harm may arise as a result of the rehabilitation process. It will first consider all the components of the

rehabilitation process – assessment, goal setting, intervening and evaluating – and will then focus upon the consequences of being involved in the overall process. It finally returns to an ethical perspective.

## Rehabilitation assessment

All health care processes start with collecting information ('making the diagnosis', 'doing an assessment'). Can simply collecting data (i.e. undertaking an assessment) be harmful? Without assessment, one might argue, it is impossible to start the process. Nonetheless it is worth considering what harms might be caused.

The first risk is simply that the procedure itself may cause direct harm and tissue damage. For example testing someone in a kitchen (to determine whether they can cook safely) might lead to an accident and harm, or someone may fall when trying to reach forward on the Functional Reach Test. These risks are generally obvious and small, and should be carefully considered and minimized by the tester.

There are other potential indirect harms. Collecting data may simply be a waste of resources, especially the patient's time and money. The assessment may not add anything to the process of rehabilitation; it may be unnecessary, not influencing any actions or decisions. For example 'routine' testing, where the routine is inappropriate, wastes time. Also collecting information for other organizations such as funding agents or quality control systems may be wasteful if the other agencies never use the data or if they are collecting data not valid for their purpose or they are collecting excessive data (more data than needed to achieve the purpose). For example the resources involved in collecting the data for the Functional Independence Measure are considerable and it is doubtful that the information is any better in any way than that collected by the Barthel ADL Index.<sup>3</sup> The major harm that follows is the lost opportunity for more therapy or other activities.

Next, the information collected may itself cause harm. This may arise in many ways. Some information is personally sensitive, for example

concerning sexual function or incontinence, and dissemination of this information may harm the patient, for example by causing embarrassment. Sometimes data collected may be misinterpreted. For example poor performance on a cognitive assessment may arise from a low mood but if this is not recognized then faulty conclusions may be drawn and poor advice given.

Lastly, and perhaps most importantly, the process of assessment may harm the person's self-esteem and mood. Assessment in rehabilitation by its very nature investigates what someone cannot do or has difficulty doing; only in this way can the team know (a) what might need treating and (b) what treatments might be useful. However it is a common complaint of patients that rehabilitation services are always assessing or looking for failure, and many patients find the process upsetting or demeaning.

Thus clinically the potential of an assessment causing harm should always be considered by asking:

- What is the reason for this assessment? There should always be a goal for any data collection.
- What harms may arise from this assessment?
- How can the risks be minimized?
- Is the method being used the most efficient and effective to achieve the goal? The minimum data needed to achieve the goal should be collected.

## Goal setting

There is some evidence (not very strong) that goal setting may be beneficial to patients in several ways<sup>4-6</sup>: motivating them, improving outcome, helping to establish realistic expectations, and in reducing anxiety. However goal setting may also cause harm.

The biggest potential harm is causing the patient to lose motivation. This is most likely to occur if the goals set are too obviously attainable; there is reasonable evidence that motivation is proportional to the degree of challenge.<sup>4</sup> However goals that are perceived (by the patient) to be completely impossible may also cause

**Table 1** Summary of possible harms associated with rehabilitation

Domain/type	Harm	Comment
Assessment		
Direct	Damage to person	e.g. Injury to patient from accident
Indirect	Waste of resources: <ul style="list-style-type: none"> <li>• data invalid for purpose</li> <li>• data not used (no reason for collection)</li> <li>• data collection inefficient (collect more than needed)</li> </ul> Information misused: <ul style="list-style-type: none"> <li>• disclosure of personally sensitive data</li> <li>• misinterpretation/invalid use</li> </ul> Inducing sense of failure; reduced self-esteem	Particularly 'routine' assessments with no clear goal and data collected mandatorily for other organizations  Assessor may not know limits of interpretation and/or what factors influence interpretation  Most assessment focuses on failure
Indirect	Goals fail to motivate: <ul style="list-style-type: none"> <li>• not challenging enough</li> <li>• perceived as impossible</li> <li>• not (perceived as) relevant</li> <li>• something made contingent on success</li> </ul> Incomplete set of goals: <ul style="list-style-type: none"> <li>• failure to identify an important need</li> <li>• not able to make SMART</li> </ul>	The research evidence which supports goal setting is sometimes overridden by other non-clinical factors  Weakness of SMART goals discussed in text
Indirect	Two classes: <ul style="list-style-type: none"> <li>• Immediate: inevitable early concomitant of an action or activity</li> <li>• Late: potential long-term harm</li> </ul> Stochastic: occasional, all-or-nothing Chance	The nature and extent of most direct, late complications is almost completely unknown  e.g. Falls
Indirect	Misinterpretation or inappropriate response to direct adverse event	e.g. Stopping an activity due to fatigue believing fatigue indicates damage
Evaluation	Feedback	If not done well, feedback may cause distress
Overall Patient	May lead to: <ul style="list-style-type: none"> <li>• prolongation of unsubstantiated hope (goal mismatch)</li> <li>• passivity as a patient rather than as an active participant</li> <li>• failure to develop new sustainable roles</li> <li>• focus on inappropriate problem</li> </ul> Consider: <ul style="list-style-type: none"> <li>• Equity – should resource go to another person who would gain more?</li> </ul>	This is a failure to consider: <ul style="list-style-type: none"> <li>• Should patient be having any rehabilitation at all?</li> <li>• Are we focused on correct goals?</li> <li>• Does patient know the goals we are focused on?</li> <li>• Should we move from activity to participation goals?</li> </ul> Question: Is it fair to give so much to this patient instead of another?
Ethical		

loss of motivation. And setting goals that the patient does not see as relevant to them will not motivate them.

Some people avoid setting challenging goals that a patient might not achieve, believing incorrectly that failure will lead to demotivation. In some health care systems, continued funding is contingent upon demonstrating goal attainment, which encourages therapists to be cautious in goal setting. But goals are known to be demotivating if future actions are made contingent upon goal achievement.<sup>4</sup> Of course failure to progress should lead to review, but explicit contingency must be avoided.

A second real risk is that important actions will be overlooked or ignored because a SMART goal cannot be written (recognizing that the exact definition of SMART varies<sup>7</sup>). Interestingly, the risks associated with adhering inappropriately to SMART goals were emphasized by the possible originator of the SMART acronym.<sup>8</sup>

Thus care is needed when setting goals with patients, ensuring that:

- Goals are sufficiently challenging without being perceived as unattainable,
- Goals are perceived as relevant by the patient,
- All relevant domains and patient concerns are considered, even if the goals set do not comply with the generally accepted SMART format,
- Reward (e.g. continued therapy) is **not** simply made contingent upon goal attainment.

## Interventions/treatments

Risks and harm associated with treatments can be divided into direct and indirect groups. The direct harms can be immediate (early) or can develop later. Most harms are a matter of degree (quantitative) but some are categorical and occur stochastically.

Quantitative harms are those that may occur in anyone, but the extent may vary from minimal to marked. For example pain after botulinum toxin injection, fatigue secondary to effort, discomfort due to stretching of stiff joints or muscles, and anxiety associated with trying an activity for the

first time are all symptoms that may arise in anyone to a greater or lesser extent. Most direct harms probably arise immediately or soon after an action or activity starts; the examples above are all early direct harms.

However there may also be late harms – long-term ‘side-effects’ – for example equivalent to the known long-term effects of steroids or major tranquillizers. Whether this actually occurs is unknown, but some plausible examples will be given.

Functional electrical stimulation (for example of the ankle dorsiflexors) could in principle have long-term adverse effects such as:

- the direct stimulation of nerve or muscle may cause tissue damage in the long-term;
- the use of a stimulator may reduce or stop other adaptive recovery processes within the central nervous system such that the person becomes dependent upon the stimulator rather than developing an intrinsic ability to use the muscle;
- the person may come to believe that all other problems can be overcome by external treatment and that they do not need to make any effort for themselves.

Another, common example relates to drugs commonly used in rehabilitation which may not necessarily lead to a net benefit. For example drugs used quite widely to improve sleep, control spasticity, reduce neuropathic pain or reduce the risk of epilepsy may have several adverse effects such as reduced cognitive function and reduction of cerebral plasticity and the speed or extent of neurological recovery.<sup>9</sup>

Even giving information and providing support carries risks and is not necessarily beneficial. For example one study on giving information suggested that some people may be harmed.<sup>10</sup>

The major long-term harm that certainly occurs to some extent is prolongation of the dependent patient role and this is discussed later.

There is a second group of direct harms that are, on an individual basis, unpredictable although they are predictable within a group. For example it is almost inevitable that a proportion of people learning to transfer or walk after a stroke will fall, some repeatedly. However one cannot know that

a particular person will or will not fall. These harms may themselves vary in extent: for example a fall may cause a bruise only, or may lead to fracture and even death.

Indirect harms may also arise from these direct adverse consequences. They arise when the meaning of the event or experience is misinterpreted or acted on in an inappropriate way. For example some people interpret fatigue as evidence that they are 'doing too much' and even causing further damage (e.g. exacerbating multiple sclerosis) and may reduce or stop a treatment. The inappropriate response can equally be generated by the treating team or the family. For example an inexperienced therapist or overcautious family member might stop walking practice after a patient falls, even though the patient could probably relearn walking.

Rehabilitation teams should minimize the risks associated with treatment 'harms'. Apart from (obviously) acting in a way that reduces the unpleasant experience (e.g. giving analgesia before a painful procedure, reassuring an anxious patient), it is vital that patients are warned of these experiences so that they do not misinterpret them. This is best done by giving the patient the expectation that these experiences are normal and to be expected, and that they are evidence of fruitful, appropriate participation in active therapy.

The rehabilitation team should also be alert to harms and should react promptly in an appropriate manner, recognizing and acknowledging that an adverse event has occurred, explaining that the risk was always there, and managing the consequences actively and in a positive way, helping the patient to be realistic about its significance and to regain any lost function.

## Evaluation and monitoring

The potential harms associated with the collection of data concerned with evaluating change, either spontaneously in people simply being monitored or after an intervention, are much the same as the risks and harms associated with initial assessment. Of particular concern are the risks of misinterpreting data or of failure to react appropriately, and the risks associated with feeding back

to patients and communicating decisions in a bad way, causing distress.

## Implications of being 'a rehabilitation patient'

So far we have considered risks specifically in relation to different parts of the rehabilitation process. However there are potential harms associated with becoming or remaining involved with the whole process that are, to an extent, different from the individual risks already identified.

Being involved with the process of rehabilitation carries several implications. First, there is an assumption that there is a benefit, and so the patient (and family) will have expectations of gain (i.e. 'hope'). Second, being involved in rehabilitation is associated with the role of being a patient. Lastly, an emphasis upon improving activities may lead the person and the treating team to overlook the need to develop alternative sustainable and meaningful roles.

Attending for rehabilitation implies that the patient will benefit in some way, and generally people assume an improvement in some activity. Several problems may arise. The patient may have an exaggerated impression of the likely benefit. The patient may expect improvement when the actual goal may be to reduce the rate of decline, or to support a family, or to provide equipment etc. rather than to improve function. Sometimes the goal of the rehabilitation service may simply be to monitor progress or change, especially in adults who are vulnerable or at risk of specific complications.

It is therefore important to ensure concordance between the team's goals, which should be made explicit, and the goals and understanding of the patient, which are usually implicit. Otherwise, when the patient finally recognizes the mismatch he or she may become distressed or angry, and may decline further involvement with the rehabilitation service even if some benefit might be expected.

The role of a 'patient', a person involved in a health care process, carries several implications.

Many people (including health care practitioners) subscribe primarily to a biomedical

model of illness,<sup>1</sup> and within that model being a patient is traditionally seen as being a passive recipient of health care; treatment is something done *to* a person that makes them better. In contrast rehabilitation is primarily a process where the patient is the most active person, learning how to recover from or adapt to their illness; passivity is usually associated with failure.

Thus involvement with rehabilitation may induce passivity, stopping the person from helping themselves. This applies both to the patient and to their family. Both often want 'more treatment' and are often reluctant to accept that practice by the patient on their own is of greater importance.

Next, some people find that being in the role of patient forms an important part of their life<sup>11</sup>; they may have few other social contacts or valued roles. For example many people with disability do not work and have difficulty getting to social events of any sort, and do not have much money to pursue leisure activities that might give them meaningful activities. For this group, being a patient receiving rehabilitation is important as a social role because they have no other available roles. In rehabilitation jargon, they have very limited social participation.

Other people may find the patient role is more satisfying than the available alternatives, perhaps allowing them to avoid some responsibilities. Being a patient may legitimize not working, or not contributing to running the house, or not looking after other family members and so on.

Thus some people may attend for rehabilitation *not* because it might increase their independence (which they may not want at all) but because it offers other social advantages.

Therefore clinical teams should always consider carefully whether the benefits of attending for treatment outweigh the costs in terms of raising or maintaining unrealistic hope and in terms of developing new sustainable and meaningful activities and roles.

More importantly, all rehabilitation teams should recognize that over time the focus of rehabilitation should move from impairment, activities and physical contextual matters to an explicit focus on social roles and social contextual matters. In other words, as time passes an increasing emphasis of rehabilitation should be on identifying alternative social roles and helping a patient

to achieve them rather than on increasing performance of activities.

## Ethical considerations

It is a professional requirement always to act in the best interests of the patient. This requires clinicians to consider the risks and benefits of any advice and proposed action, and to act in a way that minimizes risk and maximizes benefit. This approach is only possible if both the risks and the benefits are known. This editorial has so far discussed the risks to a patient associated with rehabilitation. However there are two other harms that relate to resources and their use.

For an individual patient, even if the balance between direct harms and benefits is supportive of a particular treatment, it may not always be right to have that treatment rather than an alternative. Consider walking training late after stroke. There is little doubt that high intensity gait practice will measurably improve gait. However it is by no means certain that the time and effort required is worthwhile, especially when many people may gain more putting their effort into developing pleasurable leisure activities.

One must also consider other patients and the equitable use of scarce health resources; are they being used fairly, or could the same resource help another patient more? While there may be debate about how equity is judged, there can be little doubt that resources devoted to activities that carry no benefit in terms of their intended goal (or even harm) cannot be justified. For example it is unethical to continue physiotherapy simply because it provides the patient with their only social contact and keeps them cheerful. The need for social contact is legitimate but the resource allocated is inappropriate.

## Quality improvement

This editorial has raised many different ways that the rehabilitation process *might* harm patients. The lack of evidence means that the balance between benefit and harm is rarely known.

There is an urgent need to investigate harm systematically. In the meantime it must be assumed that some patients are harmed by rehabilitation, and that in some cases the harm outweighs any benefit.

Two consequences follow. In research it is important to consider and record harm in most studies. In clinical practice there should be more focus on risk and harm because it is likely that reducing risk and harm is an effective way of increasing net benefit.

Derick Wade  
Editor

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