Summary version of Health Technology Assessment (HTA) for preventing patient falls in hospitals

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Center for Kvalitet
Region Syddanmark

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Health Technology Assessment (HTA) for preventing patient falls in hospitals
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www.ouh.dk/wm122679 and www.centerforkvalitet.dk
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FOREWORD

The most important task in hospitals is to treat and relieve the patients from their illnesses. This task should evidently be handled without inflicting the patients with additional injuries or suffering.

Unfortunately, it is not possible to avoid adverse events among these patient falls. Approximately 10% of all known adverse events in hospitals can be attributed to patient falls, but despite the fact that adverse events are inevitable, there are no excuses for not intervening.

The consequences of patient falls during hospital admission are heavy for the patients, but they also have consequences for the relatives, hospital employees/staff, the hospital, the primary health sector and municipalities. The span of consequences involves personal aspects such as anxiety and social isolation to economic consequences in terms of increased length of stay and subsequent need for rehabilitation services. Thus, prevention of patient falls during hospital admission is an important effort area in the Region of Southern Denmark, as a desire to avoid all possible adverse effects from patient falls.

In spite of a large amount of research during the past 20 years there is no one answer as to how the clinical wards should handle the problem. As a result the Region of Southern Denmark has initiated this Health Technology Assessment. Through a systematic and scientific approach it has been possible to identify alternative preventive interventions for the parties concerned.

In this effort we have succeeded in forming a general view of the strengths and weaknesses of the field of falls prevention in hospital settings, which can be continuously improved through further research. Thus, the report constitutes the foundation for future efforts and will be guiding in future preventive measures as well as in new, targeted research. There are further areas concerning fall prevention yet to be addressed and solved but the Region of Southern Denmark is continuously working on providing the best possible hospital stay for our patients. The ultimate ambition is that no patient falls during their hospital stay and, in case of an adverse event, the consequences are as light as possible.

Jens Elkjær
Executive Director of Health
Region of Southern Denmark
1. REPORT SUMMARY

1.1. Background
People are admitted to hospital in order to improve their health status. The avoidance of adverse events, such as falls, during the patient’s stay should thus be a main priority for hospitals. Falls occur frequently, however, and often have severe consequences for patients.

Recent data from a database comprising reported adverse events in hospitals within the Region of Southern Denmark show that falls accounted for approximately 10% of the 2,564 events reported in 2008 (Center for Kvalitet 2009).

The physical consequences of patient falls range from minor bruises to major fractures, but falls sometimes also end in death. A recent systematic review (Coussement et al. 2008) found that 28% of falls resulted in bruises and minor injuries, 11.4% in severe soft tissue wounds and 5% in bone fractures. Furthermore, between 14% and 36% of the falls resulting in hip fractures were associated with death within one year.

Less immediate consequences of falls include loss of function, impaired rehabilitation, depression, increased length of hospital stay and inability to return to previous residence, all of which contribute to additional health and social care costs (Oliver et al. 2007). The person who falls, their relatives and/or the hospital staff may also experience feelings of guilt and anxiety (Coussement et al. 2008; Oliver et al. 2007).

Increasing patient age is associated with a greater risk of falling and more severe consequences. In view of the increasing proportion of older people in the general population, falls and their consequences are a growing problem (Todd and Skelton 2004; 4).

Falls thus have a wide range of physical and psychological consequences that affect the individual, their social network and society in general. Furthermore, falls constitute a relatively frequent adverse event with more than 1% leading to severe injury or death. Although a certain risk of falling must be accepted during patient recovery and rehabilitation, intervention seems attractive in order to reduce the number of falls occurring in hospitals.

Aim
The HTA report aims to be a comprehensive assessment of the preconditions for and consequences of implementing technologies for the prevention of falls in hospitals. The technologies included in the literature review are those that emerge from the scientific
literature of highest possible evidence level. Risk assessment tools for the identification of high-risk patients are also included in this assessment of falls prevention strategies. This will better enable the report to serve as a foundation for developing initiatives for falls prevention in the hospitals in the region of Southern Denmark. Since the problem area is general hospital issue, the report will also be of benefit to other similar organisations.

1.1.1. Risk assessment tools and interventions
The aim of risk assessment tools is to identify the patients that are at high risk of falling. When these patients are identified, it is possible to aim interventions for falls prevention at them and perhaps the particular risk factors that places the patients at high level of fall risk. Naturally, not all risk factors are reversible (age, history of falls etc.), but other risk factors are (strength of glasses, walking aids, wrong doses of medication etc.). In order to enable correct targeting of interventions, the patients at high risk have to be identified correctly, and several tools have been developed for that, e.g. Morse and STRATIFY (Oliver et al. 2004). It may be staff in collaboration with patients that answers the questions of the risk assessment tool. In most cases the tools are designed to provide a fall risk score, and at a predefined cut off level, the patients are regarded to be at high risk of falling during their admission.

The interventions for falls prevention are divided into two categories: multiple and single interventions. The single interventions are characterised by being implemented on a one-off basis, e.g. not two or more interventions simultaneously. Several different types of interventions can be implemented on a single basis. The single interventions that have been studied in the literature that was included in the HTA report, are the following: exercise, environmental changes, alarm systems, physical restraints, medication review, dietary supplementation (Vitamin D and calcium), identification bracelets and patient education.

The only common characteristic for multiple interventions is that they consist of more than one single intervention. For instance, environmental changes could be implemented along with patient education. The types of interventions can thus be similar, but the composition varies in different studies. In the literature that has been reviewed in the HTA report, all the evaluations of multiple interventions included falls risk assessment of patients. The multiple interventions that are compared in the meta analyses included in the HTA report, are described in Appendix 1.

The HTA assesses the prerequisites for and consequences of implementing falls prevention interventions in hospitals by answering the HTA questions below. The questions are of two types: Category ‘A’ questions are aimed at risk assessment tools, while category ‘B’ questions concern specific interventions for falls prevention among hospital inpatients.
Technology
A) How well do risk assessment tools identify patients that fall?
B) What is the effect of falls prevention strategies on the number of falls among hospital inpatients?

Patient
A) How does application of the risk assessment tools affect patients’ experiences on admission to hospital?
B) How do the different interventions affect patients’ experiences during their hospital stay?

Organisation
A) What are the organisational consequences of implementing the risk assessment tools?
B) What are the organisational consequences of implementing falls prevention strategies?
Sub-questions under both A and B:
• What are the likely consequences for hospital staff if the falls prevention strategies are implemented, including effects on education and sharing of responsibility between staff groups?
• Which part of the hospital organisation will be affected, including physical surroundings?

Economy
From the societal perspective:
• What are the costs of introducing risk assessment tools and/or fall preventive interventions for hospital in-patients?
• What savings in terms of, for example, shorter length-of-stay can be made if the interventions are implemented?
• What is the cost-effectiveness for the interventions?
From the hospital perspective:
• What are the expenditures for hospitals of implementing the risk assessment tools and/or fall preventive interventions?

These HTA questions are addressed in turn in the report and the findings summarised with discussion, conclusion and recommendations.

1.2. Methodology
A systematic literature search was carried out in the databases: Pubmed, Cochrane, Embase, Cinahl, Psycinfo, Web of Science, Up to Date, Svemed+, Den danske forskningsdatabase, projektdatabasen for MTV og evaluerering, SBU, Den nationale mini-MTV-database and
Bibliotek.dk. Search terms were: accidental fall, prevention, hospital etc. Table 1.2.1 below shows the terms that were used in the databases.

Table 1.2.1 Literature search

<table>
<thead>
<tr>
<th>Database</th>
<th>Terms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pubmed</td>
<td>accidental falls, accidental fall, prevention and control, prevent,</td>
</tr>
<tr>
<td></td>
<td>hospitals, hospitalization, hospital units</td>
</tr>
<tr>
<td>Cochrane Specialized Register</td>
<td>accidental falls, fall, hospitals, hospitalization, hospital units,</td>
</tr>
<tr>
<td></td>
<td>accident prevention, prevent, accidental fall</td>
</tr>
<tr>
<td>Embase</td>
<td>accidental fall, falling, accident prevention, hospital, aged</td>
</tr>
<tr>
<td></td>
<td>hospital patients, hospitalization, hospital units</td>
</tr>
<tr>
<td>CINAHL</td>
<td>accidental fall, accidental falls, prevention, fall prevention, hospital,</td>
</tr>
<tr>
<td></td>
<td>hospital, hospitals, hospitalized, hospital unit</td>
</tr>
<tr>
<td>PsychInfo</td>
<td>fall, falls, accident prevention, hospital, hospitals, hospital</td>
</tr>
<tr>
<td></td>
<td>hospitalization, hospital units</td>
</tr>
<tr>
<td>Web Of Science</td>
<td>accidental fall, accident prevention, prevent, hospital</td>
</tr>
</tbody>
</table>

Table 1.2.2 shows the terms that were used in the databases.

The systematic literature search resulted in approximately 3,000 articles. After removal of obviously irrelevant articles, e.g. articles on falls from ladders, horseback or similar, 1,000 articles remained. Those articles were placed in a separate database that served as basis for the literature selected for the four elements of the HTA. The selection and result is presented in table 1.2.2 below.
The selection process revealed six systematic reviews and meta analyses that served as evidence base for the technology section of the HTA. The remaining chapters on patient, organisation and economy all included all types of literature identified in the initial search within the different areas.

### 1.3. Technology

The two tables below presents an overview of the systematic reviews, meta analyses and randomised trials that serves as primary evidence base for the technology section of the HTA.

#### Table 1.2.2 selection of literature

<table>
<thead>
<tr>
<th>Criteria for inclusion</th>
<th>Technology</th>
<th>Patient</th>
<th>Organisation</th>
<th>Economy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Type of publication: systematic review or meta analysis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Subject: risk assessment tool or intervention for falls prevention</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Population: hospital admitted patients</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Clear methods section</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Result</td>
<td>8 systematic reviews or meta analyses</td>
<td>5 qualitative studies</td>
<td>5 qualitative studies</td>
<td>6 descriptive studies</td>
</tr>
</tbody>
</table>

#### Table 3.3.1. Overview of systematic reviews

<table>
<thead>
<tr>
<th>Purpose</th>
<th>Risk assessment tools</th>
<th>Fall preventive interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Oliver et al 2004</td>
<td>Gillespie et al. 2007</td>
</tr>
<tr>
<td></td>
<td>Myers 2003</td>
<td>Oliver et al 2007</td>
</tr>
<tr>
<td></td>
<td>Haines et al. 2007</td>
<td>Clusseau et al. 2008</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Methods</th>
<th>Systematic Review</th>
<th>Systematic Review Meta analysis</th>
<th>Systematic Review</th>
<th>Systematic Review Meta analysis</th>
<th>Systematic Review</th>
<th>Systematic Review Meta analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>33 studies on risk factors enabling calculation of OR and CI. 2 on risk assessment tools</td>
<td>35 studies of 52 tools on evaluations of fall risk screening tools enabling calculation of sensitivity and specificity</td>
<td>4 individually randomised studies aimed at investigating effect of, or exposure to, any risk factor for falling</td>
<td>15 studies reporting rate of falls, fractures or death from hospital interventions</td>
<td>8 studies on effectiveness of fall prevention programmes with number of fallers as main outcome, prospective controlled designs</td>
<td></td>
</tr>
<tr>
<td></td>
<td>47 studies developing, testing or using tools</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**OR**: Odds Ratio  
**CI**: Confidence Interval
### Table 3.3.2. Overview of RCTs

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Study design</th>
<th>Setting</th>
<th>Age</th>
<th>Frailty</th>
<th>Length of stay</th>
<th>Cognitive status</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin D + calcium supplementation</td>
<td>Randomised, double blinded, controlled study</td>
<td>Subacute hospital in Melbourne, Australia</td>
<td>C: 83.7 (7.6); I: 82.3 (7.6)</td>
<td>Barthel (modified) /100: C: 47 (39-59), I: 44 (37-54)</td>
<td>2 days of treatment: C: 11 (10.7); l: 10 (10), P = 0.791</td>
<td>MMSE ≤ 21: C: 40 (62%); I: 52 (61.2%)</td>
<td>Gender, no. of co-morbid conditions, no. of drugs, admission from, fall/fracture history, mobility, nutritional status, Cannard score, level of Vitamin D</td>
</tr>
<tr>
<td>Education</td>
<td>RCT, subgroup analysis</td>
<td>Subacute hospital in Melbourne, Australia</td>
<td>C: 82 (75-85); I: 83 (77-88)</td>
<td></td>
<td></td>
<td>MMSE /30: C: 25 (23-27), I: 25 (22-27)</td>
<td></td>
</tr>
<tr>
<td>Exercise</td>
<td>RCT, subgroup analysis</td>
<td>Subacute hospital in Melbourne, Australia</td>
<td>C: 81 (75-86); I: 83 (77-88)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Individually targeted multifactorial intervention</td>
<td>Cluster randomised trial</td>
<td>24 elderly care wards in 12 hospitals in Sydney, Australia</td>
<td>C: 78.4 (13.2); I: 79.6 (12.3)</td>
<td></td>
<td>4-point scale measure</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

C: Control group, I: Intervention group, MMSE: Mini Mental State Examination.

Note that the two articles by Haines et al. (2006 and 2007) are part of a larger, multifactorial study. The reported length of stay in the table is the number of days exposed to the single intervention alone. It is possible that additional patient days have been spent in the intervention group, but in these cases, the patients were also receiving other interventions. Furthermore, with regard to the two Haines articles, the patient days are reported as number of patients (patient days).

This indicates that results of the technology section was based on information from systematic reviews are based on 98 studies on fall risk assessment tools, and 25 studies of falls prevention interventions in hospitals. Furthermore, four randomised controlled trials were included. They were all published between the literature search in the latest systematic review and the literature search for the HTA report.
Results

- The meta-literature on risk assessment tools showed diverging results, indicating that no risk assessment tool is good enough at identifying patients at high versus low risk to be recommended for widespread implementation. In particular, subsequent evaluation of risk assessment tools showed decreases in tool effectiveness. For this reason, the authors of the reviews suggest local adjustment of tools and more research in this area.

- There is evidence (level 1a) of a trend towards an effect of multiple interventions. But since the literature disagrees with regard to whether the effect is statistically significant, it is recommended to carefully plan and monitor the effectiveness of multiple interventions. Also, it should be noticed that there is no evidence on which composition of single interventions that should make up the package of multiple interventions.

- Medication reviews have shown to reduce the risk of falls by 47% (level of evidence 1b) Appendix 2 provides a description of the content of the intervention.

- Patient education has shown to reduce the risk of falls by 72% (level of evidence 1b) Appendix 2 provides a description of the content of the intervention.

- Other types of interventions implemented on a single basis have no scientifically documented effect on falls. For this reason, they will not be included in the following chapters (exercise, environmental changes, bed alarms, removal of physical restraints, calcium + vitamin D supplementation and identification bracelets)

1.4. Patient

The database containing all articles from the systematic literature search was reviewed for articles including patient perceptions, experiences or fear, resulting in 57 articles. Only one of these was relevant (Gallinagh et al. 2001), and described a qualitative evaluations of patients’ and relatives’ perceptions of different fall preventive interventions.

In order to reveal further relevant literature, it was decided to include the report from the UK National Patient Safety Agency, ‘Slips, trips and falls’, along with primary literature to which the report referred (Healey & Scobie 2007). The report focuses on patient falls in UK hospitals. Healey and Scobie discuss the impact of in-hospital falls, their causes and circumstances along with preventive measures.

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1 The levels of evidence is described in Appendix 3.
Results
Generally, the information in the literature on patients’ perspectives is based on small sample sizes, and the studies have methodological problems which make general conclusions or suggestions difficult.

The literature search did not reveal literature on how patients perceive exposure to risk assessment or multiple falls prevention strategies. For this reason, it is not possible to give a satisfactory answer to the HTA questions in this section of the report on how the risk assessment tools and interventions affect patients’ experiences of their hospital stay. However, the review did reveal interesting aspects that might have an impact on clinical decisions and inspire future research:

- All the affected respondents evaluate falls prevention to be a top priority (patients, relatives and HCP)
- Patients seem willing to accept a range of restrictive measures; most likely because the patients find it more important to avoid falling than to be restrained during their stay in hospital
- There is a discrepancy between what is judged to be acceptable by patients (and relatives) compared to staff, with staff being more positive towards restrictive measures
- Patients report having changed behaviour after receiving education in falls prevention
- Patients and relatives could possibly be involved in the decisions on restrictive measures.

Furthermore, the fact that the literature on patients’ preferences does not concern the interventions and risk assessment tools evaluated in the technology section of this report, indicates a need for future studies of falls prevention to include patient aspects of the problem. Until more scientific evidence is presented, collection of data on patients’ experiences should also be considered when clinical departments implement interventions.

1.5. Organisation
The systematic literature search was reviewed for literature relevant for the organisational issues linked to implementing the falls prevention strategies identified to be effective. The keywords organisation or organization were present in 29 articles, of which five were relevant.

Results
Based on the literature, it is not possible to give general recommendations concerning the specific clinically effective interventions presented in the technology section of this report. It is also impossible to answer the HTA questions on the organisational consequences of
implementing falls prevention. It is unclear what type of consequences the staff can expect if they decide to introduce risk assessment tools or interventions for falls prevention.

In a similar way as regards the part of this report dealing with the patient perspective, the literature provides some general issues to be aware of in terms of facilitating the process of implementation:

- Support from all levels of staff, including clinical and administrative staff and directors
- Clear division of roles (guidelines)
- Sufficient resources
- Clear outcome measures

Besides these aspects from the literature, it is relevant to search for experiences and knowledge from previous organisational changes in similar institutions or concerning similar aspects, e.g. other patient safety issues or quality assurance projects. Furthermore, future research within the field of falls prevention could increase feasibility of the results if organisational issues are addressed along with clinical outcomes.

1.6. Economy

The database containing the results of the literature search was searched for the words cost*, saving*, expenditure*, CEA* (cost effectiveness analysis), CUA* (cost utility analysis), CBA* (cost benefit analysis), business case. The 90 references were scrutinised for relevance and five articles were included in the analysis. The report by Healey and Scobie (2007) was included as well, because it contained useful information on the economic aspects of falls prevention.

Results

There is limited evidence on the economic aspects of falls prevention. This applies to both the number of articles and the level of evidence. In addition, the results have only limited similarity to the technologies that do reduce the risk of falling. Also, the calculations in terms of pricing and inclusion or exclusion of parameters are not clear, which makes it difficult to estimate if the results can be used when assessing the economic consequences of introducing the technologies in clinical practise within Region of Southern Denmark.

Generally, it is worth noting that no economic evaluations from the societal perspective have been identified and that there is great diversity in the presented costs of falls in different articles.

Regarding the costs of risk assessment tools and fall preventive interventions, this report has presented estimates of completing risk assessment tools for all patients on all days of
admission. If patients admitted to geriatric departments are offered screening, for Odense University Hospital, the expenditures would be 0.2 mill. DKK.

If, instead, it was decided to offer screening to all patients above the age of 65 admitted to Odense University Hospital at admission, the total hospital expenditures of screening would have been approximately: 2,200,000 DKK in 2009. If all patients above the age of 65 admitted to Odense University Hospital was offered screening daily, the total hospital expenditures would have been approximately: 4,900,000 DKK in 2009.

Also, the costs of what is regarded as a multiple intervention have been calculated to reach approximately 1,000 DKK, corresponding to four hours of nursing per admission. The costs of the intervention have been included in a cost-effectiveness analysis including level of effect of multiple intervention of 18 % as presented by Oliver et al. (2007), resulting in CE ≈ 54,000 DKK per fall prevented.

In comparison, the average hospital value of preventing a fall was calculated to be approximately 3,000 DKK if 5% of fallers expected a hip fracture and 95% no injury. If several levels of injury was included, the average hospital costs of a fall was 476 DKK per fall. Table 1.6.1 shows the hospital expenditures related to falls if the level of patient injury that the patient experiences is divided into six different levels.
Table 1.6.1 Hospital expenditures divided into six levels of injury

<table>
<thead>
<tr>
<th>Harm category or injury</th>
<th>Basis for estimate</th>
<th>Cost/ incident</th>
<th>Region of Southern Denmark</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Number incidents (+)/year</td>
</tr>
<tr>
<td>No harm incidents</td>
<td>One hour nursing time</td>
<td>244 DKK</td>
<td>169.52</td>
</tr>
<tr>
<td>Low harm incidents</td>
<td>As no harm, plus first aid (0.5 hours), plus cost of dressings (10 DKK)</td>
<td>376 DKK</td>
<td>75.16</td>
</tr>
<tr>
<td></td>
<td>X-ray costs for no and low harm incidents'</td>
<td>967 DKK</td>
<td>1.21</td>
</tr>
<tr>
<td>Moderate and severe harm incidents (excluding fractures or head injuries)</td>
<td>Emergency room visit (DRG-value)</td>
<td>1,255 DKK</td>
<td>9.09</td>
</tr>
<tr>
<td>Fractures, excluding hip fractures</td>
<td>Wrist fracture (DRG-value)</td>
<td>20,101 DKK</td>
<td>0.40</td>
</tr>
<tr>
<td>Hip fractures</td>
<td>DRG-value</td>
<td>51,812 DKK</td>
<td>0.61</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>255</strong></td>
<td><strong>121,846</strong></td>
</tr>
</tbody>
</table>

'DRG-value for complex x-ray (www.sundhedsstyrelsen.dk)
* based on falls in 2008 (Center for Kvalitet 2009)
(+ ) The distribution of falls is assumed to be similar to the original table from Healey and Scobie (2007)

The estimated costs of interventions and the estimated economic value of the effects described cannot be regarded as definitive arguments for implementing or not implementing fall preventive interventions. Moreover, the calculations are based on many assumptions that could be criticised and the perspective is only on the hospital economy.

None the less, the calculations shows that the cost of prevention of patient falls can be very high, and the economic value of preventing a fall can be quite low, since most falls do not result in injury. This should, however, be interpreted with caution. It is based on assumptions and should be improved with more precise estimates of incidence and severity of falls before conclusions are mad as to the decision to implement falls prevention interventions.
1.7. Discussion

Regarding risk assessment tools, an interesting paradox arises. No evaluation outside the setting for the development of a tool has resulted in an effective distinction between high and low risk fallers. In fact, all the later evaluations of risk assessment tools are worse at predicting who will fall than simple randomisation.

However, in spite of these results it seems that none of the scientists researching fall preventive interventions, patients’ perspectives or organisational aspects have even considered leaving risk assessment tools out. All multiple fall preventive interventions include risk assessment. None of the literature on patients’ perspectives has asked patients how they perceived being assessed for risk (i.e. if the questions increased their fear of falling or made them change behaviour). Likewise, although all the articles on organisational issues claim to have used risk assessment, none explain who carried them out, at what time(s) during admission or how long it took to complete.

These facts indicate that risk assessment tools are so deeply imbedded in the concept of falls prevention that most scientists do not consider leaving them out. In relation to this, none of the articles discuss the fact that if a wrong group of patients is identified to be at high risk this might explain why the interventions only rarely shows statistically significant results. For instance, all patients older that 65 years were offered risk assessment at admission, and that the results determined whether or not the patient was offered falls preventive interventions. If the risk assessment tool does not identify the correct patients to be at high risk, the interventions are aimed at the wrong patients. Thus, a group of patients that receive the intervention does not need it. Similarly, a group of patients that do need the intervention does not receive it. Then the results of a study on the effectiveness of the intervention will underestimate the size of effect because the intervention was given (partly) to a group that did not benefit of the effect.

The literature on economic aspects of falls prevention are noteworthy compared to patient and organisational literature in that it better matches the results of the technology section. It does provide some information regarding the costs of completing risk assessments. And it does provide information on the costs of multiple interventions.

Another noteworthy aspect of this HTA is related to the evidence on effectiveness of interventions. The amount of literature is overwhelming, and well performed, recent meta-literature exists and provides an overall picture of falls prevention. This meta-literature gives different conclusions as to the effectiveness of falls prevention. At the highest level of
evidence, two reports conclude differently, i.e. (Oliver et al. 2007) finds a possible risk reduction of 18%, whereas (Coussement et al. 2008) find that their results (26% risk reduction that is not statistically significant) are inconclusive. The two well performed systematic reviews show a tendency towards an effect of multiple interventions on the risk of patient falls of approximately 20%. The results are placed on different sides of the chosen 5% level of statistical significance. Also, the differences are results of decisions made by the authors during the process of making the meta-analyses. Knowing this, it should be left for the reader to decide which of the two results to follow, but remembering that the difference is only marginal.

Nevertheless, there is a mismatch between these indications and the foci in the literature on patient perspectives and organisational aspects of falls prevention. Because of this, it is not possible to give evidence based advice as to what should be considered before implementing multiple fall preventive interventions. Rather, it is recommended to include aspects of both patient perspectives and organisational prerequisites or consequences when studying the subject of falls prevention in the future.

The final global problem in the literature that this report is based on is the external validity. It is not discussed in the articles, and especially the systematic reviews and meta analyses do not present the parameters necessary for estimating the differences between settings.
2. RECOMMENDATIONS

Regarding prevention of patient falls in hospitals, the findings of the HTA on prevention of patient falls can be summarised in the following recommendations on technologies, patient perspectives, organisational aspects and economy:

2.1. Technology

Based on the results of the technology section of the report, three conclusions can be reached:

1) The scientific literature of evidence level 1a disagrees with regard to statistical significance of the effect of multiple interventions. Thus, it is recommended to carefully plan and monitor effectiveness of multiple interventions. Preferably as a scientific studies, but even if that is not possible, monitoring is necessary to avoid spending resources on interventions without clinical effect.

Two meta-analyses serve as reference for evidence on multiple interventions for falls prevention. One concludes that it is possible to reduce the risk of falling among patients by 18% (Oliver et al. 2007). The authors of the other meta-analysis conclude that their analysis cannot serve as basis for decision making on whether or not to implement multiple interventions for falls prevention (Coussement et al. 2008). How these multiple interventions were constructed is described in detail in Appendix 1.

2) There is level 1b evidence supporting decisions to introduce medication review or patient education as one-off interventions. These results are based on two randomised trials that presented evidence supporting single use of the interventions patient education and medication review (Haines et al. 2006; Oliver 2007) with effect sizes 72% and 47% risk reduction, respectively. The contents of these interventions are described in Appendix 2.

3) None of the developed risk assessment tools are supported by sufficient evidence of effectiveness to recommend widespread implementation. Furthermore, the time that nurses spend completing the tools is costly. It is possible that local fitting of instruments turns out to be sufficiently effective in discriminating between patients at high or low risk of falling, or that future research will be able to identify effective tools. But at present, the implementation of risk assessment tools cannot be recommended.

Generally, it should be acknowledged that studies in real life settings are influenced by their context. Thus, the results from one intervention in one setting, will most likely be different from the results of the same intervention in another setting. This means that the results of the literature included in this HTA cannot be transferred directly into any other given setting. Thus,
it is important to carefully plan measures of the local effect of risk assessment tools or interventions to assess whether the effort is worthwhile. Also, before implementation, thoughts should be given to the possible expenditures of the interventions along with the possible effects. And, in order to gain a broader understanding than clinical effectiveness and cost-effectiveness measures, evaluations of patients’ perceptions and crucial organisational prerequisites and consequences should be included.

From a pragmatic point of view, it might be desirable for research on falls prevention interventions to focus on interventions with possible additional positive effects on patient safety or quality of care.

2.2. Patient and organisation
Further measurements and evaluations are encouraged because the literature does not provide sufficient information on the patient and organisational aspects of falls prevention, and these aspects should not be disregarded.

The literature showed that there might be differences in opinion as to what is acceptable regarding restrictive measures for the group of patients compared to health care personnel. Further evaluations showed that patients’ choices were related to their perception of how their life would be if they experienced a fall. Until more evidence is generated, these aspects are worth considering when deciding on an intervention to prevent falls.

In addition, organisational aspects should be considered. Since no specific guidelines exist, inspiration could be found in other quality improving or patient safety literature.

2.3. Economy
Falls prevention is expensive. Thus, economic evaluation should be a part of any decision to implement fall preventive interventions. And, in order to avoid overspending resources on little or no clinical effect, it is necessary to monitor the expenditures related to implementation of interventions.

2.4. Research
Although the literature searches revealed that falls prevention has been subjected to research many times, there is still a need for further research within the area. Firstly, it is relevant to learn what would happen if the interventions were given to all patients without initial screening for high risk. Secondly, the interaction effects between single interventions when implemented on multiple basis is relevant for clinical departments in deciding which interventions to
implement. Thirdly, there is a need for evidence on how the interventions affect the patients and which organisational aspects to consider in relation to implementing falls prevention.
3. REFERENCES


*Sundhedsstyrelsen – DRG-takster.*

http://www.sst.dk/Indberetning%20og%20statistik/DRG%20Takster/Takster%202009.aspx 2009 [05.02.2010].
Todd, C. & Skelton, D. 2004, What are the main risk factors for falls among older people and what are the most effective interventions to prevent these falls?, WHO Regional Office for Europe, Copenhagen.
4. APPENDICES

4.1. Appendix 1: Contents of multiple interventions
In order to render visible what the multiple and single interventions were composed of, the primary literature was obtained and the information given in these articles on the contents of interventions is provided in the tables below.

Multiple interventions
The multiple interventions that were included in the two meta-analyses, which served as basis for the conclusions concerning multiple interventions are described in the table below. The table shows the reference for the primary article and the description of the intervention that is provided in the primary article.

Healey et al. “Using targeted risk factor reduction to prevent falls in older inpatients: a randomized controlled trial” (Age and Aging Vol. 33 No. 4 2004)
The intervention consisted of a brief falls risk factor screen and related interventions (Table 1) in the form of a pre-printed care plan, including risk factors for falls that could be properly addressed in the hospital where the study took place. The reverse of this plan contained a brief summary of evidence, such as medication most likely to be implicated in falls, and local advice such as optical testing arrangements.

Table 1: Components of the core plan and guidelines

<table>
<thead>
<tr>
<th>Health screening checklist</th>
<th>Targeted intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eyesight – able to recognise pen/key/watch from two meters distance</td>
<td>If unable to recognise: optician visit if lost glasses, ophthalmology referral if no known reason for poor eyesight</td>
</tr>
<tr>
<td>Medication – check for sedatives, antidepressants, diuretics, polypharmacy, etc.</td>
<td>Medical review of prescription benefit related to falls risk</td>
</tr>
<tr>
<td>Lying and standing blood pressure</td>
<td>Refer any deficit to medical staff. Advise patient on shifting position slowly</td>
</tr>
<tr>
<td>Ward test urine</td>
<td>Send mid-stream urine sample if positive for nitrites, blood or protein</td>
</tr>
<tr>
<td>Difficulty with mobility</td>
<td>Refer to physiotherapist</td>
</tr>
<tr>
<td>Environmental check</td>
<td></td>
</tr>
<tr>
<td>Review risk/benefit of bedrails for individual</td>
<td>Documentation of risk/benefit in nursing notes and removal or addition of bedrails as appropriate</td>
</tr>
</tbody>
</table>
### Footwear safety

Advise relatives on replacement

### Bed height

Keep at lowest possible height

### Position in ward

Nurse patient with history of falls as close to a nurses’ station as possible (considering other patients’ needs)

### Simple environmental cause of falls (e.g. loose cable, wet floor)

Act to correct it

### Nurse call bell

Explained and within reach

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**Vassalo et al. “The Effect of Changing Practice on Fall Prevention in a Rehabilitative Hospital: The Hospital Injury Prevention Study” (JAGS Vol. 52 No. 3 2004)**

The patients' fall-risk status was assessed using the Downton Score. A multidisciplinary team (consisting of a physician, nurse, occupational therapist, social worker, and physiotherapist) met weekly specifically to discuss patients' fall risk and formulate a targeted plan. Patients at risk were identified using wristbands; risk factors were corrected or environmental changes made to enhance safety.

**Barry et al. “Preventing Accidental Falls among Older People in Long Stay Units” (Not published in journal, data from 1998-1999)**

Staff attended a lecture and a workshop on the consequences of falling for older people and on effective ways to improve safety. An occupational therapist conducted an environmental audit of the hospital. This resulted among other things in handrails being installed on corridors together with grab rails and arm rests in bathrooms, the policy of polishing floors was discontinued and more suitable chairs with armrests replaced low chairs. In general, environmental changes were tailored to the needs of patients. For example, commodes without wheels had to be acquired for a small group of patients who persistently used the wheel-bearing variety as an aid to moving around. Obstructive furniture, particularly tables in the centre of wards, was removed. Mens trousers were fitted with braces to limit the risk of tripping. Emergency patient call bells were checked and repaired when necessary. Special rubber tiling was fitted in an outdoor patio area frequented by the patients.

Risk factors for falling were assessed and corrective action was taken where possible e.g. remediable visual problems, mobility assistance and replacement of unsuitable footwear or provision of special footwear and examination of medication. A Fall Risk Assessment Scale was adopted to identify patients at high risk of falling by assessing certain patient characteristics such as for example, gender, age, gait and medication. A risk score was calculated for each patient. Those identified as being at high risk
of falling were provided with hip protector pads and encouraged to wear them. Where possible, a profile of repeat fallers was prepared.


A Falls Management Taskforce was established, led by a nurse manager and including one nurse educator, four clinical nurse consultants and the Director of Occupational Therapy. A ‘flagging’ system was introduced, with flagging indicating that extra assistance or precaution was required. For example application of green coloured arm band to be worn permanently and application of a green coloured bed sign at the bed head. Other strategies decided were application of hip protector pads to those patients who have previously suffered a fall, documentation of a Falls Management Plan Decision Tree which was added to ward manuals and printing of posters for display in the wards.

All clinical and support staff were educated about the Fall STOP plan. This was achieved by a written memorandum, by a publication of an article in the hospital newsletter and by taskforce members presenting information at unit meetings.

**Oliver et al. “Letters to the Editor: Preventing patient falls” (British Geriastics Society 2002)**

All patients had a STRATIFY assessment on admission and all patients with a score of >2 out of 5 were categorized as high-risk. For all high-risk patients, tailored nursing and medical checklists were completed and high-risk stickers were placed in the patient’s notes.

**Cumming et al. “Cluster randomised trial of targeted multifactorial intervention to prevent falls among older people in hospital” (BMJ 2000)**

A nurse and physiotherapist each worked for 25 hours a week for three months in all intervention wards. They provided a targeted multifactorial intervention that included a risk assessment of falls, staff and patient education, drug review, modification of bedside and ward environments, an exercise programme, and alarms for selected patients.

**Haines et al. “Effectiveness of targeted falls prevention programme in subacute hospital setting: randomised controlled trial” (BMJ 2004)**

This programme consisted of a falls risk alert card with information brochure, an exercise programme, an education programme, and hip protectors. Hospital staff used their clinical judgment to determine the need and appropriateness of each of the interventions.
Fonda et al. “Sustained reduction in serious fall-related injuries in older people in hospitals” (Medical Journal of Australia Vol. 184 No. 8 2006)

Multistrategy approach phased in over 3 months from September 2001 and involving data gathering, risk screening with appropriate interventions, work practice changes, environmental and equipment changes, and staff education.

Strategies that have been successfully trialled at Caulfield General Medical Centre to reduce falls:

Bedside falls
- Review of toileting protocols and practices for patients at risk of falling
- Fitted bed sheets
- Review of use of non-slip bedside mats
- Extended bedside call bells so patients do not fall reaching out
- Non-slip chair mats
- Electric low beds that go to within 12 cm of floor
- Bed alarms that identify when patients have moved out of their bed
- Ned poles to assist patients to transfer more independently

Increasing surveillance
- Family brochure informing them about falls and encouraging their involvement
- Volunteer program
- Early feeding of dependent patients
- Engaging patients in more activities
- Orange wrist band and chart above bed to identify patients at high risk of falling

Reducing night falls
- “Glow in the dark” commode seats
- “Glow in the dark” toilet signs
- Night sensor light

Education
- Each ward appointed a “falls prevention” portfolio holder
- Ward compliance audits
- Staff orientation brochures/folders
- Falls risk assessment tool and medical record alert sticker
- Promotion of team ownership of the project and problem-solving of reasons for falls on respective wards
- Protocols for after-fall reviews
- Reporting of falls at multidisciplinary and quality improvement meetings and management forums

General environment
- Review of patients footwear
- Reducing clutter around bed and ward
- Bathroom door magnets to stop doors knocking patients
- Non-slip bathroom flooring
• Change of floor cleaning processes to reduce “high shine, high wax” finish
• Appropriate height of seating

**Mayo et al. “A Randomized Trial of Identification Bracelets to Prevent Falls Among Patients in a Rehabilitation Hospital” (Arch Phys Med Rehabil Vol. 75 1994)**

Patients assigned to the intervention group, high-risk patients, were given a blue identification bracelet in addition to the usual hospital bracelet. Persons assigned to the intervention group were told to use the bracelet as a reminder to be careful when they were moving around the hospital.

**Schwendimann et al. “Fall Prevention in a Swiss Acute Care Hospital Setting” (Journal of Gerontological Nursing 2006)**

This study used a multi-component intervention including a fall risk assessment and a protocol of nursing interventions aimed at reducing the risk of falls. In addition to these two main components, the intervention was further strengthened by a fall incident reporting system to collect systematically relevant data after a fall occurred. Nurses were trained in relation to the protocol to enhance their knowledge and skills and to enhance their competence with the protocol.

**Intervention protocol procedures:**

<table>
<thead>
<tr>
<th>Identification of physical deficits</th>
<th>Assist with transfer and ambulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>The nurse observes and addresses the patient’s ability to ambulate, stand up, transfer, and climb in and out of bed, including toilet and commode use.</td>
<td>The nurse assists and supports unsafe, frail patients, into and out of bed, chair, and while walking. The nurse instructs use of handrails.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Identification of mental deficits</th>
<th>Assists with toileting</th>
</tr>
</thead>
<tbody>
<tr>
<td>The nurse assesses the patient’s estimation of own abilities, using the call bell, asking for assistance, awareness of support needs, use of device as instructed.</td>
<td>The nurse assists the patients with toileting at frequent, individualized scheduled times, including the use of toilet (e.g., sitting down, getting up, self-cleaning). The nurse observed urgency and commode use at night if appropriate.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Orientation to hospital environment and schedules</th>
<th>Optimize the use of assistive devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>The nurse informs the patient about</td>
<td>The nurse instructs patients in use of</td>
</tr>
<tr>
<td>Physical setup</td>
<td>Physical exercises</td>
</tr>
<tr>
<td>----------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>physical “set up” in patient’s room and in the ward, and the daily routines (e.g. meal time, physician visit).</td>
<td>The nurse ensures and establishes adequate exercise routines (e.g. walking, climbing stairs), and includes physiotherapist if appropriate.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Placement of call bell, light and articles</th>
<th>Monitor confused patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>The nurse checks and places patient’s articles and personal belongings within easy reach in every shift (e.g. water, phone, urinal).</td>
<td>The nurse observed disoriented patients, informs next shift, and places patients near the nursing station.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Positioning bed height</th>
<th>Observe possible side effects of medication</th>
</tr>
</thead>
<tbody>
<tr>
<td>The nurse keeps bed in lowest position, except during care activities.</td>
<td>The nurse ensures review of psychoactive medication with referral to the physician.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Stabilize rolling furniture</th>
<th>Warning signs for high-risk patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>The nurse locks wheels on wheelchairs, beds, commodes, and gurneys.</td>
<td>The nurse puts yellow high-falls-risk-flag on the patient’s chart and bed, informs health care team members and relatives about falls risk.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Safe footwear and clothing</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>The nurse observes and ensures adequate fit of shoes, and distributes “anti-slip-socks” if appropriate.</td>
<td></td>
</tr>
</tbody>
</table>


Program components included an interdisciplinary team, alternatives to bed rail use, the art of persuasion, and audit and feedback. The interdisciplinary team consisted of the team leader, representatives from nursing staff and resident families, nurse managers, a hospital engineer, and representatives from other departments. The team conducted walking rounds monthly on
each nursing home care unit and performed individual patient and environmental assessments, determined risk, and identified and provided alternatives to bed rails. Signs were posted at bedsides to indicate which bed rails should be in the raised position and which alternatives should be used. Through the art of persuasion and education the staff convinced residents and their families of the advantages of lower bed rails. The BedSAFE coordinator chaired a monthly meeting during which bed rail use rates and other data was presented to staff and management from each unit. During the course of the intervention, nurse managers conducted independent activities to transfer bed rail knowledge among staff.

Dunn, K.S. “The Effect of Physical Restraints on Fall Rates” (Journal of Gerontological Nursing 2001)

1-hour education program was provided for nursing staff on each 12-hour day shift and night shift for 5 days. The in-service was conducted in a small group format, using visual aids, handouts, short lectures, and group discussions. Topics covered included the importance of fall prevention among older adults, fall risk factors and fall risk factors assessment, nursing interventions to prevent falls, maintenance of a fall log, and the relationship of SAFE (Safety Assessment for the Frail Elderly) protocol scores to fall risk. Following in-service sessions, nursing staff completed fall risk factors assessments for patients. The fall risk factors assessment guided the nursing staff to appraise patients in terms of 31 criteria (e.g., age, relocation, fall history, mobility, physical status, mental status, emotional status, medication regime).


Risk assessment, an alert system, reinforcing preventive actions, staff education and ongoing audits and feedback.

1. Assessment: A specific falls-assessment tool was designed and utilized, which identified the patient’s level of mobility, risk factors related to mobility, urinary alterations, sensory deficits, mental status, medications, medical condition, age and number of previous falls.
2. Alert system: For those assessed as being at risk, the clinical staff made a decision to place an orange dot in highly visible areas. This included the name board above the patient’s bed, the completed assessment form, patient’s arm band, flow sheet, and should they fall, on the incident form.
3. Preventive actions: These were incorporated in the staff and patient education programmes and care protocols.
4. Staff education: A Falls Prevention Programme was developed and implemented by the nurse educator, with the express aim of educating staff to prevent falls.
5. Audit: A pilot falls reporting document was developed and used in addition to completing the existing incident documentation. Monthly feedback was provided to the ward and the hospital’s nursing executive regarding fall numbers and rates.

Kilpack et al. “Using Research-Based Interventions to Decrease Patient Falls” (Applied Nursing Research Vol. 4 No. 2 1991)
When a patient was identified as having fallen, the clinical nurse specialist (CNS) completed the descriptive data on the instrument (the data collection instrument that the authors developed included demographic information about the patient who had fallen, medical diagnosis, risk factors for falling and descriptive data about the fall). The staff nurse caring for the patient was asked to select from the list of research-based interventions those that should be incorporated into the plan of care. Additional individualized suggestions to prevent future falls were also solicited from the staff nurse. With this information the CNS developed a written plan of care using the nursing diagnosis “potential for injury”. The staff nurse was asked to implement the plan and verbally disseminate the information at change-of-shift report. Because of failure to verbally disseminate the information, a dated “patient fell” notation in red ink was placed on the patient’s kardex. They also designed their own visual cue card to be placed on the beds of patients who fell and had local third-grade school children draw eye-catching posters depicting circumstances under which patients could fall. An educational program was implemented to increase the staff’s cognizance of fall prevention.

4.2. Appendix 2: Contents of single interventions

Single interventions
The two articles describing single interventions with a statistically significant effect is summarised in the table below.

- Retrospective study investigating the effect of a pharmaceutical intervention on patient fall rate and economic outcomes
- No other new interventions for fall reduction were initiated during the fall-focused pharmaceutical program
- The pharmaceutical interventions in this study were developed using the American Society of Consultant Pharmacists’ MDS-Med guide
- The pharmaceutical intervention includes a complete review of all medications by the consultant pharmacist
Any medications identified as causing a particular adverse effect (e.g. dizziness) or clinical condition (e.g. fall and fractures) were listed in a table format for review by pharmacist, nurse, and physician

Written recommendations for medication dosage reduction and frequency were made, and precautions for drug administration were given to nursing personnel

The consultant pharmacist and nurse immediately implemented the pharmaceutical interventions into the patient’s plan of care after collaborating with the physician

Medication administration precautions were attached to the patients’ medication administration records within 24 hours of admission to the rehabilitation center.

Haines et al. “Patient education to prevent falls in subacute care” (Clinical Rehabilitation, Vol. 20 2006)

- The education programme consisted of one-to-one education sessions with an occupational therapist working as a part of the research team.
- The duration of each session was at the discretion of the research occupational therapist and ranged between 15 and 35 min.
- Sessions were conducted twice weekly at the participant’s bedside.
- Sessions were not intended to be didactic in nature, rather the intention was to facilitate discussion between the participant and the research occupational therapist so that participants would feel free to disclose difficulties they may have had in complying with specific instructions provided to them by hospital staff members.
- The content of the programme was intended to be covered over four sessions, however individual participants could receive more than four sessions when deemed necessary by the research occupational therapist to fully cover the programme content and appropriately reinforce specific points.
- The curriculum consisted of the following steps:
  - Participants completed a falls risk factor screening, allowing them to identify their own falls risk factors in consultation with the research occupational therapist
  - Information was gathered regarding the nature of falls, including potential consequences of falls, when falls occurred, where falls occurred, and why falls were considered to have occurred
  - General information was collected on mechanisms of falls, including slips, trips, overbalancing, having legs give way, becoming dizzy or losing consciousness
  - Steps that participants could take to prevent falls were noted, specifically relating to hospital organizational processes and general mechanisms of falls
  - A participant quiz was compiled containing questions relating to how, when, where and why participants have previously fallen
A participant quiz asking participants to identify likely characteristics of falls that they could potentially incur during their hospitalization was also compiled.

Goal-setting and selection of specific strategies to prevent future falls were identified.

Goals and compliance with strategies to prevent future falls were reviewed.

- This information was contained in a booklet also provided to participants as a resource for participants during and between education sessions.
- Information regarding the epidemiology of falls was taken from a retrospective audit of fall incident reports over a six-month period prior to commencement of this study.
- The falls prevention education programme and information booklet were designed by the chief investigator, who trained the research occupational therapist as to how the sessions were to be conducted prior to study commencement.
### 4.3. Appendix 3: Hierarchy of evidence

**Oxford Centre for Evidence-based Medicine Levels of Evidence**

(March 2009)

(For definitions of terms used see glossary at [http://www.cebm.net/3o=1116](http://www.cebm.net/3o=1116))

<table>
<thead>
<tr>
<th>Level</th>
<th>Therapy/Prevention, Auditology/Harm</th>
<th>Prognosis</th>
<th>Diagnosis</th>
<th>Differential diagnosis/symptom prevalence study</th>
<th>Economic and decision analyses</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a</td>
<td>SR (with homogeneity) of RCTs</td>
<td>SR (with homogeneity) of inception cohort studies; CDR validated in different populations</td>
<td>SR (with homogeneity) of Level 1 diagnostic studies; CDR with 1b studies from different clinical centers</td>
<td>SR (with homogeneity) of prospective cohort studies</td>
<td>SR (with homogeneity) of Level 1 economic studies</td>
</tr>
<tr>
<td>1b</td>
<td>Individual RCT (with narrow Confidence Interval)</td>
<td>Individual inception cohort study with &gt; 50% follow-up; CDR validated as a single population</td>
<td>Validation** cohort study with good[±]† reference standards; or CDR tested within one clinical center</td>
<td>Retrospective cohort study with good follow-up[±]‡</td>
<td>Analysis based on clinically sensible costs or alternatives; systematic reviews of the evidence; and including multi-way sensitivity analyses</td>
</tr>
<tr>
<td>2a</td>
<td>SR (with homogeneity) of cohort studies</td>
<td>SR (with homogeneity) of either retrospective cohort studies or increased control groups in RCTs</td>
<td>SR (with homogeneity) of Level 1 diagnostic studies</td>
<td>SR (with homogeneity) of 2b and better studies</td>
<td>SR (with homogeneity) of Level 1 economic studies</td>
</tr>
<tr>
<td>2b</td>
<td>Individual cohort study (including low quality RCT, e.g., &lt;80% follow-up)</td>
<td>Retrospective cohort study or follow-up of uncensored control patients in an RCT; Derivation of CDRs validated on split sample[±]§ only</td>
<td>Empirical** cohort study with good[±]†† reference standards, CDR after derivation, or validated only on split sample[±]§ or databases</td>
<td>Retrospective cohort study, or poor follow-up</td>
<td>Analysis based on clinically sensible costs or alternatives; limited reviews of the evidence, or single studies; and including multi-way sensitivity analyses</td>
</tr>
<tr>
<td>2c</td>
<td>&quot;Outcomes&quot; Research, Ecological Studies</td>
<td>&quot;Outcomes&quot; Research</td>
<td>Ecological studies</td>
<td>Audit or outcomes research</td>
<td></td>
</tr>
<tr>
<td>3a</td>
<td>SR (with homogeneity) of case-control studies</td>
<td>SR (with homogeneity) of 3b and better studies</td>
<td>SR (with homogeneity) of 3b and better studies</td>
<td>SR (with homogeneity) of 3b and better studies</td>
<td></td>
</tr>
<tr>
<td>3b</td>
<td>Individual Case-Control Study</td>
<td>Non-consecutive study, or without consistent applied reference standards</td>
<td>Non-consecutive cohort study, or very limited population</td>
<td>Analysis based on limited alternatives or costs, poor quality</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Case-series (hand-picked quality cohort and case-control studies)**</td>
<td>Case-series (hand-picked quality cohort studies)**</td>
<td>Case-controlled study, poor on non-independent reference standard</td>
<td>Case-series or non-improved reference standard</td>
<td>Analysis with no sensitivity analysis</td>
</tr>
</tbody>
</table>

| 5 | Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles" | Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles" | Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles" | Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles" |

**Note:**

- Use an asterisk (*) to denote the level of that fact to provide a conclusive answer because:

**EITHER** a single result with a wide Confidence Interval

**OR** a Systematic Review with troublesome heterogeneity.

Such evidence is inconclusive, and therefore can only generate Grade D recommendations.

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1. By homogeneity we mean a systematic review that is free of wasteful variation (heterogeneity), in the directions and degrees of effects between individual studies. Not all systematic reviews with statistically significant heterogeneity need be wasteful, and not all statistically significant heterogeneity need be statistically significant. As noted above, studies displaying wasteful heterogeneity should be tagged with an "*" at the end of their designated level.

2. Clinical Decision Rules (These are algorithms or scoring systems that lead to a prognostic estimation or a diagnostic category)

3. See note above for advice on how to understand, cite and use tables or other studies with wide confidence intervals.

4. Met when all patients died before the RCT became available, but some now survive on it, or when some patients died before the RCT became available, but some now die on it.

5. By poor quality cohort study we mean one that failed to clearly define comparison groups and/or failed to measure exposure and outcomes in the same (preferably blinded), objective way in both exposed and non-exposed individuals and/or failed to identify or appropriately control known confounders and/or failed to carry out a sufficiently long and complete follow-up of patients. By poor quality case-control study we mean one that failed to clearly define comparison groups and/or failed to measure exposure and outcomes in the same (preferably blinded), objective way in both cases and controls and/or failed to identify or appropriately control known confounders.

6. Split-sample validation is achieved by collecting all the information in a single database, then artificially dividing this into "destruction" and "validation" samples.

7. An "Absolute Spin" is a diagnostic finding whose Specificity is so high that a Positive result rules-out the diagnosis. An "Absolute SnNeg" is a diagnostic finding whose Sensitivity is so high that a Negative result rules-out the diagnosis.

8. Good, better, and worse refer to the comparison between treatments in terms of their clinical risks and benefits.

9. Good reference standards are independent of the test, and applied blindly or objectively to applied to all patients. Poor reference standards are haphazardly applied, but still independent of the test. Use of a non-independent reference standard (where the 'test' is included in the 'reference', or where the 'testing' affects the 'reference') implies a level 4 study.

10. Better-value treatments are clearly as good or cheaper, or better at the same or reduced cost. Worse-value treatments are as good and more expensive, or worse and the equality or more expensive.
Validating studies test the quality of a specific diagnostic test, based on prior evidence. An exploratory study collects information and tests the data (e.g., using a regression analysis) to find which factors are ‘significant’.

By poor quality prognostic cohort study we mean one in which sampling was biased in favour of patients who already had the target outcome, or the measurement of outcomes was accomplished in <30% of study participants, or outcomes were determined in an unblinded, non-objective way, or there was no correction for confounding factors.

Good follow-up in a differential diagnostic study is >50%, with adequate time for alternative diagnoses to ensue (for example 1-6 months acute, 1-5 years chronic).

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Consistent level 1 studies</td>
</tr>
<tr>
<td>B</td>
<td>Consistent level 2 or 3 studies or extrapolations from level 1 studies</td>
</tr>
<tr>
<td>C</td>
<td>Level 4 studies or extrapolations from level 2 or 3 studies</td>
</tr>
<tr>
<td>D</td>
<td>Level 5 evidence or overwhelmingly inconsistent or inconclusive studies of any level</td>
</tr>
</tbody>
</table>

“Extrapolations” are where data is used in a situation that has potentially clinically important differences than the original study situation.