

Säker Vård

patientskador, rapportering
och prevention

Synnöve Ödegård



NHV – Nordiska högskolan för folkhälsovetenskap

Säker Vård – patientskador, rapportering och prevention
Doktorsavhandling i folkhälsovetenskap
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*“Wissen ist nicht genug, wir müssen es anwenden.
Wollen ist nicht genug, wir müssen es tun.”*

– Goethe 1749–1832.

ABSTRACT

Safe Health Care patient injuries, reporting and prevention

Aims. The purpose of this thesis is to expand the body of knowledge on factors that can be assumed to affect patient safety on the system and individual levels.

Methods. For this thesis, the Swedish national reporting system, Lex Maria, was analysed before and after the National Board of Health and Welfare regionalised its supervisory organisation in 1990/91. A follow-up study was conducted focusing especially on cases that were forwarded to the Medical Responsibility Board (MRB) for disciplinary review. Three empirical studies were carried out to analyse additional reporting methods that could provide information on risks in health care. Staffs were interviewed as to their perception of potential risks to patient safety. A questionnaire was used to investigate how much nursing aides and assistant nurses knew about diabetes. A follow-up study then investigated any links between level of knowledge and the perception of safety-related issues by medically responsible nurses. Finally, a qualitative study analysed methods used by civil aviation for safety-related work and compared them with those used in public health care.

Results. After the regionalisation of the supervisory authority, Lex Maria reports increased but fewer cases were forwarded to the MRB for disciplinary review. The additional methods investigated for identifying risks proved to be valuable complements to traditional reporting. The interviews conducted in paediatrics demonstrated a different risk pattern than that indicated by Lex Maria reporting. The questionnaire to nursing aides and assistant nurses showed a clear link between lack of knowledge about diabetes and an increased risk of carrying out a risky measure. The study indicated systemic flaws, which were confirmed by the results of the questionnaire to medically responsible nurses in the corresponding municipalities. The study demonstrated a need for greater attention to how the supporting systems in health care affect professionals on the front line. The comparison between civil aviation and the public health care system showed that civil aviation had a more proactive, broader approach to safety than the health care system.

Conclusions. This study showed that health care professionals on the front line, dealing with individual patients, are particularly vulnerable to deficiencies in their supporting systems. Preventive safety analyses as a complement to reporting were found to provide valuable information for preventive safety measures. A coherent strategy based on current research into safety issues could contribute to advancing work with safety in health care

Keywords: Patient safety, reporting system, prevention, safety analysis, risk analysis, Lex Maria, disciplinary measures.

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SAMMANFATTNING

Säker Vård patientskador, rapportering och prevention

Syfte. Avhandlingen syftar till att bidra med ökad kunskap om faktorer som kan antas påverka patientsäkerheten dels på system-, dels på individnivå.

Metod. Det nationella rapporteringssystemet Lex Maria analyserades före och efter Socialstyrelsens regionalisering av tillsynsorganisationen 1990/91. I en av de två studierna analyserades särskilt ärenden som överförts till HSAN för prövning av disciplinär påföljd. I tre empiriska studier analyserades kompletterande metoder till rapportering för att få information om risker i hälso- och sjukvården. Personal har intervjuats om deras uppfattning av potentiella risker som skulle kunna hota patienternas säkerhet. Vårdbiträdens och undersköterskors kunskaper om diabetes undersöktes i en enkätstudie. Eventuella samband mellan vårdbiträdens och undersköterskors kunskapsnivå och medicinskt ansvariga sjuksköterskors uppfattning om säkerhetsrelaterade frågor undersöktes i en uppföljande enkätstudie. I en kvalitativ studie undersöktes flygets metoder för säkerhetsrelaterat arbete vilket jämfördes med motsvarande arbete inom hälso- och sjukvården.

Resultat. Lex Maria-rapporteringen ökade efter regionaliseringen av tillsynsverksamheten och en minskad andel ärenden överfördes till HSAN för disciplinär prövning. De kompletterande metoder för att identifiera risker som undersökts visade sig vara värdefulla tillägg till traditionell rapportering. Intervjuerna inom barnsjukvården uppvisade en annan riskbild än den som fås genom rapporteringssystemet Lex Maria. Enkäten till vårdbiträden och undersköterskor visade ett tydligt samband mellan bristande kunskap om diabetes och en ökad risk att vidta en riskfylld åtgärd. Studien indikerade brister på systemnivå, vilket bekräftades av resultaten från enkätstudien till medicinskt ansvariga sjuksköterskor i motsvarande kommuner. Studien visade på behovet av ökad uppmärksamhet på hur sjukvårdens stödsystem påverkar yrkesutövarna i frontlinjen. Jämförelsen mellan flyget och hälso- och sjukvården visade att flyget hade ett mera proaktivt och bredare förhållningssätt till säkerhet än vad hälso- och sjukvården uppvisade.

Slutsatser. Studien har visat att yrkesutövare som befinner sig i frontlinjen och möter den enskilde vårdtagaren är särskilt sårbara när hälso- och sjukvårdens stödsystem uppvisar brister. Förebyggande säkerhetsanalyser som komplement till rapportering visade sig ge värdefull information för det förebyggande säkerhetsarbetet. En sammanhållen strategi baserad på aktuell säkerhetsforskning kan bidra till att utveckla hälso- och sjukvårdens säkerhetsarbete.

Nyckelord: Patientsäkerhet, rapportering, prevention, händelseanalys, säkerhetsanalys, Lex Maria, ansvarsärenden, disciplinära åtgärder.

AVHANDLINGENS DELSTUDIER

Denna avhandling baseras på följande originalstudier, vilka refereras till i texten med romerska siffror:

- I. Ödegård S. From punishment to prevention? Medical errors reported in Sweden 1989 and 1993. *Safety Science Monitor*. 1999;3:(special issue). <<http://www.monash.edu.au/muarc/ipso/vol3/te1>> tillgänglig den 10 mars 2006).
- II. Ödegård S, Edgren L. Reporting system, disciplinary measures and patient safety – A Swedish study. (In manuscript).
- III. Ödegård S. Safety management in civil aviation – A useful method for improved safety in medical care? *Safety Science Monitor*. 2000; 4(1). <<http://www.monash.edu.au/muarc/ipso/vol4/4odegard.pdf>> tillgänglig den 10 mars 2006).
- IV. Ödegård S, Hallberg L. Perceived potential risk factors in child care. *Journal of Health, Organization and Management*. 2004;18:38–52.
- V. Ödegård S, Andersson DKG. Knowledge of diabetes among personnel in home based care: how does it relate to medical mishaps? *Journal of Nursing Management*. 2001;9:107–114.
- VI. Ödegård S, Andersson DKG. Insulin treatment as a tracer for identifying latent patient risks in home-based diabetes care. *Journal of Nursing Management*. 2006;14:116–27.

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INTRODUKTION

Hälso- och sjukvård kan betraktas som en högriskverksamhet där marginalerna mellan "rätt och fel", mellan framgångsrik behandling och livshotande tillstånd, ibland kan vara små. Till skillnad från t.ex. en kemisk processindustri med ett på förhand planerat produktionsflöde med exakt temperatur, tryck och kemisk sammansättning i varje del av processen, är hälso- och sjukvårdande verksamhet dess motsats i många avseenden. I mötet mellan patienter och dem som utövar vården uppträder mänskliga variationer som inte på förhand kan kontrolleras.

Antalet patienter som skadas i samband med vård och behandling har visat sig vara omfattande (1–7). Under senare år har detta fått alltmer uppmärksamhet runt om i världen (8–11). I USA beräknas misstag i hälso- och sjukvården utgöra den åttonde största dödsorsaken (8). Studier visar dessutom att över hälften av identifierade patientskador sägs ha varit möjliga att undvika (1–3, 12). Att bedöma om en patientskada är förorsakad av hälso- och sjukvården eller om den beror på patientens underliggande sjukdom är inte alltid enkelt. En skada kan orsakas av ett kalkylerat risktagande för att rädda liv, men den kan också vara en komplikation som med rådande och tillgängliga behandlingsalternativ varit omöjlig att undvika. En skada kan också bero på att medicinska åtgärder inte varit adekvata beroende på t.ex. bristande erfarenhet eller kompetens. Andra skador kan tillskrivas den osäkerhet som all mänsklig verksamhet är förknippad med. Det kan i efterhand t.ex. visa sig att en felläsning skett, att ett decimalkomma hamnat på fel plats eller att en bedömning av patientens tillstånd varit felaktig.

Den säkerhetsforskning som branscher såsom flyg, kärnkraft och vägtrafik har anammat i sitt säkerhetsarbete har inte haft samma genomslag inom hälso- och sjukvården. Möjligheterna att lära av andra branscher med höga krav på säkerhet har emellertid under det senaste decenniet fått ökad uppmärksamhet inom hälso- och sjukvården och allt oftare görs jämförelser med t.ex. flyget och kärnkraftsindustrin (13–24). Det område som tidigt tagit del av och tillämpat erfarenheterna från framförallt flyget är anesthesiologin (25–31).

Syftet med denna avhandling är att bidra till ökad kunskap om faktorer som kan antas påverka patientsäkerheten dels på system-, dels på individnivå. Avhandlingen bygger på tre delar och omfattar sex delstudier. Den första delen tar sin utgångspunkt i det svenska nationella rapporteringssystemet för patientskador, Lex Maria (SOSFS 2002:4), vars huvudsyfte är att lära av

begångna misstag så att liknande händelser förhindras. Lex Maria omfattar både offentlig och privat vård, samt alla typer av verksamheter inom hälso- och sjukvård. Rapporteringssystemet kan därför antas ha ett högt värde för patientsäkerhetsarbetet och utgör en central del i avhandlingen. Den andra delen omfattar en jämförelse mellan delar av flygets säkerhetsrelaterade arbete och motsvarande arbete inom hälso- och sjukvården. Den tredje beskriver alternativa metoder att få information om risker i hälso- och sjukvården.

Patientskador – förekomst

Internationella studier

Redan 1964 visade Schimmel (32) i en sjukhusbaserad studie från Connecticut som omfattade 1 014 patienter att 20 procent drabbades av skador som berodde på vård och behandling. Senare studier, samtliga sjukhusbaserade, i USA, Australien, England, Danmark och Canada visar att patienter som drabbas av skada i samband med vård och behandling är ett omfattande och globalt problem (1–7). En av de mest uppmärksammade studierna är Harvard Medical Practice Study som genomfördes på 51 sjukhus i New York State år 1984 i USA (1). I studien som baserades på 31 121 slumpvist valda journaler fastställdes andelen "adverse event" till 3,8 procent. Av dessa avled i sin tur 13,6 procentandelar till följd av den inträffade händelsen. En "adverse event" definierades som en skada orsakad av medicinska åtgärder snarare än av bakomliggande sjukdom och som antingen medfört förlängd vårdtid eller kvarstående funktionsnedsättning vid tiden för utskrivningen. I en studie som genomfördes i Utah och Colorado år 1992 (4) var motsvarande andel "adverse events" 3,2 procent, varav 8,7 procentandelar avled. Utifrån dessa två studier har Institute of Medicine (IOM) i rapporten "To err is human" (8) bedömt att mellan 44 000 och 98 000 patienter i USA årligen beräknas avlida på grund av skador i samband med vård och behandling. Resultaten är extrapolerade till de 33,6 miljoner patienter som vårdades på sjukhus i USA under 1997. Siffrorna indikerar problemets omfattning. Av den engelska rapporten "An organisation with a memory" (9) framgår att cirka 11 procent av sjukhusvårdade patienter drabbas av en "adverse event", vilket omräknat till befolkningen i Storbritannien motsvarar cirka 850 000 patientskador årligen. Cirka 400 människor beräknas avlida eller skadas svårt i samband med behandling med hjälp av medicinteknisk utrustning och 1 150 patienter som nyligen haft kontakt med psykiatrisk vård begår självmord. Rapporterade allvarliga skador till följd av läkemedelsbehandling uppgår till cirka 10 000 årligen.

Från Australien rapporteras att andelen skadade patienter som vårdats på sjukhus uppgick till 16,6 procent (3). I 13,7 procent av dessa fall fick patienten en bestående skada eller ett handikapp och 4,9 procent av patienterna dog till följd av händelsen. Femtioen procent av dessa patientskador bedömdes möjliga att förhindra. Tjugosex procent av de identifierade skadorna var läkemedelsrelaterade. Den första epidemiologiska studien i Norden, vilken genomfördes i Danmark (6), visade att 9 procent av sjukhusvårdade patienter drabbades av en "utisigted hendelse" (oavsiktlig händelse). Dessa beräknades förlänga vårdtiden med i genomsnitt 7 vård dagar. Baserat på studiens resultat bedöms 5 000 människor årligen avlida i Danmark till följd av skador som förorsakats av vård och behandling och inte av underliggande sjukdom eller skada. En studie från Canada visade en incidens för patientskador på 7,5 procent (7). Resultaten, som har estimerats till de cirka 2,5 miljoner patienter som sjukhusvårdas årligen, visar att cirka 185 000 av dessa patienter beräknas drabbas av en skada som inte beror på underliggande sjukdom. Nästan 70 000 av dessa skador bedöms vara möjliga att förhindra. Nedan följer en sammanställning över redovisade studier inom ämnesområdet.

Tabell 1. Sammanställning över studier – samtliga genomförda på sjukhus inom akutsjukvård.

Studie	År	Antal journaler	Antal adverse events	Andel adverse events
Harvard Medical Practice study, USA (1)	1984	30 195	1 133	3,8
Utah-Colorado study, USA (4)	1992	14 565	475	3,2
The Quality in Australian Health Care Study (QAHCS), Australien (3)	1992	14 179	2 353	16,6
Danmark (6)	1998	1 097	176	9,0
England (5)	1999–2000	1 014	119	11,7
Canada (7)	2000	3 745	255	7,5

Samtliga ovan refererade studier baseras på granskade journaler. En prospektiv studie, där tränade etnografer observerade personal på en kirurgisk

vårdavdelning och två intensivvårdsavdelningar, visade betydligt högre andel skador (33). Nästan hälften av patienterna hade drabbats av en skada som inte berodde på bakomliggande sjukdom och i en tredjedel av fallen var händelsen allvarlig. Kriteriet för definitionen av en "adverse event" (allvarlig händelse) skiljer sig något i studierna. I de båda amerikanska studierna (1, 4) var kriteriet att skadan varit orsakad av medicinska åtgärder, snarare än av bakomliggande sjukdom, och att den antingen medfört förlängd vårdtid eller kvarstående funktionsnedsättning vid tiden för utskrivningen. I den australienska studien, som visade en betydligt högre incidens, definierades "adverse event" som en oavsiktlig skada eller komplikation förorsakad av hälso- och sjukvården och som resulterat i funktionsnedsättning, död eller förlängd vårdtid (3). Gemensamt för samtliga studier är att den uppkomna skadan eller sjukdomen inte ska vara föranledd av den skada eller sjukdom som patienten sökt för.

Problemet omfattning i Sverige

I Sverige saknas vetenskapliga studier som belyser omfattningen av patientskador på nationell nivå. En viss uppfattning om problemet ger anmälningarna till Landstingens Ömsesidiga Försäkringsbolag (LÖF) (Patientskadeförsäkringen), HSAN och händelser rapporterade till Socialstyrelsen enligt Lex Maria. Informationen från dessa källor är dock inte helt jämförbar. En anmälan till LÖF innebär att patienten önskar ekonomisk ersättning för en skada eller ett oönskat resultat som uppkommit i samband med vård och behandling. En anmälan till HSAN, som har en domstolsliknande funktion, kan göras av patient eller dennes närstående eller av Socialstyrelsen för att pröva om hälso- och sjukvårdspersonal gjort sig skyldig till fel i sin yrkesutövning. Anmälningarna till Socialstyrelsen, som baseras på uppgifter från hälso- och sjukvården enligt det nationella rapporteringssystemet Lex Maria (SOSFS 2002:4), avser allvarlig skada eller risk för allvarlig skada. Ytterligare en informationskälla om patientskador utgör Socialstyrelsens ICD-registrering (International Classification Disease). Av rapporten för år 2003 framgår att nästan 26 000 patienter skadades i samband med vård på svenska sjukhus (34). I tabell 2 redovisas en sammanställning över antal anmälningar till de svenska nationella informationssystemen under åren 2000–2005.

Tabell 2. Antal anmälningar till Socialstyrelsen enligt Lex Maria, LÖF och HSAN.

Informationssystem	2000	2001	2002	2003	2004	2005
Lex Maria (Socialstyrelsen)	905	918	996	1 059	1 022	1 050
LÖF	8 871	9 003	9 395	8 717	8 938	9 250
HSAN	3 070	3 250	3 227	3 377	3 663	3 670

Källa: Socialstyrelsens riskdatabas, LÖF och HSAN.

Ekonomiska konsekvenser

I USA beräknas samhällskostnaderna årligen uppgå till mellan 17 och 29 miljarder dollar enbart för skador som har bedömts varit möjliga att förhindra (8). Av dessa kostnader beräknas hälso- och sjukvården svara för över hälften. I Storbritannien beräknas motsvarande kostnader uppgå till 2 miljarder pund per år beräknat på förlängda vårdtider på sjukhusen (9). Kostnaderna för vårdrelaterade infektioner, varav cirka 15 procent bedöms möjliga att förebygga, beräknas uppgå till 1 miljard pund. I Danmark beräknas 10 procent av de ekonomiska resurserna som används i hälso- och sjukvården gå till behandling av patientskador och deras konsekvenser (36). Inom anesthesiologin beräknas de årliga samhällsekonomiska kostnaderna för patientskador uppgå till 60 miljoner danska kronor enligt samma källa.

För svensk hälso- och sjukvård saknas studier som belyser de ekonomiska konsekvenserna av patientskador. LÖF:s årsredovisningar ger viss information (37). Kostnaden för ett års skador inklusive skadereglering uppgår till cirka 600 miljoner kronor årligen. Av de 9 000 patienter som anmälde en skada till LÖF år 2003 beräknas cirka 45 procent bli ersättningsberättigade. Därtill kommer samhällsekonomiska kostnader i form av sjukskrivningar och förlorad arbetsinkomst, produktionsbortfall och myndigheters hantering av anmälda händelser. Kostnaderna för handläggning av rapporterade Lex Maria-ärenden bedöms uppgå till mellan 20–25 miljoner kronor per år för de cirka 900 ärenden som årligen anmäls, vilket innebär cirka 27 000 kronor per ärende (38). För HSAN uppgick kostnaderna för ärendehantering till 6 700 kronor per ärende år 2001. Totalt anmäldes cirka 3 250 ärenden vilket innebär kostnader för administration till cirka 22 miljoner kronor (39). En svensk studie visade att 10 procent av läkarnas arbetstid användes till arbetsuppgifter som kunde betecknas

som kliniskt tveksamma och som kunde relateras till risker att bli anmäld till HSAN. Motsvarande andel var för laboratorie- och röntgenuppgifter 20 procent (40). Utifrån skadornas omfattning, dess konsekvenser för den enskilde individen och samhället kan patientskador betecknas som ett angeläget folkhälsoproblem.

Hälso- och sjukvården – en komplex verksamhet

År 2002 fick cirka 865 000 patienter vård vid 1,4 miljoner vårdtillfällen där patienten varit inskriven för sluten vård (41). Därtill kommer besök inom öppen vård, hemsjukvård samt övrig verksamhet såsom tandvård, rådgivningsverksamhet, ambulanssjukvård och apotek. År 2003 fanns drygt 300 000 personer sysselsatta inom hälso- och sjukvården i Sverige.

Hälso- och sjukvården har blivit alltmer komplex där allt fler aktörer ofta samverkar kring den enskilde patientens vård och behandling. Inom det medicinska området finns det t.ex. ett 60-tal olika subspecialiteter. Införandet av ny avancerad teknologi med nya diagnostik- och behandlingsmöjligheter har inneburit att nya yrkesgrupper tillkommit, vilket kan leda till att ansvarsgränser blir svårare att definiera. Brister i kommunikationen mellan befattningshavare är en känd riskfaktor inom många verksamhetsområden (14, 42–47). Datoriserade journalhanteringssystem, digitaliserad bildbehandling inom radiologin, elektronisk receptföreskrivning och avancerade övervakningssystem är några exempel på förändringar avsedda att både effektivisera vården och göra den säkrare. Strävanden att göra komplexa avancerade tekniska system tillförlitliga kan emellertid i sig medföra nya risker (48–52).

Omfattande organisatoriska förändringar har genomförts under senare år i den svenska hälso- och sjukvården (41). År 1992 genomfördes den s.k. Ädelreformen vilket innebar att kommunerna fick ett större ansvar för vård av äldre och funktionshindrade. Landstingen behöll ansvaret för läkarinsatserna, men i övrigt skulle kommunen stå för den vård som boende på exempelvis äldreboende eller särskilda boenden behöver. Ädelreformen innebar således att vården av de äldre delades upp på två huvudmän – kommun och landsting. Organisationen ställer höga krav på väl fungerade rutiner som tydliggör ansvarsfördelning mellan huvudmännen. Det dubbla huvudmannaskapet har sedan reformen trädde i kraft fått kritik, främst för bristerna i ansvarsfördelningen.

I samband med omorganisationen fastställdes att det medicinska ansvaret för den kommunala hälso- och sjukvården skulle åläggas en medicinskt ansvarig sjuksköterska. En av de viktigaste uppgifterna var att skapa rutiner inom äldre vården så att kraven på hög patientsäkerhet och god kvalitet kunde tillgodoses (SOSFS 1997:10). En viktig yrkesgrupp inom den kommunala hälso- och sjukvården är undersköterskor och vårdbiträden. De tillhör den personal som har den närmsta kontakten med den enskilde vårdtagaren och är därmed de som har att ta ställning till behovet av att tillkalla sjuksköterska eller läkare. Studier har visat att den medicinska kunskapen är låg i förhållande till de uppgifter denna yrkesgrupp utför (53–57).

Ett flertal medicinska uppgifter kräver att dessa utförs av yrkesutövare med formell kompetens (legitimation). Antalet yrkesutövare med legitimation motsvarar dock inte behovet, vilket medfört att vissa uppgifter får delegeras (SOSFS 1997:14). Det innebär att en arbetsuppgift kan överlätas från en befattningshavare som har formell kompetens (legitimation) till en som har reell men som saknar formell kompetens. Den som delegerar en uppgift är ansvarig för att kontrollera att den som tar emot uppgiften har den reella kompetensen och den som mottagit uppgiften är ansvarig för hur uppgiften utförs. Delegationer är vanliga i den kommunala hälso- och sjukvården. Insulingivning till vårdtagare som inte klarar detta själv är en uppgift som ofta överläts till undersköterskor och vårdbiträden. Det innebär höga krav på medicinsk kompetens även hos dessa yrkesgrupper som finns ytterst i vårdkedjan. Detta ställer också ökade krav på sjuksköterskorna vars arbetsuppgifter har fått en alltmer konsultativ karaktär.

Läkemedelshändelser dominerar Lex Maria-rapporteringen till Socialstyrelsen och en hög andel av rapporterade ärenden kommer från den kommunala hälso- och sjukvården. Ett flertal händelser har samband med insulingivning där bristande kunskaper har varit en bidragande orsak till händelsen. Av 12 418 rapporterade Lex Maria-ärenden under åren 1994–2003 avsåg 4 409 läkemedelsärenden varav 675 var relaterade till insulingivning (58). Av dessa kom 498 (74 procent) från den kommunala hälso- och sjukvården. Läkemedelsrelaterade händelser är troligen en av de vanligaste orsakerna till misstag i vården och såväl svenska som internationella studier visar att detta är ett omfattande problem (59–64). Många moment är involverade innan patienten får läkemedlet vilket ökar risken för att misstag begås.

Hälso- och sjukvård ställer höga krav på samordning av insatser även över huvudmannaskapsgränser. En väl fungerande kommunikation mellan de olika

aktörer som är involverade i vården är betydelsefull. Detta blir allt viktigare att uppmärksamma i samband med att en ökande andel hälso- och sjukvård bedrivs utanför den slutna sjukhusvården, vilket är en trend såväl i Sverige som i andra länder. Att risken för misstag ökar i samband med överföring av patienter mellan olika verksamheter är väl känt (65–66) och ett flertal fall har rapporterats enligt Lex Maria. Analyser av inträffade olyckor och katastrofer inom andra branscher har visat att ändrad organisation och bristande ledning av verksamheten är en betydande riskfaktor (49, 67–70). Risken med organisationsförändringar utan föregående riskanalys har även uppmärksammats i Socialstyrelsens verksamhetstillsyn (47).

Behovet av riskinformation

Organisatoriska förändringar och den snabba utvecklingen av vård- och behandlingsmetoder inom hälso- och sjukvården ställer krav på tydlig styrning av säkerhetsarbetet. Vidare kräver en tydlig säkerhetsstyrning tillgång till information om verksamhetens risker (71–76). Det finns svårigheter som är relaterade till rapportering av händelser som givit upphov till skada. Faktorer som framhålls är rädslan för negativa konsekvenser för rapportören vilket kan medföra försök att dölja händelsen (77–86). Andra orsaker kan vara betingade av bristande tid eller upplevd brist på nytta med rapporteringen, vilket kan leda till låg motivation att rapportera (87–92). Problemen kan också vara av kvalitativ karaktär genom bristande information om händelseförlopp och vad som har påverkat detta. En bidragande orsak kan vara otillräcklig analys av händelsen. Det leder i sin tur till att bakomliggande faktorer som påverkat händelseförloppet inte identifieras, vilket kan leda till felaktigt fokus vid förebyggande åtgärder (12).

En annan fråga med relevans för rapportering är allmänhetens rätt till information och pressens bevakning av medicinska misstag. När en patient kommer till skada får händelsen ofta omfattande publicitet. Beskrivningen är inte sällan ytlig med fokus på den yrkesutövare som begått misstaget vilket kan ge felaktiga signaler om orsakerna till händelsen och skapa frustration hos dem som varit involverade. Detta kan leda till bristande motivation att i framtiden rapportera riskhändelser.

Rapporteringssystemet Lex Maria

Kännedom om verksamhetens risker har avgörande betydelse i ett förebyggande säkerhetsarbete och många länder har inrättat nationella rapporteringssystem för händelser där patienter kommit till skada. Det svenska rapporteringssystemet för patientskador, Lex Maria, har funnits sedan 1937 (SFS 1937:6). Ett flertal förändringar i den lagstiftning och de föreskrifter som reglerar rapporteringen och myndighetens tillsyn har skett under åren med syfte att förbättra tillgången till information om risker i hälso- och sjukvården. Den 1 januari 1983 sattes patientsäkerheten i förgrunden när Lex Maria fick ett uttalat preventivt syfte (SOSFS 1982:79). Den dubbla anmälningsskyldigheten slopades och anmälan till polis krävdes inte längre. Även risk för skada skulle nu anmälas.

En viktig förändring som kom att påverka Socialstyrelsens hantering av rapporterade Lex Maria-händelser genomfördes under verksamhetsåret 1990/1991. Då regionaliserades Socialstyrelsens tillsynsverksamhet, vilket innebar att sex regionala enheter bildades. Den strategiska inriktningen av den nya tillsynen beskrevs som mer utåtriktad med ökad betoning på ett förebyggande arbetssätt, med förbättrade analyser och återföring samt effektiviserad ärendehandläggning (93). Före regionaliseringen genomförde Socialstyrelsen 5-10 inspektioner årligen. Under verksamhetsåret 1992/93 genomfördes totalt 531 tillsynsbesök varav 295 var av förebyggande karaktär. Under 2004 uppgick antalet besök till 1 503. En annan skillnad inom Socialstyrelsens tillsynsverksamhet var att fler handläggare jämfört med tidigare hade sjukvårdserfarenhet. Dessutom skulle analysen av en inträffad händelse primärt inriktas mot händelsen och inte mot enskild individ. Med syfte att avdramatisera rapporteringen förändrades också texten på uppgiftsblanketten från "anmälan" till "rapport/anmälan". Vidare genomfördes omfattande informationsinsatser med syfte att tydliggöra Lex Marias förebyggande intention för att därmed stimulera till ökad rapportering från hälso- och sjukvården till Socialstyrelsen (38, 94).

År 1996 infördes begreppet avvikelshantering och en generell rapporteringsskyldighet för all hälso- och sjukvårdsverksamhet infördes (SOSFS 1996:23). Syftet med avvikelshantering var att öka personalens kunskap om riskfaktorer. Hanteringen av den lokala rapporteringen berodde på allvarlighetsgraden av det som rapporterats. Den som utsetts till anmälningsansvarig till tillsynsmyndigheten avgjorde om en händelse skulle vidareanmälas till Socialstyrelsen som ett Lex Maria-ärende.

År 2002 kom en ny Lex Maria-föreskrift (SOSFS 2002:4). På nytt framhölls Lex Marias preventiva syfte och betydelsen av rapportering (95). Även med denna föreskrift skulle rapportering ske i flera steg med en rapporteringsansvarig på varje vårdnivå och en anmälningsansvarig som svarade för bedömningen om händelsen skulle rapporteras som ett Lex Maria-ärende. I tabell 3 definieras ett antal begrepp som Lex Maria-föreskriften innehåller.

Tabell 3. Definitioner av begrepp ingående i Lex Maria-föreskriften (SOSFS 2002:4).

Begrepp	Definition
<i>Allvarlig skada eller sjukdom</i>	En patient har avlidit eller åsamkats livshotande tillstånd. Begreppet omfattar här även kroppsskada, sjukdom eller funktionsnedsättning som medfört eller borde ha medfört vårdinsatser.
<i>Normal risk</i>	Risktagande som enligt vetenskap och beprövad erfarenhet är förbundet med en viss behandling eller diagnostik och som trots korrekta medicinska åtgärder kan medföra att en patient skadas (kalkylerad risk).
<i>Avvikelse</i>	En icke förväntad händelse i verksamheten som medfört eller skulle kunnat medföra skada för en patient.

Som tidigare gäller vissa begränsningar i anmälningsskyldigheten för patienter som i samband med, eller i nära anslutning till, undersökning, vård eller behandling drabbats av skada eller sjukdom. Förutom att vissa skador enbart skall rapporteras i begränsad omfattning skall endast allvarliga skador, eller risk för sådana, rapporteras till Socialstyrelsen. En händelse behöver inte rapporteras till Socialstyrelsen om den anmälningsansvarige bedömer att skadan eller sjukdomen:

- hade kunnat förutses
- har utgjort normal risk
- utgör en välkänd komplikation – en sådan skall enligt föreskriften endast anmälas om hälso- och sjukvårdspersonal handlat uppenbart felaktigt
- berott på brister i säkerhetsanordningen eller tillsynen av patienten vid fallskador och självmord.

Socialstyrelsens skyldighet att anmäla till HSAN

Den policyförändring som genomfördes i samband med regionaliseringen av Socialstyrelsens verksamhet innebar att kriterierna för överföring av ett Lex Maria-ärende till HSAN förändrades (96). Avsikten var att yrkesutövare med övergripande ansvar för verksamheten skulle åläggas ett större ansvar för säkerheten. Hittills var det i huvudsak den individ som begått misstaget som anmälts till HSAN. En HSAN-anmälan från Socialstyrelsen skulle dessutom endast bli aktuell när det fanns ett påtagligt individualpreventivt motiv eller om ett rättsligt prejudikat kunde förväntas ge effekt på säkerhetsnivån. Det saknades emellertid lagstöd både i förarbeten och i författningar som reglerade när Socialstyrelsen borde göra en anmälan till HSAN i ett disciplinärende. Policyförändringen, med en minskad andel ärenden till HSAN, bedömdes möjlig att genomföra inom ramen för gällande lagstiftning. Socialstyrelsen hade tidigare rättighet men inte skyldighet att föra ett ärende vidare till HSAN för prövning av ansvarsfrågan.

År 1994 ändrades bestämmelserna för när en Lex Maria-anmälan skulle medföra en HSAN-anmälan. Förändringen bedömdes av Socialstyrelsen vara en följd av den kritik som riktats mot den nya policyn i samband med regionaliseringen av tillsynen 1990/91 (38). De nya kraven framgick av åliggandelagen som numera tillförts lagen om yrkesverksamhet för hälso- och sjukvårdens område (SFS 1998:531). Av denna framgår att; "*Om Socialstyrelsen **anser** (författarens markering) att det finns skäl för disciplinpåföljd, föreskrift om prøvotid, återkallelse av legitimation, återkallelse av annan behörighet att utöva yrke inom hälso- och sjukvården eller begränsning av förskrivningsrätt enligt 5 kap., **skall** (författarens markering) styrelsen anmäla detta hos Hälso- och sjukvårdens ansvarsnämnd*" (6 kap 18 §).

Lex Maria har under åren debatterats och ifrågasatts (97–100). Ifrågasättandet har dels riktats mot hur väl rapporteringen speglar de faktiska riskerna i hälso- och sjukvården, dels huruvida myndighetens hantering av rapporterade händelser uppfyller lagstiftarens intentioner att öka säkerheten i hälso- och sjukvården. Främst har kritiken riktats mot rapporteringssystemets koppling till disciplinära åtgärder. Även i nu gällande föreskrift (SOSFS 2002:4) finns ett samband mellan personalens rapportering av avvikelser och risk för påföljd för den som rapporterat eftersom Socialstyrelsen fortfarande har skyldighet att överföra vissa ärenden till HSAN.

Det medicinska yrkesansvaret

All hälso- och sjukvårdspersonal har ett eget medicinskt yrkesansvar som innebär att arbetet skall utföras i överensstämmelse med vetenskap och beprövad erfarenhet, vilket är kopplat till disciplinpåföljd om kraven inte uppfylls (SFS 1998:531). Åtgärder kan i sådana fall vidtas antingen mot individen eller mot den som är ansvarig för verksamheten. För händelser som medfört skada på patient kan hälso- och sjukvårdspersonal ställas till svars för sina handlingar enligt dels ett offentligrättsligt disciplinansvar, dels ett straffrättsligt ansvar, det senare är dock ovanligt.

Disciplinansvar

Det offentligrättsliga disciplinansvaret har tillkommit för att tillförsäkra patienterna en opartisk prövning om de anser sig ha fått felaktig vård eller behandling. Det ger därmed patienter en möjlighet att ifrågasätta hur hälso- och sjukvårdspersonal har utövat sitt yrke. Det har också till syfte att borgen för personalens rättssäkerhet. Åtgärderna inom det disciplinrättsliga ansvarssystemet kan utifrån dess övergripande syfte indelas i två kategorier (101):

- skyddsåtgärder för att upprätthålla patientsäkerheten
- straffliknande åtgärder.

Skyddsåtgärder för att upprätthålla patientsäkerheten innebär att yrkesutövaren döms till prövotid, återkallelse av annan behörighet samt indragning och begränsning av förskrivningsrätt eller återkallelse av legitimation (SFS 1998:532, 5 kap, 1 §). Återkallelse av legitimation kan bli aktuellt vid grov oskicklighet i yrkesutövandet, vid sjukdom eller på egen begäran. Under år 2003 återkallades 23 legitimationer varav 15 avsåg sjuksköterskor och barnmorskor, 7 läkare samt 1 tandläkare (39).

Straffliknande åtgärder som omfattar disciplinär påföljd i form av en varning eller erinran syftar till en framtida individual- eller allmänpreventiv effekt. Det innebär att den enskilde individen förväntas bättra sig och att andra skall vägledas av fallet. Kriterierna för en disciplinpåföljd är formulerade enligt följande: "Om den som tillhör hälso- och sjukvårdspersonalen uppsåtligen eller av oaktsamhet inte fullgör en sådan skyldighet enligt 2 kap. 1, 2, 2a, 4, 6, 8 eller 9 § eller någon annan föreskrift som är av direkt betydelse för säkerheten i vården, får disciplinpåföljd åläggas. Om felet är ringa eller om det framstår som ursäktligt får disciplinpåföljd underlåtas" (SFS 1998:532, 5 kap. 3 §).

Under år 2004 avgjordes 3 676 ärenden i HSAN (39). Av dessa ledde 357 till påföljd varav 156 utgjorde en varning och 201 en erinran. Av dem som ålagts påföljd under år 2004 var 158 läkare, 36 sjuksköterskor och barnmorskor samt 42 tandläkare. Övriga yrkesgrupper ålades 139 påföljder. Av de ärenden som Socialstyrelsen överförde till HSAN för prövning av disciplinär påföljd ledde 87 % till påföljd.

Straffrättsligt ansvar

Det *straffrättsliga ansvarssystemet* (enligt brottsbalken) kan bli aktuellt vid misstanke om t.ex. vållande till annans död, vållande till kroppsskada eller brott mot tystnadsplikt. Det har hittills varit relativt sällsynt att åtal har väcks mot yrkesutövare inom hälso- och sjukvården. En uppmärksammande händelse är dialysolyckan år 1983 i Linköping då en sjuksköterska åtalades och dömdes för vållande till annans död (102). Ett annat exempel under senare år är då en sjuksköterska i Kalmar år 2002 åtalades och dömdes för att ha blandat en infusionslösning med en tio gånger för hög dos läkemedel (103). Ytterligare exempel är en sjuksköterska i Landskrona år 2001 som åtalades för brister i samband med vården av en patient på ett äldreboende och att sjuksköterskan inte tillgodosett att patienten fick erforderlig medicinsk behandling och tillräcklig smärtlindring (104). År 2003 åtalades en läkare i Göteborg för att ha underlåtit att lägga in en patient som bedömdes vara självmordsbenägen (105).

Kvalitet och säkerhet

År 1993 kom föreskriften *Kvalitetssäkring i hälso- och sjukvård inklusive tandvård* (SOSFS 1993:9). Av föreskriften framgick att systematiskt kvalitetsarbete var nödvändigt för att säkerställa målinriktningen med verksamheten och kraven på patientsäkerhet. Ansvar för kvalitetssäkringen låg på chefsöverläkaren eller den som hade motsvarande befattning. Föreskriften inriktades på att personalen skulle informeras och instrueras om system, rutiner och metoder. Denna föreskrift ersattes år 1996 med föreskriften; *Kvalitetssystem i hälso- och sjukvården* (SOSFS 1996:24). Kraven på vårdgivaren blev tydligare. Med vårdgivare avses i lagstiftningen fysisk eller juridisk person som bedriver hälso- och sjukvård, vilket i landsting och kommuner betyder att det är den eller de nämnder som ytterst har ansvar för verksamheten. Ansvar innebär att vårdgivaren skulle ge direktiv och säkerställa att det fanns ett ändamålsenligt kvalitetssystem för varje verksamhet. Verksamhetschefens uppgift var att fastställa ett kvalitetssystem för sin verksamhet. Hälso- och sjukvårdspersonalen hade å sin sida krav på att medverka så att de fastställda riktlinjerna och målen för verksamheten

uppfylldes. År 2005 kom den nu gällande föreskriften; *Ledningssystem för kvalitet och patientsäkerhet i hälso- och sjukvården* (SOSFS 2005:12). I föreskriften skärps vårdgivarens ansvar med utökat krav på uppföljning av verksamheten. Verksamhetschefen ansvarar för att inom ramen för vårdgivarens ledningssystem ta fram, fastställa och dokumentera rutiner för hur det systematiska kvalitetsarbetet kontinuerligt skall bedrivas så att verksamheten kan styras, följas upp och utvecklas. Hälso- och sjukvårdspersonalen har ansvar att delta i kvalitetsarbetet.

Frågorna om kvalitet och säkerhet är integrerade i föreskriften. Det nära sambandet mellan dessa frågor framgår av föreskriftens benämning *Ledningssystem för kvalitet och patientsäkerhet i hälso- och sjukvården* (SOSFS 2005:12). Av denna framgår att kvalitetsarbetet skall syfta till att förebygga vårdskador, utgå från vårdprocesserna och vara anpassat till verksamhetens inriktning storlek och omfattning. De områden som lyfts fram i föreskriften är:

- bemötande av patient
- metoder för diagnostik, vård och behandling
- kompetens
- samverkan och samarbete
- riskhantering
- avvikelshantering
- försörjning av tjänster, produkter och teknik
- spårbarhet.

Samtliga dessa områden har hög relevans för både kvalitets- och säkerhetsarbetet och visar hur integrerade dessa frågor är. Patientsäkerhetsfrågorna har i de senare föreskrifterna getts allt större utrymme. Likaså är ledningens ansvar för säkerheten tydligare i den senaste föreskriften. Kvalitet och säkerhet hänger nära samman och brister i patientsäkerheten är också en indikator på bristande kvalitet. Utvecklingen av synen på kvalitets- och säkerhetsfrågor inom hälso- och sjukvården speglas delvis i benämningen av föreskrifterna; *Kvalitetssäkring...* (SOSFS 1993:9), *Kvalitetssystem...* (SOSFS 1996:24) och *Ledningssystem...* (SOSFS 2005:12).

Att patientsäkerheten inte kan skiljas ut från övriga kvalitetsperspektiv på hälso- och sjukvården uttrycker Andreen Sachs (106) enligt följande:

"Säker vård handlar inte enbart om undvikbara skador i samband med medicinska åtgärder (misuse), utan även om risker som följer med onödig, icke evidensbaserad

vård (overuse), respektive undanhållen, evidensbaserad vård för vilken det finns ett behov (underuse). Patientsäkerheten är alltså en väsentlig del av kvaliteten i hälso- och sjukvården, och den kan inte skiljas ut från övriga kvalitetsperspektiv på hälso- och sjukvård.” (106, s. 2538).

En systematisk utvärdering av vårdens kvalitet är väsentlig och tydliga och mätbara mål är en viktig förutsättning för att uppnå en verklig förbättring av säkerheten. Kvalitetsarbetet i vården har under de senaste decennierna tagit sin utgångspunkt i Donabedians modell: Struktur, Process och Resultat (107). Med strukturkvalitet avses de resurser, strukturer och organisatoriska lösningar som används för att tillhandahålla hälso- och sjukvård, d.v.s. förutsättningarna för vården. Ett mått kan vara typ av vårdpersonal, medicinsk utrustning eller den form som vården bedrivs i. Processkvaliteten avser de åtgärder som vidtas för att diagnostisera eller behandla sjukdomar. Ett mått på processkvalitet är personalens följsamhet avseende fastställda rutiner och riktlinjer. Resultatkvalitet, som är kärnan i vårdens kvalitet, avser effekterna på hälsan av den vård som ges. Exempel på resultatindikatorer är symtomfrihet, komplikationer, upplevelser av bemötande samt dödlighet och överlevnad. Aktuell säkerhetsforskning inriktas alltmer mot en ökad uppmärksamhet mot hälso- och sjukvårdens stödsystem (the blunt end). Det kan sägas motsvara Donabedians strukturkvalitet, d.v.s. hur stödsystemen påverkar processkvaliteten och yrkesutövarna i frontlinjen (the sharp end). Resultatkvaliteten kan t.ex. mätas i antal patienter som skadas eller avlider på grund av vård och behandling.

Behovet av uppföljning av vårdens kvalitet har uppmärksammats alltmer under senare år. Ett exempel är nationella kvalitetsregister vilka ger möjlighet till aggregering av data och epidemiologisk forskning samt kvalitetsjämförelser. Kvalitetsregister spelar en allt större roll för verksamhetsuppföljning av hälso- och sjukvården. Totalt finns 57 nationella kvalitetsregister (108). Ett annat exempel är framtagande av kvalitetsindikatorer, d.v.s. kvantitativa mått som kan användas för att registrera och utvärdera kvaliteten i vården. Svensk Sjuksköterskeförening (SSF) har utarbetat ett antal kvalitetsindikatorer t.ex. för trycksår, risk för fallskador och cancerrelaterad smärta (109). För varje indikatorsområde finns bakomliggande vetenskaplig kunskap beskriven.

TEORETISK ANKNYTNING

Säkerhetsforskningens utveckling

Säkerhetsarbetet inom högriskverksamheter såsom flyg, offshoreverksamhet och kärnkraft har utvecklats mot en integrerad syn på säkerhet med fokus på systemets funktionssätt. Initialt riktades uppmärksamheten mot de tekniska systemens säkerhet för att senare uppmärksamma vikten av interaktionen mellan individ och omgivande miljö, där både teknik och organisation är faktorer som tillmäts betydelse. Under senare år diskuteras säkerhetsfrågor allt oftare också utifrån ett samhällsperspektiv, där t.ex. ökad konkurrens, ekonomi och politiska beslut vägs in i debatten. I figur 1 redovisas översiktligt säkerhetsforskningens utveckling.



Figur 1. Säkerhetsforskningens utveckling.

Ett av de första exemplen som illustrerar hur ekonomiska incitament kan påverka säkerheten utgör postflygets utveckling i USA i början av 1900-talet. Postverkets krav på snabb postgång innebar hög arbetsbelastning för piloterna och de tvingades att ibland flyga trots svåra väderförhållanden. Inte mindre än 31 av de första 40 piloterna som anställdes omkom i flygolyckor i samband med postflyg (49).

Den enskilda händelse som starkt kommit att påverka säkerhetsforskningen under senare tid är kärnkraftsolyckan 1979 på Three Miles Island (TMI). Erfarenheterna från olyckan visade att synen på säkerhet inom kärnkraftsindustrin tills dess hade dominerats av en alltför snäv teknisksyn (67). En lärdom var att även mänskliga och organisatoriska aspekter behöver inkluderas i analyser av olyckor. I samband med utvecklingen av det amerikanska rymdprogrammet utvecklades metoden Human Performance Enhanced Safety (HPES) av The National Aeronautics and Space Administration

(NASA). Efter Three Miles Island-olyckan fick metoden ökad aktualitet och modifierades senare av Institute of Nuclear Power Operations (INPO). Händelsen ledde till att det så kallade MTO-perspektivet introducerades av Svenska Kärnkraftsinspektionen (SKI) i mitten av 1980-talet (110). MTO representerar ett systemperspektiv på säkerhet där människan, organisationen och tekniken tillmäts lika stor betydelse. Den kan sägas utgöra ett ramverk för tillämpning av olika teoribildningar som omfattar både human factor-området och ergonomi. Rollenhagen (111, s. 165) har definierat MTO som:

"ett perspektiv på säkerhet vars syfte är att studera hur människors fysiska, psykologiska och sociala förutsättningar samspelar med olika teknologier och organisationsformer samt utifrån denna kunskap verka för ökad säkerhet".

Inom det svenska kärnkraftsområdet, såväl industri som tillsynsmyndighet, utgör MTO-perspektivet numera en viktig grund i säkerhetsarbetet.

Redan före TMI-olyckan visade Turner (68) hur sociala och organisatoriska faktorer påverkat händelseförloppet i 84 stora olyckor i England under en 10-årsperiod. Han fann att det för varje olycka fanns ett antal gemensamma kännetecken som utvecklats under ett flertal år men som hade ignorats. Turner definierade denna gradvisa utveckling som inkubationsperiod "disaster incubation period". Andra exempel som belyser att svagheter i systemet varit kända i organisationen lång tid före olyckan är brandkatastrofen 1987 i Londons tunnelbanesystem vid Kings Cross Station (69). Trähissarna som installerades i slutet på 1930-talet hade identifierats som brandfarliga i över 50 år. Vid utredningen av flygolyckan på Linate-flygplatsen utanför Milano 2001 framkom ett flertal brister på övergripande nivå som varit kända sedan länge. Initialt lades skulden på piloten. Det framkom dock betydande brister på såväl lokal som nationell ledningsnivå (112). Ett exempel på hur organisatoriska faktorer troligen bidragit till spårvagnsolyckan i Göteborg 1992 framkom i olycksutredningen av Statens Haverikommission (SHK) (70). Ett flertal omorganisationer inom spårvägstrafiken i Göteborg hade genomförts inom en relativt kort tidsrymd före olyckan. Dessa bedömdes i utredningen ha haft en negativ inverkan på det övergripande trafiksäkerhetsarbetet. Spårvägstrafikens säkerhetsarbete hade dessutom styrts av en icke nedtecknad praxis.

Vägrafiken i Sverige är ett område där det skett en tydlig förskjutning från individ- till systemperspektiv i synen på olyckor. Risken att dö eller skadas har tidigare huvudsakligen ansetts vara ett individrelaterat problem där den enskilde trafikanten genom sitt beteende ansetts vara den som förorsakat

trafikolyckorna. Det långsiktiga säkerhetsarbetet inom vägtrafiken inriktas nu i högre utsträckning än tidigare på människans begränsningar och att vägtrafiksystemet måste utformas på ett sådant sätt att det medger och om möjligt förlåter mänskliga misstag eller mildrar dess konsekvenser. Ett exempel är mittbarriärer på vägarna för att förhindra kollisioner. Ett annat är utveckling av utrustning i bilar, t.ex. krockkuddar och olika typer av stabilitetssystem. Riksdagen har för vägtrafiken formulerat en konkret bild av ett önskvärt tillstånd genom den s.k. "nollvisionen" vilken innebär en tydlig målsättning med ett högsta antal dödade och skadade inom en viss tidsperiod. För att Nollvisionen skall kunna uppnås fastställdes tre övergripande mål (113, s. 51):

- Systemutformarna har alltid det yttersta ansvaret för vägtransportsystemets utformning, skötsel och användning och har därmed tillsammans ett ansvar för hela systemets säkerhetsnivå.
- Trafikanterna har ansvar för att följa de spelregler som systemutformarna ställt upp för användningen av vägtransportsystemet.
- Om trafikanterna inte följer spelreglerna – på grund av t.ex. bristande kunskap, acceptans eller förmåga – eller om personskador uppstår, måste systemutformarna vidta ytterligare åtgärder i den mån detta krävs för att motverka att människor dödas eller skadas allvarligt.

Nollvisionen lägger stort ansvar på systemutformarna, vilka har det yttersta ansvaret för säkerheten i vägtransportsystemet. Exempel på systemutformare är kommuner och väghållare, fordonstillverkare, polis och transportföretag. Politiker och tjänstemän som arbetar med samhällsplanering är andra systemutformare.

Referensramens betydelse

En referensram har en viktig funktion när det gäller att förstå hur en olycka uppkommer eftersom den avgör hur vi ser på individens roll i olyckan. Det har blivit särskilt tydligt i olycksfallsforskningen, där synen på människans roll har förändrats i takt med att nya metoder för olycksanalyser har introducerats. Under de senaste 75 åren har olycksmodellerna kraftigt förändrats vilket kommit att påverka utvecklingen av analysmetoder inom området. I en översiktsartikel redogör Hollnagel (114) för utvecklingen inom området och beskriver tre typer av olycksmodeller: sekventiella, epidemiologiska och systemiska modeller.

I den *sekventiella olycksmodellen* ses olyckan som ett resultat av handlingar som inträffar i en speciell ordning eller sekvens. Sökprincipen bygger på att försöka finna specifika orsaker och tydliga länkar mellan orsak och verkan. Man antar att olyckan är ett resultat av en sekvens händelser och att orsaker kan elimineras eller kapslas in så snart de är upptäckta för att därmed undvika framtida olyckor. Denna modell lanserades som dominoteorin i början av 1930-talet och visualiserades genom ett antal dominobrickor (115). Om en dominobricka representerar en olycksfallsfaktor representerar modellen hur dessa faktorer slås ihop till en sekvens av händelser där brickorna slår ner varandra. Sambandet mellan orsak och verkan framstår som enkelt och avgörande. En annan olycksmodell som också kan tillföras kategorin sekventiella olycksmodeller är Accident Evolution and Barrier model (116). Denna modell bygger på det som gick fel och de barriärer som brustit. Även händelseträdet som representeras i form av en hierarki, med under- och överordnade händelser kan hänföras till gruppen sekventiella olycksmodeller (117). De sekventiella modellerna visade sig emellertid otillräckliga för att förstå olyckor i komplexa system.

Den epidemiologiska olycksmodellen liknar en olycka vid en sjukdom och beskrevs redan i början av 1960-talet. Modellen bedöms ge en bättre grund för diskussioner kring olycksfallens komplexitet än de sekventiella modellerna. Olyckor förstås som resultatet av en kombination av olika faktorer, där vissa är uppenbara och andra dolda, men som av tillfälligheter existerar i samma tid och rum. I denna modell söker man efter hinder och dolda tillstånd i systemet. Det underliggande antagandet är att hinder kan etableras och/eller förstärkas antingen för att förhindra framtida olyckor eller för att minska effekten av en inträffad olycka. Ett exempel på den epidemiologiska olycksmodellen är Organizational accident model (118).

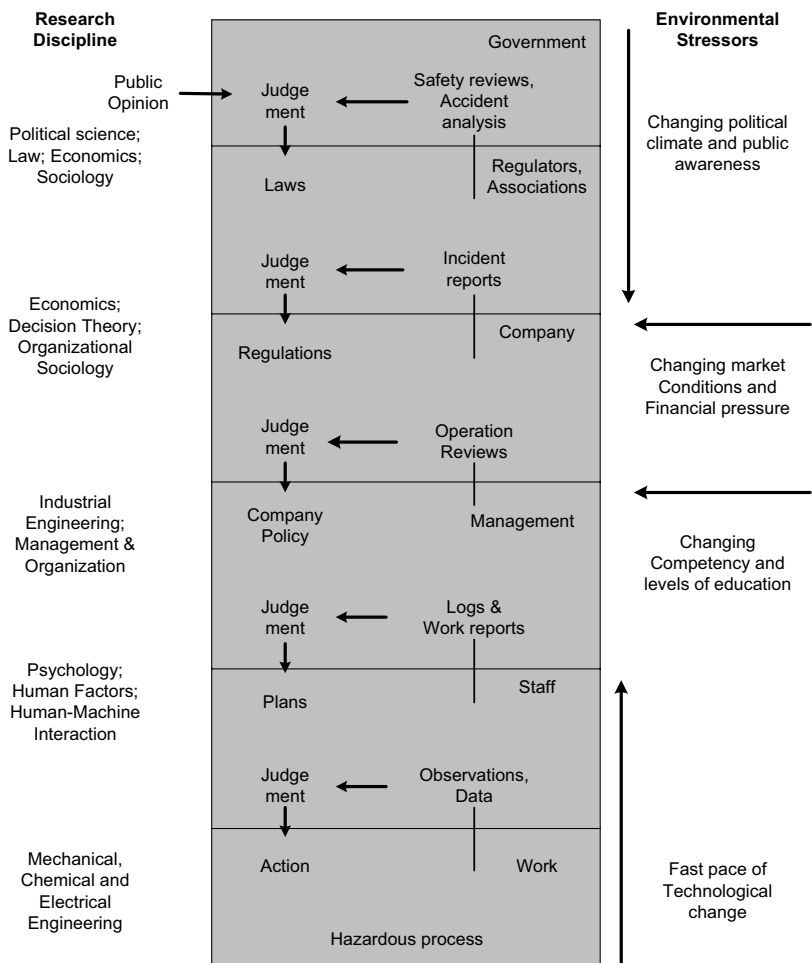
Den *systemiska olycksmodellen* syftar till att beskriva hela systemet istället för vissa nivåer av specifika "orsak-verkan" - mekanismer eller epidemiologiska faktorer. Denna modell försöker avsiktligt undvika en beskrivning av en olycka som en sekvens mellan individuella händelser och är därför svårare att grafiskt avbilda. Utgångspunkten är att verksamheten ses som ett system med tekniska, mänskliga och organisatoriska resurser som skall samverka för att åstadkomma ett givet resultat. Det är egenskaperna hos de olika ingående komponenterna och samspelet mellan dessa som avgör hur stor risken är för en olycka. Den systemiska modellen betonar behovet av att grunda olycksanalysen på en förståelse av systemets funktionella karaktär istället för antagande om interna mekanismer. Exempel på denna modell är Cognitive reliability and error analysis method (CREAM) (119).

Ur ett systemiskt perspektiv har en olycka flera bidragande orsaker. Ingen av de tre modellerna bedöms vara överlägsen de andra. Hollnagel (114) menar att det är det studerade problemet som i stor utsträckning avgör val av analysmetod.

Systemperspektivet

Flera säkerhetsforskare menar att system ofta fallerar på grund av brister i systemet som helhet och inte på grund av enskilda komponenter (118–123). Förenklat kan sägas att ett system består av ett antal ömsesidigt beroende komponenter som skall fungera som en helhet. Komponenterna interagerar inom en viss systemgräns och har gemensam uppgift. Varje komponent kan i sin tur betraktas som ett system som i sig innehåller olika komponenter. Systemperspektivet kan sägas beskriva dessa ömsesidigt påverkande faktorer. De flesta system kan också betraktas som hierarkiska strukturer. Det kan förstås som att många människor, på olika nivåer och med olika uppgifter är involverade i arbetet med att styra de yrkesutövare som har direkt kontakt med patienterna och som därmed direkt konfronteras med riskerna. Påverkan kan ske genom lagar, föreskrifter, regler, instruktioner och genom utbildningsinsatser. Beroende på analysnivå kan ett system analyseras som mer eller mindre överordnat andra system där även den nationella nivån med politiska beslut, lagstiftningens utformning och myndigheters agerande kan vara en sådan analysnivå (123).

Systemsäkerhet är beroende av hur interaktionen mellan olika komponenter i systemet fungerar. Av systemperspektivet följer också att om man förändrar en komponent i systemet får detta återverkningar på andra komponenters funktion. Vi behöver därför förstå vilka mekanismer som påverkar agerandet hos aktörerna på olika systemnivåer och hur dessa nivåer påverkas av omgivningen. Från ett samhällsperspektiv kan hälso- och sjukvården betraktas som ett system med ett givet uppdrag, formulerat i lagstiftning. Rasmussen (123) menar att systemets olika nivåer ofta studeras separat trots att effekterna av beslut på olika beslutsnivåer inom ett system starkt påverkar varandra. Rasmussen illustrerar detta i följande modell.



Figur 2. Illustration av systemperspektivet enligt Rasmussen (1983).

Av figur 2 framgår bl.a. att varje nivå i systemet påverkas av olika interna faktorer genererade på andra nivåer i systemet samt en rad externa "stressorer" som t.ex. politiska och teknologiska drivkrafter.

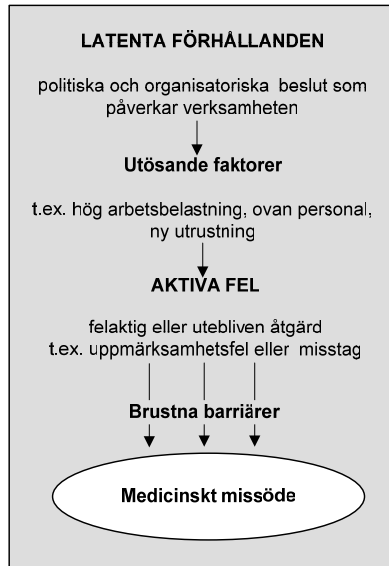
Organizational accident model

En modell som kommit att få stort inflytande under senare år är Reasons (118) "Organizational accident model". Reason beskriver modellen enligt följande:

"The organizational accident model views human error more as a consequence than as a cause. Errors are the symptoms that reveal the presence of latent conditions in the system at large" (118, s.226).

För att förklara utvecklingen av en olycka använder Reason termerna latent tillstånd (latent conditions) och aktiva fel (active failures). Latenta tillstånd kan definieras som svagheter i systemet som ibland är kända men ej prioriterade, och ibland är dolda. Latenta tillstånd kan, ibland upp till flera år efter det att de uppkommit, i samverkan med lokala triggers (utlösande faktorer) leda till olyckor. Exempel på lokala triggers kan vara hög arbetsbelastning, bristfällig utrustning, tidspress och ovan personal. Ett aktivt fel definieras som en felhandling som direkt leder till en negativ konsekvens. Det begås av individer i frontlinjen (the sharp end) och av dem som sist i en lång händelsekedja blir de som utlöser en olycka, t.ex. piloter, sjuksköterskor och läkare där handlingen leder till en direkt konsekvens. De latenta tillstånden uppkommer i systemets stödfunktioner (the blunt end). Skillnaden mellan aktiva fel och latenta tillstånd utgörs framförallt av tiden från beslut eller handling till dess att en olycka inträffar.

Reason menar att latenta tillstånd "övervintrar" i systemet och i samband med lokala triggers kan de leda till aktiva fel. Det aktiva felet blir då den utlösande faktorn till händelsen. Latenta tillstånd är överordnade i den bemärkelsen att de kan generera olyckor som primärt kan tyckas vara helt olika till sin karaktär men som vid en analys visar sig ha samma ursprung. Svagheter kan härröra från beslut som ofta tagits av dem som inte är direkt involverade i den operativa verksamheten. Det kan t.ex. vara omstrukturering av verksamheten där man inte tagit tillräcklig hänsyn till utbildningsbehov hos personalen i frontlinjen. Det kan också vara otillräckliga ekonomiska resurser som medför personalminskningar. Andra exempel är bristande tillgång till adekvat kompetens under jourtid och schemaläggning där man t.ex. inte tar hänsyn till de fysiologiska begränsningar som människor har i samband med trötthet (124–125). Med denna utgångspunkt blir det enligt Reason viktigare att identifiera och fokusera på latenta tillstånd i systemet än på den individ som begått ett fel. Modellen illustreras i figur 3.



Figur 3. Utveckling av en "organisatorisk" olycka efter Reason (118)

Riskfyllda verksamheter har ofta omfattande säkerhetssystem som i princip omöjliggör "enkelfel", både mänskliga, mekaniska och administrativa (116, 126–128). För att en olycka ska inträffa krävs därför att ett flertal säkerhetsåtgärder brister.

De flesta system har latent svagheter. Eftersom svagheter i enskilda systemkomponenter sällan leder till olyckor uppfattas de inte alltid som svagheter. Att helt eliminera dessa svagheter menar Reason är omöjligt genom att vissa svagheter inte är kända eller inte prioriteras på grund av de kostnader som är förknippade med dem. Andra svagheter elimineras inte därför att det är svårt att förutse hur de kan bidra till en olycka. Av detta följer att åtgärder som enbart riktas mot en händelse som inträffat sannolikt inte reducerar framtida olyckor. Istället för att öka säkerheten kan denna typ av åtgärder medföra motsatt effekt genom att de ökar komplexiteten i systemet, och därmed ökar också det potentiella antalet dolda brister.

Mänskliga felhandlingar

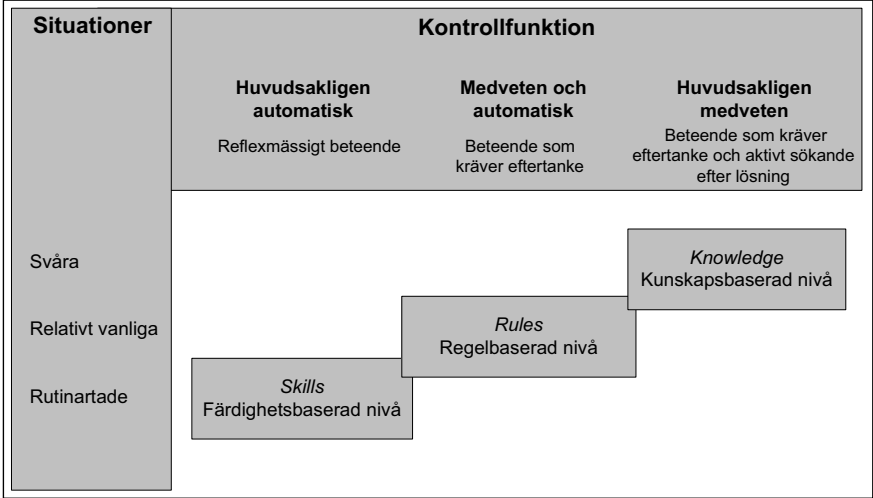
I dagligt språkbruk uppfattas ordet fel oftast relativt okomplicerat. Ordets betydelse är emellertid inte entydig. En orsak till dess olika innebörd kan vara skilda utgångspunkter för bedömningen av den handling som ledde fram till felet. Fel kan t.ex. analyseras utifrån individens subjektiva mål och intentioner med handlingen. Fel kan också analyseras utifrån ett vidare perspektiv där ledning och organisationsstruktur tillmäts betydelse. I en rättslig prövning bedöms felet efter de kriterier som ställs upp för vad som skall betraktas som rätt eller fel, vilket utgår från de lagar och förordningar som styr verksamheten. Reasons definition av "human error" är; *"the failure of planned actions to achieve their desired ends – without the intervention of some unforeseeable event"* (118, s. 71). Oavsett hur man definierar felhandlingar är de för det mesta negativa händelser som på ett eller annat sätt avser ett misslyckande att möta ett i förväg definierat mål. Hollnagel (119) använder begreppen, "erroneous action" (felaktig åtgärd) eller "performance failure" (misslyckad åtgärd). Ett fel är dessutom alltid något som konstateras i efterhand. Den som analyserar en händelse har facit i handen och riskerar att förenkla händelseförloppet, s.k. "hindsight bias" (129).

Skills-, Rules- and Knowledge-based model

Trots att fel inträffar under till synes helt olika omständigheter anses mänskliga felhandlingar ha sitt ursprung i några få psykologiska mekanismer (130). Ett sätt att beskriva mänskligt handlande utgår från de kognitiva nivåerna, medveten eller automatisk kontroll, som är involverade i beslutsfattande (Figur 4). I Rasmussens "SRK-model" (Skills-, Rules- and Knowledge-based model) (123, 131) förklaras individens handling utifrån att vissa handlingar är av problemlösningsskaraktär och fordrar koncentration och uppfinningsrikedom. Andra handlingar kan rubriceras som regelföljande, dvs. vi tillämpar en viss handling i en viss situation. Dessa aktiviteter kräver ibland mindre koncentration än problemlösande aktiviteter och kan i vissa fall utföras relativt mekaniskt. Båda dessa kategorier kräver att man dels identifierar situationen korrekt, dels att man väljer att utföra rätt handling. Ytterligare en kategori handlingar är de automatiska, sådana som går att utföra mer eller mindre med "autopiloten", dvs. där handlingsmönstret sitter i ryggmärgen.

I Rasmussens modell identifieras tre nivåer för mänskligt handlande: "Skills" hänför sig till en färdighetsbaserad nivå. Detta är den lägsta kontrollfunktionsnivån som styr rutinartade uppgifter vilka kan utföras utan medveten kontroll. Den andra nivån är "Rules" som hänförs till en regelbaserad nivå, vilken kontrollerar "know how". Den antas bestå av ett antal i

ordningsföljd automatiserade rutiner. Dessa är ordnade efter en särskild plan, bygger på erfarenhet och är kända för att fungera från tidigare tillfällen. Individens handling förklaras utifrån om åtgärden är väl känd eller inte för individen. När det inte finns någon plan att följa styrs handlingen av den tredje nivån "Knowledge" som hänförs till en kunskapsbaserad nivå. Där krävs att en plan utformas som baseras på grundläggande förståelse för uppgiften. I figur 4 illustreras mänskliga handlingar med utgångspunkt i Rasmussens SRK-modell.



Figur 4. Skills- Rules- and Knowledge-based model (SRK) (123).

Van der Schaaf (132) har beskrivit Rasmussens SRK-modell utifrån en bilförarens perspektiv. En van bilförare som kör den vanliga vägen till arbetet kör bilen på en färdighetsbaserad nivå, dvs. en huvudsakligen automatisk kontrollfunktionsnivå. Det möjliggör att hon obehindrat kan föra en diskussion med en medpassagerare. Det *färdighetsbaserade* beteendet är kopplat till rutinuppgifter som kräver liten eller ingen uppmärksamhet för att utföras och innebär att andra uppgifter kan göras parallellt.

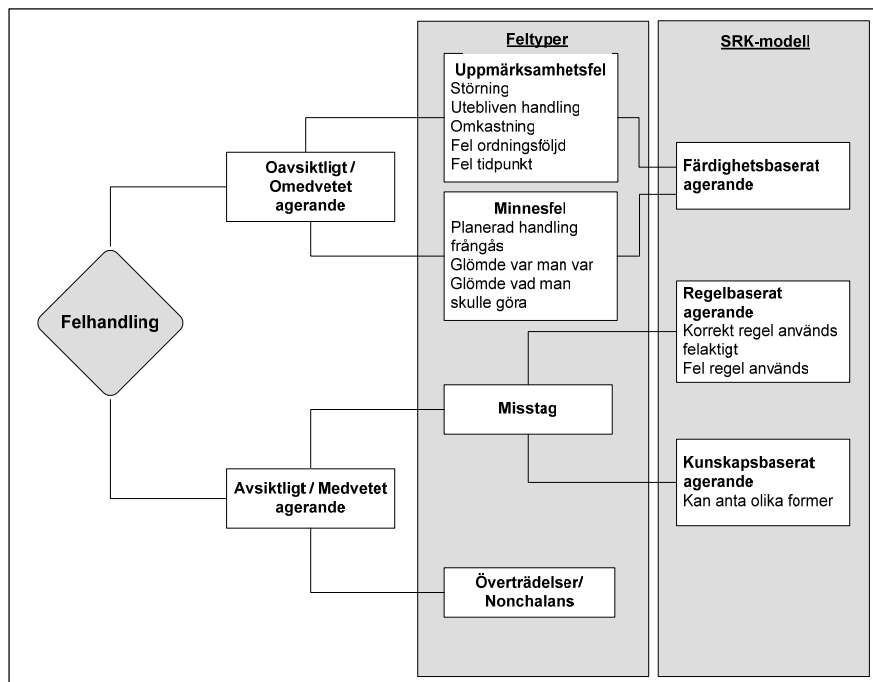
Det *regelbaserade* beteendet är kopplat till aktiviteter som är vanliga men som kräver ett visst mått av beslutsfattande. En bilförare integrerar de kända reglerna för hur hon beter sig när hon passerar en korsning med stoppljus, för

att bedöma om hon skall köra eller stanna. Medan hon tar dessa beslut krävs viss, men inte total, uppmärksamhet. Däremot kör hon bilen utifrån den färdighetsbaserade kunskapen.

Det *kunskapsbaserade* beteendet är kopplat till problemlösande aktiviteter, t.ex. när man konfronteras med situationer för vilka det saknas kända lösningar. En bilförare som under rusningstid kommer till en korsning, där trafikljusen inte fungerar, måste först bestämma hur hon skall passera korsningen. Samtidigt måste hon bedöma om andra trafikregler, t.ex. högerregel, tillämpas i den uppkomna situationen. Som ett resultat av detta måste hon rikta all uppmärksamhet på att lösa problemet att ta sig igenom korsningen och upphöra med andra aktiviteter.

Oavsiktlig respektive avsiktlig handling

Reason (118) utgår från Rasmussens SRK-modell (131) när han diskuterar och utvecklar begreppet fel. Reasons utgångspunkt är huruvida intentionen med handlingen var oavsiktlig eller avsiktlig. I de fall där händelsen kategoriseras som *oavsiktlig* har intentionen med handlingen varit adekvat. Däremot uppnås inte det avsedda målet med handlingen. Dessa fel benämns vanligen "slips" eller "lapses". Slips är relaterat till observerbara handlingar t.ex. kirurgen som slinter med kniven eller sjuksköterskan som tar "fel" injektionsflaska. Lapses är i högre grad relaterade till minnet och kan t.ex. vara att sjuksköterskan går in till "fel" patient eller glömmer att ge ett läkemedel. Förenklat kan man säga att individen tänkt rätt men handlat fel, dvs. individen har varit omedveten om handlingen. Händelser där handlingen som lett till felet bedöms ha varit *avsiktlig* benämns misstag. Dessa handlingar är medvetna och följer den avsedda intentionen, men planen för handlingen var inadekvat. Det kan bero på att man valt fel "regel" eller att regeln använts felaktigt. Reason delar in *misstag* i två subgrupper, regelbaserade och kunskapsbaserade misstag, vilka bygger på Rasmussens SRK-modell. Vid överträdelser/nonchalans är både intentionen och utfallet av handlingen avsiktlig men skiljer sig från de två övriga kategorierna på många sätt. I figur 5 ges en översikt av psykologiska variationer av en felhandling (unsafe acts) klassificerade utifrån om handlingen var oavsiktlig eller avsiktlig.



Figur 5. Förklaringsmodell till feltyper efter Reason (118, s. 207).

Barriärbegreppet

Barriärbegreppet är väsentligt inom säkerhetsforskningen för att beskriva och förstå händelseförlopp och är därmed också väsentligt för det förebyggande arbetet (116, 127–128). En barriär är ett hinder som antingen syftar till att förhindra att en handling utförs eller en händelse inträffar, eller för att minska deras konsekvenser. Barriärer kan indelas i två huvudgrupper – förebyggande och skyddande – vilka tar utgångspunkt i det tidsmässiga förhållandet mellan en barriär och en olycka. Barriärer kan också beskrivas utifrån deras beskaffenhet:

- *Materiella eller fysiska barriärer* hindrar en handling från att bli utförd eller inträffa. Exempel är byggnad, vägg eller liknande. En materiell barriär är inte beroende av att personen ser den eller uppfattar den.

- *Funktionella barriärer* hindrar en handling från att äga rum. Innebörden är att en eller flera förutsättningar införs vilka måste uppfyllas innan handlingen kan utföras. Dessa behöver inte alltid vara synbara. Exempel är hänglås, kodlås eller alkolås.
- *Symboliska barriärer* kännetecknas av att de kräver en aktiv uppfattning och tolkning för att fungera. Ett exempel är reflexer som markerar väggkanten. Alla slags tecken och signaler utgör symboliska barriärer, särskilt visuella eller auditiva signaler. Detsamma gäller för varsel och alarm och utformning av visuella gränssnitt.
- *Immateriella barriärer* är inte fysiskt närvarande utan beroende av användarens kunskap och erfarenhet. Typiska immateriella barriärer är regler, riktlinjer, föreskrifter och lagar, vilka oftast har en fysisk form. De kan också vara organisatoriska barriärer såsom regler för handlingar som är upprättade för verksamheten. Exempel på immateriella barriärer i hälso- och sjukvårdens stödsystem på nationell nivå är t.ex. läkemedelsföreskriften (SOSFS 2001:17) och kvalitetsföreskriften (SOSFS 2005:12).

PROBLEMSAMMANFATTNING

- Internationella uppskattningar visar att ett stort antal patienter beräknas skadas i samband med vård och behandling. Förutom det lidande som drabbar den enskilde patienten och dennes närstående leder patientskador till höga kostnader för hälso- och sjukvården och samhället i stort. Konsekvenserna drabbar också de som arbetar inom hälso- och sjukvården och patientskador kan därför troligen också betraktas som ett arbetsmiljöproblem.
- Ett komplext och dynamiskt system som hälso- och sjukvården, där riskbilden kontinuerligt förändras beroende på förändrad organisation och nya vård- och behandlingsmetoder, ställer höga krav på tillgång till riskinformation. Rapporteringen enligt Lex Maria tyder på under-rapportering vid jämförelse med internationella studier.
- Omfattande förändringar genomfördes inom Socialstyrelsens tillsyns-verksamhet åren 1990/91 med syfte att förstärka myndighetens stödjande roll i det förebyggande patientsäkerhetsarbetet samtidigt som skyldigheten att överföra vissa ärenden till HSAN kvarstod. En anmälan till HSAN antas ha en preventiv effekt.
- Inom den kommunala hälso- och sjukvården är läkemedelsrelaterade händelser ett känt riskområde och samtidigt den vanligaste rapporterade ärendekategorin till Socialstyrelsen. Bland de rapporterade händelserna är misstag där läkemedlet insulin förekommer vanligt.
- Inom säkerhetsforskningen har en förskjutning skett från en individ- till en systemsyn på säkerhet.

SYFTE, METOD OCH MATERIAL

Syfte

Det övergripande syftet med avhandlingen är att bidra till ökad kunskap om faktorer som kan antas påverka patientsäkerheten, dels på systemnivå, dels på individnivå.

Översikt över tillämpade metoder

Avhandlingens första huvudområde tar sin utgångspunkt i rapporterings-systemet Lex Maria, med särskilt fokus på ärenden som överförts till HSAN (I och II). I det andra huvudområdet beskrivs valda delar av flygets säkerhetsrelaterade arbete, vilket jämförs med motsvarande arbete inom hälso- och sjukvården (III). I det tredje huvudområdet beskrivs alternativa metoder för identifiering av risker inom hälso- och sjukvården (IV–VI). I delstudie IV beskrivs och analyseras personalens uppfattning om potentiella risker som skulle kunna hota patienternas säkerhet. Delstudien genomförs på ett barnsjukhus. Delstudierna V och VI genomförs inom den kommunala hälso- och sjukvården där både yrkesutövare som arbetar i frontlinjen, vårdbiträden och undersköterskor samt medicinskt ansvariga sjuksköterskor ingår. Nedan följer frågeställningar samt ett sammandrag av datainsamling, dataanalys och resultat för avhandlingens olika delstudier. En översikt av tillämpade metoder i avhandlingens delstudier visas i tabell 4.

Tabell 4. Tillämpade metoder i avhandlingens delstudier.

Studie	Metod	Urval	Datainsamling
I	Dokument-analys	Samtliga Lex Maria-ärenden som inkom till Socialstyrelsen under åren 1989 respektive 1993, n= 1 590. Samtliga Lex Mariaärenden som anmäldes till HSAN perioden 1989 t.o.m. 1993, n= 339	Genomgång av anmälningsärenden på Socialstyrelsen och HSAN
II	Dokument-analys	Samtliga Lex Maria-ärenden som anmäldes till Socialstyrelsen under år 1998, n=1 116, och som överförts till HSAN, n= 98 ärenden, omfattande 109 individer	Genomgång av anmälningsärenden på Socialstyrelsen och HSAN
III	Empirisk kvalitativ studie	12 informanter på verksamhets- och myndighetsnivå inom flyget med ansvar för kvalitets- och säkerhetsfrågor	Intervjuer baserade på halvstrukturerat frågeformulär
IV	Empirisk kvalitativ studie	28 informanter omfattande sjuksköterskor, läkare, undersköterskor, barnsköterskor och sekreterare på ett barnsjukhus	Intervjuer baserade på modifierad "critical incident technique"
V	Empirisk kvantitativ studie	2 966 vårdbiträden och undersköterskor i hemvården i 15 kommuner	Skriftligt frågeformulär
VI	Empirisk kvantitativ studie	12 Medicinskt ansvariga sjuksköterskor i 12 kommuner, representerande 2 463 vårdbiträden och undersköterskor	Skriftligt frågeformulär

Delstudie I och II

Frågeställningar

Delstudie I: Har Socialstyrelsens förändrade tillsynspolicy påverkat rapporteringen av Lex Maria-ärenden till Socialstyrelsen och vilka ärenden har myndigheten överfört för prövning av disciplinär påföljd?

Delstudie II: Kan en teoretisk modell för analys av felhandlingar öka förståelsen för motiven att anmäla yrkesutövare till HSAN för disciplinär påföljd?

Metod

Delstudie I och II baseras på dokumentanalys (133) av rapporterade Lex Maria-ärenden från hälso- och sjukvården till Socialstyrelsen under åren 1989 respektive 1993. För båda delstudierna har ett särskilt urval gjorts för ärenden som överförts från Socialstyrelsen till HSAN för disciplinär påföljd. Inledningsvis granskades varje ärende ur fyra aspekter – anmälare, verksamhetstyp, ärendekategori samt eventuell vidareanmälan till HSAN. För dessa senare ärenden registrerades om individen som begått misstaget eller om den som varit ansvarig för verksamheten där misstaget skedde anmälts till HSAN. I analysfasen gjordes komprimerade beskrivningar av det återgivna händelseförloppet i respektive anmälan i syfte att göra materialet överskådligt beroende på det stora antalet ärenden. I delstudie II identifierades och analyserades den felhandling som föranlett en vidare anmälan till HSAN. Analysen utgick från Reasons förklaringsmodell (118) och baserades på den skriftliga beskrivning av händelseförloppet som återfanns i Socialstyrelsens beslut. Två huvudkategorier användes i analysen "oavsiktligt" respektive "avsiktligt agerande".

Resultat

Under perioden 1989–1993, dvs. före och efter Socialstyrelsens förändrade tillsynsorganisation, visar delstudien att det skedde en markant ökning av antalet rapporterade ärenden från hälso- och sjukvården till Socialstyrelsen. Ökningen förklaras delvis av det höga antalet ärenden från den kommunala hälso- och sjukvården. Även när dessa ärenden exkluderas från materialet kvarstod en nästan trefaldig ökning av rapporterade Lex Maria-ärenden under den period som studerats. Läkemedelsrelaterade ärenden ökade mest i rapporteringen. Under år 1989 rapporterades t.ex. 38 ärenden jämfört med 666 ärenden under år 1993. Av dessa hade 521 rapporterats från den kommunala hälso- och sjukvården. Totalt omfattade läkemedelsrelaterade ärenden 49 procent (n=666) av samtliga rapporterade ärenden under år 1993 mot 15 procent år 1989. Den uppföljande studien år 1998 (II) visade en viss nedgång i rapporteringsfrekvens från 1 348 ärenden år 1993 till 1 116 ärenden år 1998.

Lex Maria-ärenden till HSAN. Lex Maria-ärenden som anmäldes från Socialstyrelsen till HSAN för disciplinär åtgärd minskade från 35 procent år 1989 till 5 procent under år 1993 (I). Motsvarande resultat för år 1998 var 9 procent men med variationer mellan de regionala enheterna mellan 5 och 17 procent (II). Om ärenden från kommunal hälso- och sjukvård utesluts utgör andelen överförda ärenden till HSAN 11 procent år 1993, vilket innebär en minskning med 24 procent jämfört med år 1989. Både delstudie I och II visade

att det i så gott som samtliga fall var den individ som begått misstaget som också anmälts till HSAN. Den tydligaste förändringen i anmälningarna från Socialstyrelsen till HSAN noterades för läkemedelsrelaterade ärenden, vilka under år 1989 utgjorde 55 procent. Under år 1993 var motsvarande andel 17 procent trots att de fortfarande utgjorde den största ärendekategorin till Socialstyrelsen. År 1998 utgjorde läkemedelsärenden 37 procent av det totala antalet Lex Maria-anmälningar till HSAN.

Feltyper som motiverat en anmälan till HSAN. Analysen av de ärenden som Socialstyrelsen överfört till HSAN och som baserades på en kategorisering utifrån Reasons (118) feltyper visade att 85 procent (n=92) av de 109 individerna hade begått en handling som antingen kategoriserades som *uppmärksamhetsfel* eller *misstag*, undantaget misstag som kategoriserats som *överträdelse/nonchalans* (II). Andelen *uppmärksamhetsfel* uppgick till 26 procent av samtliga anmälda individer. De senare var främst relaterade till läkemedel och till förväxlingar. Totalt har 59 procent av individerna tillförts kategorin *misstag* (n=64). De händelser som i analysen tolkats som *överträdelse/nonchalans* uppgick till 16 procent av samtliga individer som anmälts av Socialstyrelsen till HSAN. I 10 av de 17 fallen hade den anmälda underlåtit att utföra relevanta åtgärder trots upprepade påpekande från annan personal. Studien visar att 85 procent av de yrkesutövare som anmälts för att ha brustit i sin yrkesutövning har handlat i "god tro", dvs. de har vidtagit en åtgärd i tron att den var korrekt. I ett antal händelser fanns brister som kan hänförs till systemnivå och som kan ha påverkat händelseförloppet. Oavsett bakomliggande orsaker till analyserade händelser tyder studiens resultat på att det antingen saknats barriärer eller att dessa inte varit tillräckligt effektiva för att förhindra uppkomsten av en patientskada.

Sammantaget visar delstudie I att hälso- och sjukvårdens rapportering till Socialstyrelsen enligt Lex Maria ökade markant efter förändrad organisation och handläggning av rapporterade Lex Maria-ärenden. Trots ökningen styrks antagandet om kraftig underrapportering. Studien visade dessutom en markant minskning av Lex Maria-ärenden som överförts från Socialstyrelsen till HSAN för disciplinär påföljd. Den modell som använts i delstudie II för att analysera Socialstyrelsens motiv för en disciplinär åtgärd kan i flertalet fall inte förklara motivet till en disciplinär påföljd utifrån dess individual- eller allmänpreventiva syfte. Delstudien visar att denna modell för klassificering av feltyper kan vara värdefull i en databas där informationen i aggregerad form kan indikera systembrister.

Delstudie III

Frågeställning

Har flygets metoder för riskhantering relevans för det förebyggande arbetet med patienternas säkerhet?

Metod

Tolv individuella intervjuer baserade på ett strategiskt urval (134) genomfördes med säkerhets- och kvalitetsansvariga inom civilflyget i Sverige och USA samt representanter för Statens Haverikommission och Luftfartsinspektionen, OPS-utvalget (tillsynsmyndigheten för SAS) och Federal Aviation Administration (FAA) i USA. En intervjuguide utarbetades som underlag för intervjuerna med följande frågeområden:

- myndighetsstyrning/lagstiftning/föreskrifter för säkerhetsarbetet
- organisering av säkerhetsarbetet
- system för riskinformation
- rapporteringskrav
- organisation för hantering och analys av riskinformation
- erfarenhetsåterföring.

Ovanstående frågeområden har genererats ur säkerhetslitteratur och genom intervjuer med säkerhetsforskare. Samtliga intervjuer i delstudien gavs karaktär av halvstrukturerat samtal (134). I samband med intervjuerna erhöles relevant skriftlig information. Intervjuerna spelades in på band och varierade mellan 35 och 90 minuter vardera. En fokusgruppsintervju genomfördes med sex företrädare och analytiker som arbetar med det amerikanska civilflygets program för säkerhetsrapportering, Aviation Safety Reporting Program. Intervjun koncentrerades på rapporteringssystemet Aviation Safety Reporting System (ASRS). Fokusgruppsintervjuns frågeområden gällde program för rapportering, analys och återföring av rapporterade händelser. Samtliga intervjuer har transkriberats i sin helhet. Efter intervjusammanställning och sammanställning av materialet från skriftliga dokument har det kommunicerats med informanterna i syfte att säkerställa att informationen uppfattats korrekt. I några fall har kompletterande frågor ställts via telefonintervjuer. I analysfasen systematiserades materialet från datainsamlingen i följande fyra huvudområden med hjälp av innehållsanalys (133):

- organisation av säkerhetsarbetet
- riskrapportering och riskanalyser
- arbetstidsbegränsning
- kunskapskontroller.

Resultat

En skillnad mellan flyget och hälso- och sjukvården är att det vid allvarliga incidenter inom flyget i Sverige skall tillsättas en statlig haverikommission (SFS 2001:877). Motsvarande krav saknas för svensk hälso- och sjukvård. Syftet med en haverikommission är att så långt möjligt klarlägga händelseförlopp och orsaker. Utredningen skall också ge underlag för beslut om åtgärder som har som mål att förebygga en upprepning av händelsen eller begränsa effekten av liknande händelser. Ett skäl till att Statens Haverikommission (SHK) upprättades var att man ville undvika jäv, dvs. att den myndighet som har ansvaret för tillsynen av säkerheten också svarar för utredningar av säkerheten, vilket skulle kunna innebära att myndigheten underlåter alltför sträng kritik mot verksamheten. För flyget finns också internationella riktlinjer för utredning av olyckor. Enligt dessa skall alla juridiska eller administrativa åtgärder som kan innebära klander eller straff separeras från en haveriutredning.

Delstudien har visat på några grundläggande skillnader mellan det svenska rapporteringssystemet Lex Maria och det amerikanska rapporteringssystemet ASRS. En viktig skillnad är att ASRS endast omfattar rapportering av incidenter där således ingen kommit till skada, medan rapportering enligt Lex Maria avser allvarlig skada eller risk för allvarlig skada. För händelser där en skada har inträffat i det amerikanska flyget sker rapportering till National Transport Safety Board (NTSB). Rapporteringen till ASRS är konfidentiell och den som rapporterar har immunitet om FAA av andra skäl utreder händelsen.

Erfarenhetsåterföring till berörda aktörer såsom tillverkare, flygbolag och myndigheter från rapporterade incidenter och analyser har hög prioritet inom ASRS. Informationen från ASRS finns tillgänglig "on-line" (135). Förutom snabb återföring av principiellt intressanta händelser, sker fördjupade analyser av materialet vilka läggs ut på nätet. Dessa utgör underlag för åtgärder på både myndighetsnivå och hos de olika aktörerna inom flyget. Vidare finns särskilda monitoreringssystem, "skvallersystem", i syfte att öka underlaget för det förebyggande arbetet. ASRS håller regelbundna telefonkonferenser med FAA om inträffade incidenter men FAA har endast tillgång till avidentifierat material.

Luftfartsmyndigheten i Sverige har särskilda bestämmelser för tjänstgöringsperiodens längd utöver arbetstidslagstiftningen (LFS 1980:6). Tjänstgöringsbegränsningen omfattar besättningsmedlem vid luftfart i regelbunden och icke regelbunden trafik med flygplan. För svenskt civilflyg finns ett poängberäkningssystem, vilket baseras på en planläggningsperiod på sju dagar. Även omfattningen av viloperioder är reglerade. Företagen har skyldighet att föra löpande journal över varje besättningsmedlems poängbelastning. Inom hälso- och sjukvården saknas särskilda bestämmelser som reglerar arbetstiden utöver de krav som ställs i arbetstidslagstiftningen.

Inom den civila luftfarten ställs krav på regelbundna kunskapskontroller, vilket för piloterna sker var sjätte månad. För piloterna omfattar testerna en teoretisk och en praktisk del med träning i simulator. Den teoretiska kontrollen omfattar förutom kontroll av regelverk också kunskapskontroll av flygplanets tekniska system, men framförallt bolagets operativa rutiner. Motsvarande krav saknas för svensk hälso- och sjukvårdspersonal. Legitimation är i Sverige livslång och utan krav på omprövning. Prövning av lämpligheten för legitimation sker i samband med ansökan om legitimation hos Socialstyrelsen som kontrollerar att de formella villkoren är uppfyllda. Den egentliga lämplighetsprövningen sker i tillsynen, dvs. efter det att legitimationen har utfärdats.

Sammanfattningsvis visar jämförelsen mellan flygets och hälso- och sjukvårdens säkerhetsrelaterade arbete att flygets arbete följer en delvis annan säkerhetstradition än den som återfinns i hälso- och sjukvården:

- säkerhetsarbetet har en tydligare förebyggande inriktning med en bredare ansats
- rapportering, analys och erfarenhetsåterföring ges hög prioritet
- återkommande kunskapskontroller krävs för att bibehålla certifikat
- tjänstgöringsperiodens längd begränsas
- oberoende utredning vid allvarliga incidenter eller olyckor är ett krav.

Studien visar att flygets metoder för riskhantering förtjänar uppmärksamhet i arbetet med att öka patientsäkerheten.

Delstudie IV

Frågeställning

Kan vårdpersonals uppfattning av potentiella riskfaktorer fördjupa kunskapen om bakomliggande orsaker till patientskador?

Metod

En modifierad form av "critical incident technique" (136) användes som intervju-metod för delstudie IV. Utgångspunkten för metoden är att den lokala kunskapen om risker i arbetet och hur dessa kan undvikas finns hos de människor som hanterar och är exponerade för dessa risker. Studien genomfördes med hjälp av individuella intervjuer vid akutmottagning, akutavdelning och röntgenavdelning på ett större barnsjukhus. Totalt intervjuades 26 informanter: 13 sjuksköterskor, 8 läkare, 3 undersköterskor, 1 läkarsekreterare och 1 barnsköterska. Inför intervjuerna genererades ett antal frågeområden från litteraturen relaterade till patientsäkerhet inom teknik, organisation, kommunikation och samverkan. Respondenterna ombads att utifrån sin yrkeserfarenhet medvetandegöra specifika situationer i vårdarbetet som de upplevt som kritiska och som direkt eller indirekt skulle kunna leda till att en patient kom till skada. Intervjuerna bandades och pågick var och en i cirka 60 minuter.

Det transkriberade materialet analyserades i två steg. Den inledande kodningen genomfördes med hjälp av ett datoriserat program för kvalitativ analys (Atlas ti). I nästa steg reducerades och sammanfattades data och koderna grupperades i övergripande kategorier, vilka så tydligt som möjligt beskrev "vad det handlade om". En huvudkategori fastställdes när det tydligt framgick att mönstret i intervjuerna kunde relateras till denna kategori. Denna del av analysen genomfördes manuellt. I varje fas av analysen lades vikt vid att verifiera att kategoriseringen stämde med den ursprungliga "meningen" i intervjumaterialet.

Resultat

Av intervjuerna framkom en komplex riskbild. Fem kvalitativt skilda kategorier som beskriver personalens upplevelser av potentiella riskfaktorer inom barnsjukvården identifierades:

- hög patienttillströmning
- bristande professionell erfarenhet
- bristande interprofessionell kommunikation och samverkan

- brister relaterade till den fysiska miljön
- brister relaterade till arbetstider.

Av intervjuerna framkom att personalen ibland tvingas ta vissa risker för att "systemet ska fungera". De hinna inte bedöma varje patient så som de skulle önska och är medvetna om att detta ibland innebär avkall på patientsäkerheten. Exempel på risker som direkt kan leda till en patientskada var ofullständiga och felaktiga ordinationer, bristande kontroll, felaktig prioritering, felaktiga beslut, förväxlingar, remissvar som inte granskas i tid och feltolkning av röntgenbilder.

Övervägande delen av de risker som identifierades var indirekta risker som tydde på att beslut fattade på övergripande organisatorisk nivå indirekt ansågs kunna hota patienternas säkerhet. Den indirekta risk som informanterna upplevde vara det största hotet mot barnens säkerhet var bristande erfarenhet hos personal, eftersom barnsjukvård ansågs kräva specifik kunskap om hur barn beter sig vid olika sjukdomstillstånd. Även beslut relaterade till projektering och design av den fysiska miljön och dimensionering av vårdplatser bedömdes indirekt leda till ökade risker. Andra exempel var bristande akututrymme på operationsavdelningen under dagtid eller platsbrist på vårdavdelningar som kan leda till att barnen läggs in på en avdelning som har en annan inriktning än vad barnets sjukdom kräver. Med utgångspunkt i Reasons "organizational accident model" (118) kan de indirekta risker som identifierats ses som latenta brister i organisationen. I samverkan med lokala riskhöjande faktorer kan de påverka händelseförlopp och leda till att en yrkesutövare begår ett misstag.

Sammantaget visar studien att förebyggande riskinventeringar kan utgöra ett värdefullt komplement till traditionell rapportering. En fördel med undersökningsmetoden är att riskerna identifieras innan de lett till någon olycka och att riskinformationen därför är aktuell sett ur ett förebyggande perspektiv. En annan fördel, i förhållande till traditionell rapportering som oftast bygger på redan inträffade händelser, är att intervjuerna inte har genomförts med anledning av att en patient har kommit till skada. Studien visar att personal som arbetar i frontlinjen och som möter patienter är en viktig resurs för att få fördjupad kunskap om faktorer som kan påverka patientsäkerheten.

Delstudie V

Frågeställning

Kan bristande teoretiska kunskaper om diabetes påverka det praktiska medicinska handlandet hos vårdbiträden och undersköterskor i äldreboenden på ett sådant sätt att vårdtagarnas säkerhet äventyras?

Metod

I delstudierna V och VI har sjukdomen diabetes använts som markör för att identifiera potentiella risker som skulle kunna utgöra ett hot mot vårdtagarnas säkerhet i äldreboenden. Delstudie V, och delvis också delstudie VI, baseras på bearbetning av material från en tidigare utvärderingsstudie genomförd på Socialstyrelsen (137). Det ursprungliga urvalet av de 15 kommuner som ingick i studien gjordes med syfte att utvärdera effekten av en försöksverksamhet, som innebar att fem kommuner under åren 1992–1997 övertog huvudmannaskapet för primärvården från landstingen.

Enkäten i delstudie V riktades till samtliga vårdbiträden och undersköterskor som arbetade inom äldreboenden i de valda kommunerna under förmiddagen den 15 januari 1997. Med hjälp av medicinskt ansvariga sjuksköterskor och arbetsledare distribuerades totalt 3 144 enkätformulär till respektive arbetsplatser i de 15 medverkande kommunerna. Formulären fylldes i och lämnades in under arbetspasset. Totalt besvarades enkäten av 2 966 individer, motsvarande en svarsfrekvens på 94 procent. Formuläret omfattade kunskapsfrågor om diabetes, samt frågor som berörde utbildning och fortbildning inom diabetesområdet. Efter sammanställning och bearbetning av samtliga svar i enkäten genomfördes en särskild riskanalys baserad på svaren på en fallbeskrivning som illustrerade symtom på en patient med lågt blodsocker. Felaktiga svar kategoriserades som "riskfylld åtgärd". Därefter genomfördes analyser av eventuella samband mellan kunskapsfrågorna och kategorin riskfylld åtgärd. Bivariata samband undersöktes först, därefter genomfördes multivariata regressionsanalyser där de variabler som blev statistiskt signifikanta i de bivariata analyserna togs in i den logistiska regressionsmodellen.

Resultat

Den logistiska regressionsanalysen visade att 15 procent av dem som angav fel svar på frågan om blodsockernivån vid en insulinkänning tillhörde kategorin riskfylld åtgärd jämfört med fem procent av dem som besvarade frågan korrekt

(OR 2,7). Resultaten visade också att en större andel vårdbiträden än undersköterskor valde svar som kategoriserades som "riskfylld åtgärd" (OR 1,6). Detsamma gällde de som arbetade i patientens ordinära boende. Även för dem som hade otillräcklig kunskap om orsakerna till en insulinreaktion visade resultaten signifikans för kategorin "riskfylld åtgärd". Av de undersköterskor och vårdbiträden som hade delegation på att ge insulin bedömde 78 procent att deras kunskaper om diabetes var otillräckliga. Sexton procent svarade att de fick återkommande utbildning inom området. Frågor relaterade till kontroll i samband med att de erhöll delegation visade att nio procent uppgav att de utfört ett skriftligt prov i samband med delegeringstillfället. På frågan om kontroll av praktiska färdigheter gjordes, såsom att ge injektioner svarade 81 procent ja. Femton procent uppgav att de kände sig osäkra i samband med insulingivning och 23 procent uppgav att de ibland känt sig tvingade att på ta sig arbetsuppgifter som de känt sig osäkra inför.

Sammanfattningsvis visade riskanalysen i delstudie V att bristande teoretiska kunskaper om diabetes ledde till ökad risk för att en "riskfylld åtgärd" skulle vidtas i mötet med en vårdtagare som hade tydliga tecken på lågt blodsocker. Resultatet antyder att kunskapsbristerna skulle kunna hänföras till brister på övergripande ledningsnivå.

Delstudie VI

Frågeställning

Kan undersköterskors eller vårdbiträdens kunskaper om diabetes relateras till medicinsk ansvarig sjuksköterskas uppfattning om sådana frågor som hon eller han har ansvar för eller bör ha inflytande över och som kan relateras till vårdtagarnas säkerhet?

Metod

Delstudie VI baseras dels på material från delstudie V, dels ett nytt frågeformulär riktat till de medicinskt ansvariga sjuksköterskorna i de 15 kommuner som ingick i delstudie V. Frågeformuläret distribuerades ett år efter det att den första studien genomförts. Beroende på att tre av de medicinskt ansvariga sjuksköterskorna ej var i tjänst då den föregående studien genomfördes uteslöts de från undersökningen. Denna studie baseras därför på 12 medicinskt ansvariga sjuksköterskor, vilka representerar 2 463 av de totalt 2 966 deltagande undersköterskorna och vårdbiträdena i delstudie V.

Frågeformuläret konstruerades utifrån ett antal huvudområden som bedömdes ligga inom medicinskt ansvarig sjuksköterskas ansvarsområde och ha relevans för patientsäkerhetsarbetet. Analysen genomfördes i tre steg. I steg 1 gjordes en poängberäkning för kunskapsnivån hos vårdbiträden och undersköterskor utifrån materialet i delstudie V och ett medelvärde fastställdes för respektive kommun. Poängberäkningen baserades på sju kunskapsfrågor om diabetes. Varje rätt svar gav 1 poäng och den totala poängen kunde därför anta värden mellan 0 och 7. I steg 2 bearbetades svaren från enkäten till medicinskt ansvariga sjuksköterskor. I steg 3 analyserades eventuella samband mellan medicinskt ansvariga sjuksköterskors enkätsvar och vårdbiträdenas och undersköterskornas kunskapspoäng i motsvarande kommun. De medicinskt ansvariga sjuksköterskornas svar utgjorde förklaringsvariabler och kunskapspoängen för respektive kommuns resultatvariabel. Eventuella samband testades med multipel linjär regressionsteknik. Alla förklaringsvariabler i de bivariata analyserna togs in i de multivariata analyserna. De variabler som minst bidrog till att förklara kunskapsnivån hos vårdbiträden och undersköterskor eliminerades stegvis tills enbart variabler med p -värde $< 0,05$ kvarstod. Alla test var tvåsidiga. Generellt accepterades p -värden $< 0,05$ som uttryck för statistisk signifikans. Mycket små p -värden har noterats som $p < 0,0001$.

Resultat

Resultaten i delstudie VI visade ett flertal statistiskt säkerställda samband som indirekt skulle kunna påverka den medicinska säkerheten hos vårdtagare med diabetes som har behov av hjälp med insulingivning. Nedan redovisas exempel över positiva och negativa samband mellan medicinskt ansvarig sjuksköterskas svar och kunskapspoäng hos undersköterskor och vårdbiträden.

Positiva samband (= hög kunskapspoäng):

- Mitt ledningsansvar för hälso- och sjukvården är tydligt.
- Sjuksköterskorna har en uttalad "pedagogisk" funktion inom äldre- och handikappomsorgen.
- I kommunen finns en "diabetessköterska" med uppgift att särskilt ansvara för "kunskapspridning" och samordning av diabetesvården.

Negativa samband (= låg kunskapspoäng):

- Sjuksköterskorna deltar i det dagliga direkta omvårdnadsarbetet.
- Vi har tillräckligt antal sjuksköterskor i kommunen.
- Uppgiften att ge insulin delegeras på grund av att vi har tillgång till undersköterskor med tillräcklig kompetens.
- Alla sjuksköterskor erbjuds återkommande utbildning om diabetes.

I sammanfattning visar studien statistiskt säkerställda samband mellan medicinskt ansvarig sjuksköterskas förhållningssätt till olika frågor med relevans för säkerheten och vårdbiträdens och undersköterskors kunskaper om diabetes. Trots att studien bygger på medicinskt ansvarig sjuksköterskas uppfattning om sin roll visar resultaten betydelsen av att identifiera latenta tillstånd i organisationen och sådana samband som tycks bidra positivt till ökad säkerhet för vårdtagarna.

Metodreflektioner

I detta avsnitt kommenteras några av de förutsättningar som gällt för de olika delstudierna samt vägval som gjorts. I delstudie I och II bygger materialet på indirekt information där beskrivningen av en inrapporterad händelse till tillsynsmyndigheten kan ha passerat ett flertal "händer" innan den slutligen beskrivs i beslutet, vilket kan påverka tillförlitligheten i data. Den individ som begått misstaget får sällan möjlighet att direkt kommunicera med myndigheten. Det innebär att ett händelseförlopp först skall dokumenteras skriftligt av den eller de som varit involverade i en händelse, vilket i sig kan innebära svårigheter och medföra att delar av det faktiska händelseförloppet inte blir korrekt beskrivet. En svaghet i delstudie II är att analysen endast genomförts av en av författarna. Analysmetoden har dock bedömts intressant utifrån dess möjlighet att indikera systembrister. Ett motiv till att enbart besluten och inte underliggande utredningsmaterial har använts i analysen är att besluten har bedömts vara en viktig informationskälla i det förebyggande arbetet. Det är beslutstexten som Socialstyrelsen återför till hälso- och sjukvården och som utgör underlag för registrering i Socialstyrelsens riskdatabas. Besluten är offentlig handling och därmed tillgängliga.

För att tillförsäkra att informationen i delstudie III har uppfattats korrekt har materialet efter sammanställning återförts till informanterna. För att undvika missförstånd i samband med intervjuerna på United Airlines (UA) i USA och

på NASA deltog en svensk pilot anställd på UA, som dessutom var examinator på den amerikanska luftfartsmyndigheten i USA, FAA.

Delstudie IV innebär att man i förväg identifierar brister som personalen upplever kan hota patienternas säkerhet. För att bedöma relevansen i de risker som framkom i riskinventeringen krävs en riskanalys, vilket inte har varit syftet med denna studie. Resultaten har emellertid stöd i säkerhetsforskningen, där latent svagheter bedöms vara viktiga faktorer i utvecklingen av ett händelseförlopp som leder till en olycka. För att metoden skall få positiva effekter på säkerheten utgör en riskinventering endast ett första steg. Studiens resultat styrks av händelser rapporterade till Socialstyrelsen där ett flertal av de riskfaktorer som identifierades i delstudien visat sig relevanta.

Valet av ett hypotetiskt fall som underlag för riskanalysen i delstudie V har gjorts utifrån att ett flertal liknande fall rapporterats till Socialstyrelsen. Fallet speglar därför en verklighetsnära situation. Bland de vårdbiträden och undersköterskor, som tillfördes kategorin "riskfylld åtgärd", som riskanalysen baserades på, ingick även de som inte besvarat frågan. Det baserades på en uppfattning att de som har delegation på att ge insulin bör kunna ta ställning till vilka åtgärder som är lämpliga att vidta. Inför konstruktionen av frågeformuläret till delstudie V fick ett antal vårdbiträden och undersköterskor med lång erfarenhet av arbete i äldreården i uppgift att delge sina erfarenheter av problem som de upplevde inom äldreården vilka kunde relateras till diabetes. Frågorna bedöms därför ha hög relevans. Den kunskapsbrist som upptäcktes genom delstudien understryks av att ett flertal liknande fall har rapporterats enligt Lex Maria. Resultaten av delstudien har föranlett åtgärder efter det att de medicinskt ansvariga sjuksköterskorna har tagit del av resultaten, vilket tyder på hög reliabilitet.

En av svagheter i delstudie VI är att sjuksköterskor inte har besvarat enkäten. I en mindre undersökning med identiska enkätfrågor medverkade förutom medicinskt ansvarig sjuksköterska, vårdbiträden och undersköterskor även sjuksköterskor (138). Sjuksköterskornas diabeteskunskap var bristfällig, vilket är allvarligt eftersom delegeringen till undersköterskor och vårdbiträden av rätten att ge insulin ges av denna yrkesgrupp. Det tyder på att den medicinskt ansvariga sjuksköterskans inflytande över patientsäkerhetsarbetet kan påverkas såväl positivt som negativt av sjuksköterskornas förhållningssätt till säkerhetsfrågorna. Tillförlitligheten i frågeinstrumentet för att mäta den medicinskt ansvariga sjuksköterskans betydelse för säkerhetsarbetet kan diskuteras. Vid tidpunkten för undersökningen bedömdes det dock relevant

att utgå från föreskriften om kvalitetssystem i hälso- och sjukvården. Efter det att delstudien genomfördes har instrument för att mäta säkerhetskulturen inom hälso- och sjukvården utvecklats (139–140).

DISKUSSION

Patientskador och rapporteringsbenägenhet

Svårigheter att få en väl fungerande skaderapportering är ett känt problem inom många verksamhetsområden även utanför hälso- och sjukvården (12, 88–92). En jämförelse med internationella studier (1–7) visar att den svenska hälso- och sjukvårdens rapportering enligt Lex Maria inte speglar omfattningen av antalet patienter som skadas i samband med vård och behandling (I–II). Eftersom Lex Maria avser all hälso- och sjukvård, inkluderat apotek, tandvård, öppenvård, larmcentraler och all privat vård torde underrapporteringen vara betydande. Ett verksamhetsområde där underrapportering troligen är omfattande är primärvården där endast 89 ärenden rapporterades under år 2004 (58). Liknande resultat har uppmärksammats i det engelska rapporteringssystemet National Reporting and Learning System (NRLS) där 0,5 % av 85 324 rapporterade händelser kom från "general practice" (141). Vid tidpunkten för mätningen hade endast 230 av National Health Service (NHS) 607 organisationer anslutits till NRLS.

Ett annat område med underrapportering är vårdrelaterade infektioner som enligt Lex Maria är rapporteringspliktiga men som av allt att döma rapporteras i ringa omfattning i förhållande till deras förekomst. Under en 10-årsperiod rapporterades endast ett 15-tal händelser, vilket kan jämföras med studier som har visat att omkring 10 procent av patienterna på svenska sjukhus behandlas med antibiotika för infektioner som de har fått under sin sjukhusvistelse. Enligt en beräkning av Socialstyrelsen skulle det enbart för den slutna vården innebära att 60 000 patienter drabbas årligen (35). En konsekvens av låg rapportering från hälso- och sjukvården till tillsynsmyndigheten är att återföringen av riskinformation till hälso- och sjukvården reduceras.

Ökningen av rapporterade Lex Maria-ärenden till Socialstyrelsen under perioden 1989 till 1993 (I) är intressant mot bakgrund av regionaliseringen av

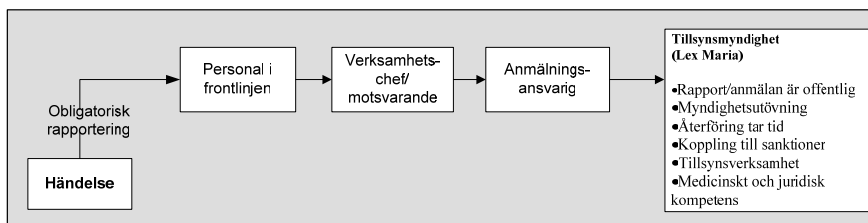
tillsynsverksamheten och de förändringar som genomfördes avseende hanteringen av rapporterade Lex Maria-ärenden. Den ökning som skedde under perioden 1989–1993 blev relativt kortvarig. En kontinuerlig minskning har skett från år 1995 då 1 418 ärenden rapporterades till år 2005 då 1 050 ärenden rapporterades. Att rapporteringsbenägenheten ökar om nyttan av rapporteringen tydliggörs har stöd i litteraturen. Studier som belyser personalens uppfattning av värdet av rapportering visade att faktorer som möjligheter att förbättra vården och möjligheter till ökat lärande genom att ta del av andras erfarenheter var viktiga incitament (12, 142–143).

Särskilda faktorer som påverkar rapporteringsbenägenheten

Föreskriftens utformning. För händelser inom hälso- och sjukvården som skall rapporteras till Socialstyrelsen finns restriktioner som kan medföra att viktig information om skademönster inte tydliggörs. Ett exempel i Lex Maria-föreskriften är att endast *allvarlig* skada eller risk för *allvarlig* skada skall rapporteras. Andra exempel på händelser som inte skall rapporteras är *komplikationer* och händelser som bedöms utgöra *normal risk*. Begreppen ger relativt stort utrymme för tolkningar. Behovet av tydlighet avseende vad som skall rapporteras har uppmärksammats i litteraturen (142, 144). Inom ASRS uppmuntras all rapportering och det är den som mottar informationen som "sällar" vilken information som bedöms vara relevant ur ett förebyggande perspektiv och som därmed ska analyseras och registreras i databasen (III). Reason (118) menar att såväl nära-misstag som incidenter är särskilt värdefulla därför att de ännu inte har lett till en allvarlig konsekvens. Stora volymer ger dessutom ökade möjligheter att söka orsaksmönster och upptäcka signaler om dolda brister i hälso- och sjukvårdens stödsystem (latenta tillstånd). Delstudierna V och VI, vilka utgick från informationen i Socialstyrelsens riskdatabas utgör ett sådant exempel. Ett flertal läkemedelshändelser relaterade till insulingivning fanns rapporterade och indikerade latenta tillstånd som skulle kunna inverka negativt på yrkesutövare i frontlinjen och leda till patientskador. Resultaten styrkte indikationerna. Sammantaget visar studien att Lex Maria-föreskriftens restriktioner får konsekvenser för det förebyggande säkerhetsarbetet.

Rapporteringsförfarande. Av resultaten framgår att en annan faktor som kan antas påverka antalet rapporterade händelser är rapporteringsförfarandet. I studien beskrivs det amerikanska civilflygets rapporteringssystem, där det är den individ som begått misstaget som själv rapporterar händelsen till dem som är ansvariga för rapporteringssystemet (III). En orsak till låg rapportering enligt Lex Maria kan vara att bedömningen av om en händelse bör rapporteras

vidare "uppåt" i systemet hanteras på flera nivåer. Det är den som har anmälningsansvaret till Socialstyrelsen som slutligen avgör om händelsen skall betraktas som ett Lex Maria-ärende och därmed rapporteras vidare. I det danska rapporteringssystemet rapporterar hälso- och sjukvårdspersonalen till Amtskommunen. Efter analys av händelsen överförs informationen avidentifierad till Sundhetsstyrelsen där den lagras i en nationell databas (145). Ytterligare en orsak till låg rapportering enligt Lex Maria kan vara kollegiala hänsynstaganden (146) eller att ledningen inte önskar ge händelsen offentlighet genom en anmälan, eftersom såväl anmälan som beslut är offentlig handling. En Lex Maria-anmälan medför ofta en stor press både för de individer som varit involverade i händelsen och för sjukhuset (eller motsvarande) där händelsen inträffat genom den publicitet dessa händelser många gånger får (102–105). I figur 6 illustreras rapporteringssystemet Lex Maria.



Figur 6. Förenklad figur av rapporteringssystemet Lex Maria.

Öppenhet. Patientens medverkan i arbetet med att göra vården säkrare uppmärksammas alltmer och allmänhetens rätt till information om patientskador är viktig och självklar (147). Frågan hur information om inträffade händelser skall kommuniceras är emellertid komplicerad från ett patientsäkerhetsperspektiv. Även om det endast är händelsen som anmäls i ett Lex Maria-ärende och utgör offentlig handling kan det framförallt på mindre sjukhus medföra att enskilda individer kan identifieras. Med syfte att förekomma pressen och nyhetsvärdet samt att öka öppenheten kring inträffade händelser har t.ex. Landstinget i Kalmar och Region Skåne börjat publicera Lex Maria-anmälningar på sina respektive webbplatser (148–149).

Ofta är det den enskilde individens tillkortakommanden som uppmärksammas i massmedia. Ett exempel är då 80 ärenden som beslutats i HSAN under år 2000 gavs stort utrymme i kvällspress (150), där såväl namn, ålder, klinik,

sjukhus och vad som skett redovisades. Publiceringen medförde en omfattande debatt huruvida det var rimligt att "hänga ut" enskilda läkare (151). Ett annat exempel utgör en uppmärksammas händelse i Kalmar (152), där pressen publicerade händelsen i lokaltidningen innan sjukhuset gjort någon Lex Maria-anmälan. Från ett säkerhetsperspektiv kan publicering av rapporterade händelser, och särskilt personuppgifter, skada trovärdigheten med rapporteringssystemet och därmed indirekt påverka säkerheten negativt genom minskad benägenhet att rapportera. Ett viktigt krav i samband med att ASRS infördes var att rapportören garanterades anonymitet (III).

Frågan huruvida rapportering bör vara frivillig eller obligatorisk diskuteras i flera länder. All rapportering är emellertid beroende av rapportörens vilja att rapportera och rapporteringssystem mäter därmed endast benägenheten att rapportera (89). Några av de grundläggande kriterierna när det amerikanska flygets rapporteringssystem ASRS bildades 1975 var rapportörens tillit till och nytta av systemet. ASRS bygger på frivillighet och ger samtidigt incitament för rapportering genom immunitet (III) (153). Rapporteringssystemet har blivit förebild för ett flertal rapporteringssystem runt om i världen. Ett exempel är det engelska NRLS (141). Ett annat exempel är Nederländerna, som förutom obligatorisk rapportering till tillsynsmyndigheten, har ett frivilligt rapporteringssystem där rapportering kan ske anonymt. Det obligatoriska rapporteringssystemet har en betydande underrapportering (154). Ytterligare ett exempel på ett frivilligt rapporteringssystem där rapportering sker anonymt är Australian Incident Monitoring System (AIMS) (155). Detsamma gäller Veteran health Administrations (VA) rapporteringssystem i USA (156). En orsak till att rapporteringsfrekvens ofta är hög i frivilliga rapporteringssystem kan vara att dessa inte har koppling till myndighetsutövning. Ett viktigt krav från piloterna vid tillkomsten av ASRS var total frihet av insyn från myndigheten. Studier har visat att tillit till rapporteringssystemet är en viktig faktor för att nå en hög rapportering (143).

Sanktioner och rapporteringsbenägenhet. Resultaten i delstudie II visade att samtliga individer som anmälts till HSAN var de individer som begått den handling som ledde till skadan, dvs. de individer som befann sig i frontlinjen. Resultaten visade också att övervägande delen (85 %) av dem som rapporterats vidare till HSAN hade begått handlingar där yrkesutövaren handlat i tron att åtgärden var korrekt. En norsk studie om administrativa reaktioner visade att hälso- och sjukvårdspersonalen upplevde en "advarsel" (varning) som djupt orättfärdig (157). Det orättfärdiga i att individen "straffas" trots tydliga brister i det omgivande systemet framkom även i delstudie IV. Det råder stor enighet

bland säkerhetsforskare att ett av de största hindren för rapportering är risken för sanktioner (12, 48, 74, 92, 118–119). Det samband som finns mellan Lex Maria-anmälان och HSAN har också varit föremål för debatt under många år (97–100, 158–159).

Konsekvenserna av att sanktionen riktas mot individen kan diskuteras utifrån *accident organizational model* där bakomliggande faktorer på systemnivå har avgörande betydelse för uppkomsten av en olycka. Sannolikheten för att två identiska olyckor ska inträffa är mycket låg eftersom mönstret av latent svagheter på systemnivå kontinuerligt förändras (118). Utifrån rådande syn inom säkerhetsforskningen är det i de flesta fall svårt att förklara såväl det individual- som allmänpreventiva syftet med en disciplinär åtgärd (I, II). Den preventiva effekten av en anmälan till HSAN är därför svår att förklara (12, 42, 48, 118–121).

I delstudie III framkom att en av de viktigaste framgångsfaktorerna för ASRS bedömdes vara rapportörens immunitet. FAA har valt att underlåta bestraffning i utbyte mot information om riskhändelser. Principen om "transactional immunity" representerar en ömsesidig balans mellan systemet och individen som även är reglerad i lagstiftningen (153). I Danmark har i en särskild lag fastställts att rapportören inte skall kunna åläggas disciplinära påföljder till följd av rapporteringen (160). Lagen trädde i kraft hösten 2003. Under perioden januari till oktober 2005, hade 6 415 "utsläppta händelser" rapporterats till Dansk Patient-Sikkerheds-Database. Av dessa hade under motsvarande period 4 983 rapporter skickats vidare till Sundhedsstyrelsen (145). Även det engelska NRLS är ett ickebesträffande (non-punitive) rapporteringssystem. Under perioden november 2003 till mars 2005 rapporterades 85 342 incidenter, varav 68 procent ej ledde till skada för patienten. Cirka en av hundra ledde till svåra skador eller till att patienten avled (141). Erfarenheter från rapporteringssystem kopplade till sanktioner tyder på att dessa medför underrapportering. Diskussionen om disciplinära åtgärders påverkan på det förebyggande säkerhetsarbetet kan utifrån den enskilde patientens perspektiv tyckas felaktigt. Dessa frågor diskuteras emellertid i denna studie inte med utgångspunkt från den enskilde patienten.

Rapportering som källa till kvalitetsförbättring

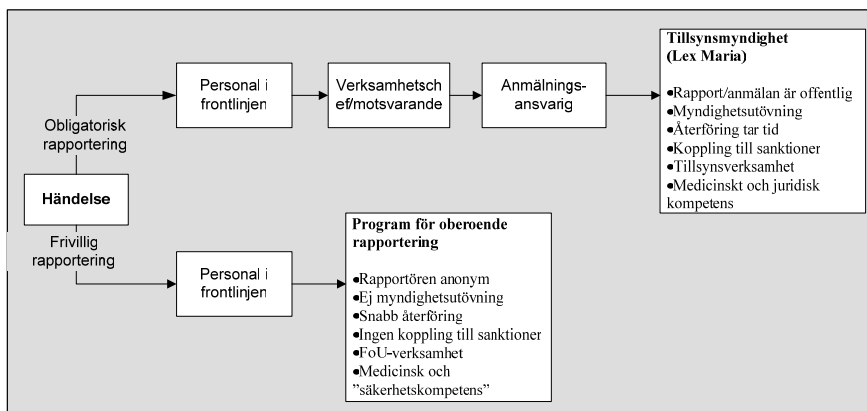
Rapportering av incidenter och patientskador har inget värde i sig om inte informationen leder till åtgärder som påverkar säkerheten. En viktig föreskrift

för hälso- och sjukvårdens arbete med patientsäkerhet är kvalitetsföreskriften. De krav som ställs i denna är viktiga parametrar i en analys av en inträffad händelse och kan ge värdefulla indikatorer om brister i verksamheten. En reflektion vid analysen av de händelser som anmälts till HSN är att de i liten omfattning relaterar till kraven på verksamheten så som de var formulerade i kvalitetssystemföreskriften (SOSFS 1996:24, nuvarande föreskrift SOSFS 2002:4). Utifrån strukturen på Lex Maria-besluten är det svårt att bedöma om och hur bakomliggande faktorer påverkat händelseförloppet. Utformningen av besluten påverkar kategoriseringen i riskdatabasen och får därmed även konsekvenser för återföring av riskinformation från tillsynsmyndigheten. Sammantaget visar studien på en förbättringspotential avseende harmoniseringen mellan Lex Maria-beslutens utformning och kraven i kvalitetssystemföreskriften (I, II). Harmoniseringen har att göra med möjligheten att söka orsaksmönster avseende bakomliggande brister.

Studien visar även att klassificering av feltyper på individnivå kan tillföra värdefull information i aggregerad form och indikera brister på systemnivå (II). Ett exempel hur en sådan kategorisering kan ske har utformats vid Eindhoven University of Technology (132, 161). Ett annat är klassifikationssystemet i det australiensiska Australian Incidents Monitoring System (AIMS) (155) som är baserat på Generic Reference Model (GRM) utvecklad av Reason (69). Systemet anses vara ett av de mest välutvecklade inom området (154). Betydelsen av att klassificering baseras på vetenskaplig grund där både individ- och systemrelaterade faktorer beaktas uppmärksammas i flera studier (162–164).

Hälso- och sjukvården blir alltmer internationaliserad och problemen avseende patientsäkerhet är ofta likartade. Det finns därför skäl att uppmärksamma behov av omvärldsbevakning och utformning av strategier för metodutveckling av säkerhetsrelaterade frågor. WHO:s Alliance for Patient Safety är ett initiativ i riktning mot ett ökat lärande över nationsgränser (165). Ett omfattande förslag till gemensamma riktlinjer för "Reporting and Learning system" har utarbetats med syfte att dela erfarenheter från rapporterade händelser världen över (154). Förebild har varit flygets internationella rapporteringssystem och dess system för erfarenhetsåterföring. Ett annat exempel där behovet av omvärldsbevakning uppmärksammas är National Patient Safety Observatory i England som tillkommit bl.a. för att öka lärandet från det engelska rapporteringssystemet NPSA (141).

Ur delstudie I-III framträder en alternativ modell för rapportering och prevention med syfte att förbättra lärandet av inträffade händelser. I figur 7 illustreras en sådan modell där nuvarande obligatoriska rapportering kompletterats med en frivillig rapporteringskanal. I motsats till Lex Maria utgör ett programarbete ingen myndighetsutövning, vilket möjliggör snabb återföring av rapporterade händelser. En annan skillnad är att programverksamheten ges en renodlad preventiv funktion och således saknar koppling till sanktioner. Kompetensen kännetecknas av både medicinsk kompetens och "säkerhetskompetens". Genom FoU-resurser ges ökade möjligheter till fördjupad analys av riskområden.



Figur 7. Alternativ modell för rapportering av patientsäkerhetsrelaterad information inom svensk hälso- och sjukvård.

Prevention

Resurser läggs på tillskapandet av riskdatabaser runt om i landet i både kommuner och landsting. Det kan finnas en risk att alltför stor uppmärksamhet riktas mot rapporteringsfrekvensen. En brist med ovan nämnda databaser är att informationen många gånger inte är anpassad till ett förebyggande säkerhetsarbete beroende på otillräcklig analys av händelsen (89).

Händelseanalyser

Studien ger underlag för slutsatsen att grundläggande för värdet av en "riskdatabas" är kvaliteten på den information som registreras. I detta avseende har analysen av händelsen avgörande betydelse (90, 129). För att syftet med en analys skall uppnås krävs "säkerhetskompetens" samt metodkunskap att genomföra själva analysen. Risker för att analysen dels inte blir tillräckligt djupgående, dels att det sker en förenkling av händelseförloppet, s.k. hindsight bias, är uppenbar vid bristande teoretiska kunskaper inom säkerhetsområdet (118–119, 129). Inom ett flertal länder har både nationella och lokala initiativ tagits för att öka kunskapen hos hälso- och sjukvårdspersonalen om analysmetoder om varför patientskador inträffar. I Sverige har behovet av utbildning uppmärksamats och sedan våren 2005 finns ett utbildningsmaterial inom patientsäkerhetsområdet (166).

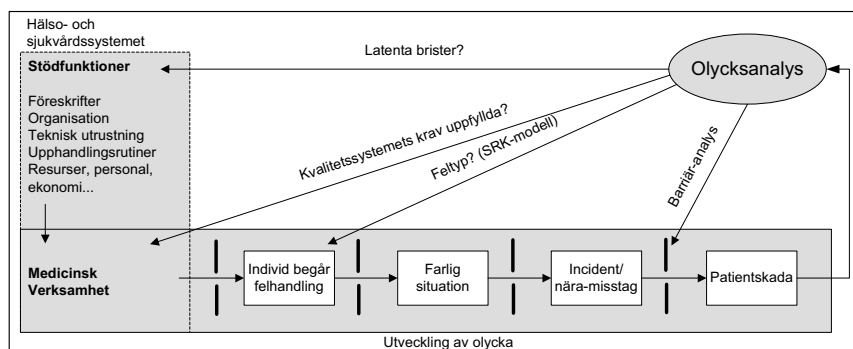
Begreppen inom säkerhetsområdet är delvis otydliga. T.ex. används begreppen olycksanalys (accident analysis), riskanalys (risk analysis) och säkerhetsanalys (safety analysis) synonymt delvis beroende på verksamhet. Harms-Ringdahl redogör i en översiktsartikel för begreppen och dess användningsområden (167). Behovet av en gemensam taxonomi för patientsäkerhetsområdet har bl.a. uppmärksamats av WHO:s World Alliance for Safety (154). I denna studie används begreppet *händelseanalys* för analyser av olyckor, händelser eller närmisstag/tillbud medan begreppet *säkerhetsanalys* används för explicit preventiva analyser för att identifiera risker i verksamheten.

Identifiering av barriärer

Analysen av rapporterade händelser i delstudie I och II tydliggjorde hur mänskliga tillkortakommanden, i kombination med avsaknad av barriärer, i vissa fall ledde till allvarliga konsekvenser. Studien har även uppmärksammat vissa svagheter i immateriella barriärer på nationell nivå. Ett exempel är att det saknas krav på kontinuerliga kunskapskontroller för personal inom svensk hälso- och sjukvård. Ytterligare ett exempel är att det hittills saknats begränsningar av arbetspassets längd inom hälso- och sjukvården. År 2007 införs EU:s arbetstidsdirektiv (168), vilket innebär reglering av arbetstidens längd. Ett annat exempel på svagheter i en barriär var otydliga doseringsanvisningar i FASS, vilket uppmärksammades i samband med analys av en rapporterad händelse där felaktig styrka av ett läkemedel ordinerats. Delstudierna IV–VI har visat att latenta tillstånd i hälso- och sjukvårdens stödsystem kan bidra till ökad risk för patientskador. Att människor begår fel är inte möjligt att förhindra och latenta tillstånd i det omgivande systemet som kan komma att påverka personalen i frontlinjen negativt kommer alltid att

finnas. Inom High Reliability Organizations (HRO), verksamheter med höga krav på säkerhet, förväntas att fel skall inträffa och verksamheten är därför förberedd på att klara mänskliga felhandlingar (126). Studien visar att barriärtänkandet har relevans för hälso- och sjukvården även på nationell nivå. Systemet måste utformas på ett sådant sätt att det medger och om möjligt förlåter mänskliga misstag eller mildrar dess konsekvenser (123). Inom säkerhetsforskningen har sökandet efter såväl systembrister, brister på individnivå som brustna eller obefintliga barriärer hög prioritet (116, 127, 129).

Delstudierna IV-VI har gett underlag till en modell för händelseanalys som fokuserar ett individ- och systemperspektiv. Klassificering av information från en inträffad händelse är betydelsefullt för tolkningen av informationen (48, 119). I modellen analyseras både hälso- och sjukvårdens stödfunktioner (latenta tillstånd) och den medicinska verksamheten med utgångspunkt i bl.a. föreskriften om ledningssystem för kvalitet och patientsäkerhet (SOSFS 2005:12). Även analys av feltyper och behovet av barriäranalys uppmärksammas. I figur 8 illustreras en modell för händelseanalys inom hälso- och sjukvården.



Figur 8. Händelseanalys med individ- och systemperspektiv.

Alternativa källor till rapportering

Ett effektivt förebyggande arbete tar i anspråk alla de källor till information om verksamhetens risker som finns att tillgå. I Sverige fanns år 2005 sammantaget cirka 200 000 patientskador registrerade i databaserna på Socialstyrelsen, LÖF och HSAN. Därtill finns lokala rapporteringssystem. Rapportering ger

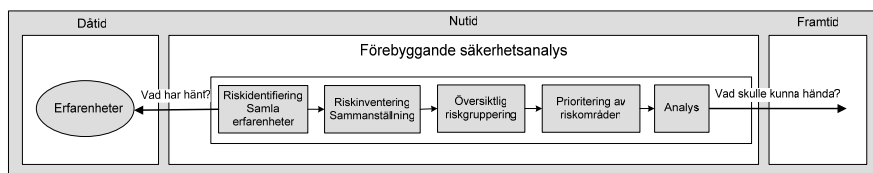
emellertid en otillräcklig bild av vad som kan leda till patientskador och informationen behöver kompletteras med andra källor. Förutom omfattande internationella databaser utvecklade inom evidensbaserad medicin (169) finns det i Sverige en unik källa för jämförande studier i de nationella kvalitetsregistren (108). Ovanstående informationskällor är ett viktigt "fönster" mot hälso- och sjukvårdens risker och kan ge indikationer om områden för vidare analys. Utvecklingen inom IT-området medför ökade möjligheter att snabbare spåra nya risker i hälso- och sjukvården jämfört med t.ex. manuella journalgranskningar (170).

Förebyggande säkerhetsanalyser

Föreskriften om kvalitetssystem ställer krav på att det finns metoder för att identifiera, analysera och bedöma riskerna i verksamheten, att åtgärda dess orsaker samt att göra en särskild riskbedömning vid väsentliga förändringar i verksamheten. Delstudie IV visar att yrkesutövare i frontlinjen utgör en viktig informationskälla om verksamhetens risker och att systematiserade riskinventeringar kan utgöra ett värdefullt komplement till traditionell avvikelserapportering. Riskerna som identifierades i delstudie IV kategoriserades till övervägande delen som latenta tillstånd i verksamhetens stödssystem. Exempel var hög arbetsbelastning, hög personalrörlighet samt bristande erfarenhet. Resultaten har stöd i en studie där 48 kirurger på tre sjukhus i Massachusetts intervjuades med critical incidentmetoden (171). Studien visade att bristande erfarenhet/kompetens, bristande kommunikation samt hög arbetsbelastning var de tre vanligaste bidragande faktorerna till allvarliga incidenter. Intervjumetoden i delstudie IV, Critical Incident Technique (CIT), som utvecklades under andra världskriget (136), har visat sig vara värdefull för att få kännedom om verksamhetens risker (27, 172). Sammantaget visade delstudierna IV–VI brister på olika nivåer i hälso- och sjukvårdens olika stödssystem.

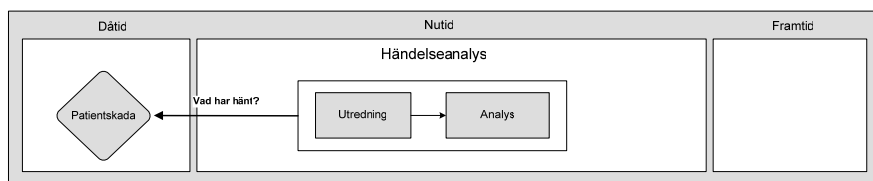
Utifrån delstudie IV har den modell för säkerhetsanalys konstruerats som visas i figur 8. Med hjälp av personalens samlade erfarenheter möjliggörs identifiering av verksamhetens risker. Med denna som grund sammanställs uppfattade risker vilka utgår från personalens erfarenheter av riskfyllda situationer. Därefter sker en översiktlig riskgruppering vilken mynnar ut i prioritering av riskområden. De prioriterade riskområdena ligger sedan till grund för beslut om detaljerad riskanalys. I arbetsprocessen visar det sig viktigt att både dokumentera den översiktliga riskgrupperingen och de riskområden som bör prioriteras för vidare riskanalys. Även icke-prioriterade risker bör dokumenteras eftersom de utgör ett viktigt instrument i

verksamhetens uppföljning och kvalitetsarbete. I händelse av en inträffad skada kan de icke-prioriterade riskerna ge värdefull information för omprövning av riskområden för riskanalys. Prioritering av riskområden och resultaten av detaljerade riskanalyser är frågor för systemets ledning. Sammantaget visar studien att utöver den riskinformation som erhålls genom rapportering är säkerhetsanalyser ett viktigt styrinstrument för säkerhetsarbetet (IV–VI). I figur 9 illustreras modellen för säkerhetsanalys.



Figur 9. Modell för säkerhetsanalys.

Den principiella skillnaden mellan en säkerhetsanalys och en händelseanalys är att den senare i efterhand söker identifiera faktorer som kan ha påverkat ett visst händelseförlopp, medan en säkerhetsanalys genomförs i ett preventivt syfte. Resultatet av en händelseanalys är däremot framåtsyftande i så motto att den syftar till att förbättra säkerheten. I figur 10 illustreras principen för händelseanalys.



Figur 10. Principen för händelseanalys.

Behovet av förebyggande säkerhetsanalyser illustreras av en studie som Apoteket AB genomfört i Region Skåne. Studien visade 147 felaktiga recept under en 2-månadersperiod (174). Vid analys av orsakerna visade det sig att fönstret i datorn inte stängts till föregående patient när ett nytt recept skulle

utfärdas. I Landstinget Östergötland genomfördes en riskinventering innan ett datoriserat beslutsstödsystem för läkemedel skulle införas (173). Ett stort antal risker identifierades som kunde hänföras till MTO-området. En av de risker som identifierades var att "fel patient" kunde visas på datorskärmen. Ovanstående utgör exempel på ett latent tillstånd i ett av hälso- och sjukvårdens stödsystem (the blunt end), som vid t.ex. bristande uppmärksamhet hos personal i frontlinjen (the sharp end) kan medföra att patient kommer till skada. Exemplet illustrerar hur tekniska system som bl.a. tillkommit för att öka säkerheten också kan öka riskerna. Ett antal metoder för förebyggande säkerhetsanalyser har utvecklats för att identifiera risker i verksamheten där var och en har såväl styrkor som svagheter (167, 175).

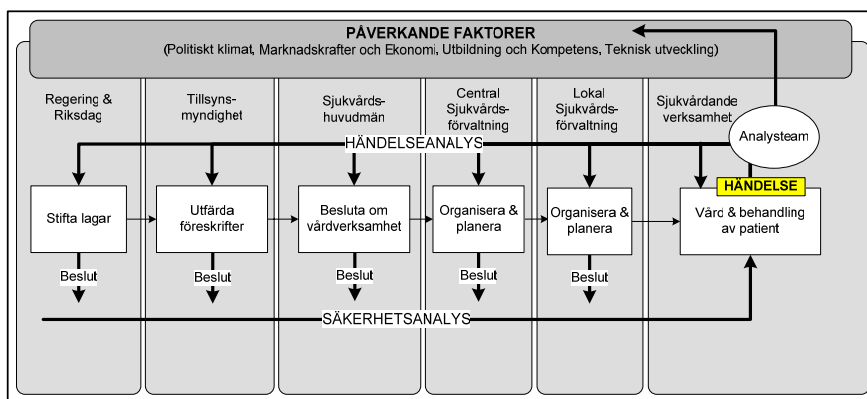
Säkerhetskultur

Studien visar att ledningens attityder och förhållningssätt till säkerhetsrelaterade frågor indirekt kan påverka säkerheten (V, VI). Frågor relaterade till området säkerhetskultur har under lång tid uppmärksammas både inom flyget och inom kärnkraftsindustrin. Dessa frågor har under senare år allt oftare kommit att diskuteras även inom hälso- och sjukvården (139–140). Studier inom andra verksamheter med höga krav på säkerhet uppmärksammar särskilt ledningens betydelse i säkerhetsarbetet (121, 176). En forskningsöversikt över kvalitet och säkerhet visar att de mest betydelsefulla egenskaperna för ett effektivt ledarskap var tydliga visioner, fasta värderingar, tydliga mål och personalens delaktighet i dessa (177). I en litteraturöversikt över begreppet säkerhetskultur sammanfattar Rollenhagen (178) att det verkar

"...rimligt att tro att välgrundad kunskap om risker har en positiv inverkan på säkerheten och av detta följer att institutionella arrangemang som stödjer sådan kunskap rimligtvis också borde vara positivt för säkerheten ..." (178, sid. 295).

SLUTSATSER

Studien visar att en ändrad tillsynsstrategi ledde till en ökad rapporteringsfrekvens från hälso- och sjukvården. I förhållande till antalet patientkontakter inom hälso- och sjukvården är andelen patienter som kommer till skada lågt, däremot är antalet drabbade betydande. Av studien framgår att skade- och incidensrapportering ger otillräcklig information för förebyggande säkerhetsarbete. Denna behöver kompletteras med information från andra källor. Studien har uppmärksammat betydelsen av att information om verksamhetens risker kommuniceras till olika nivåer i hälso- och sjukvårdssystemet. I studien har ett antal metoder och modeller från säkerhetsforskningen tillämpats och anpassats till hälso- och sjukvården med inspiration från andra verksamhetsområden. Studien visar på behovet av ökad uppmärksamhet mot hälso- och sjukvårdens stödfunktioner och systemutformarnas ansvar för patientsäkerheten. En generell modell för händelse- och säkerhetsanalys som inkluderar hälso- och sjukvårdens stödfunktioner på olika nivåer redovisas i figur 11.



Figur 11. Generell modell för händelse- och säkerhetsanalys inom hälso- och sjukvården.

Frågorna om disciplinära åtgärder har uppmärksamrats utifrån dess tänkbara effekter på patientsäkerheten. Litteraturen visar att disciplinära åtgärder påverkar säkerheten negativt och kan utgöra ett hinder i det förebyggande

arbetet. Studien visar att det i flertalet fall är svårt att förklara det preventiva syftet med disciplinära åtgärder mot hälso- och sjukvårdspersonal. En strategisk fråga som studien väcker handlar om svårigheten att förena preventiva och repressiva uppgifter i ett och samma uppdrag. Strukturen på hur säkerhetsfrågor hanteras i Sverige, med bland annat en särskild ansvarsnämnd för hälso- och sjukvården och en patientskadeförsäkring, har många fördelar och har också blivit föremål för intresse från andra länder. Studien ger dock belägg för att det utifrån ett säkerhetsperspektiv torde vara svårt att förena den övervakande myndighetsfunktionen med ett offensivt förebyggande säkerhetsarbete.

Studien antyder att frågor som omvärldsbevakning, strategier för riskinformation, frivillig rapportering av risker utan koppling till sanktioner och goda exempel på förebyggande insatser är en väsentlig del av det säkerhetsförebyggande arbetet. Detsamma gäller djupanalyser och metodutveckling inom området och initierandet av FoU-frågor som stöd till hälso- och sjukvården i dess utvecklingsarbete inom säkerhetsområdet. Inom ramen för nuvarande struktur har studien genererat en alternativ modell för rapportering av patientsäkerhetsrelaterad information inklusive kanal för frivillig rapportering och prevention. I denna studie har flygets säkerhetsrelaterade arbete uppmärksamats. Trots betydande skillnader mellan flyg och hälso- och sjukvård är de vetenskapliga grunderna för säkerhetsarbete desamma.

Studien visar att yrkesutövare som befinner sig i frontlinjen och möter den enskilde vårdtagaren är särskilt sårbara när hälso- och sjukvårdens stödsystem uppvisar brister. Ett tydligare barriärtänkande och en ökad uppmärksamhet på hur stödsystemen påverkar yrkesutövarna i frontlinjen kan öka förutsättningarna för en vård kännetecknad av hög säkerhet.

Fortsatt forskning

Fortsatt forskning om förebyggande säkerhetsarbete inom hälso- och sjukvården och vad detta innebär för patienten, vårdens olika yrkesgrupper och samhällsekonomin är angelägen. Följande forskningsområden har identifierats för fortsatt forskning:

- *Tillsynsstrategier.* Effekter av myndigheters tillsynsstrategier för patientsäkerheten.

- *Styrinstrument.* Analys av incitament och styrinstrument för patientsäkerhetsarbetet.
- *Beslutsfattande.* Hur beslut på olika nivåer påverkar hälso- och sjukvårdspersonalen som arbetar i frontlinjen.
- *Kommunikationsstrategier.* Hur risk/säkerhetsinformation kan anpassas till olika mottagare i hälso- och sjukvårdssystemet.
- *Säkerhetskultur.* Ledarskapets roll för utvecklandet av en god säkerhetskultur
- *Patienternas delaktighet.* Hur patienter kan göras delaktiga i säkerhetsarbetet.
- *Disciplinära påföljder.* Effekter av disciplinära påföljder för såväl enskilda yrkesutövare och berörd verksamhet.

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Det var på Socialstyrelsen i Örebro mitt engagemang för patientsäkerhetsfrågor började. Jag vill särskilt nämna *Bengt Wadman*. Det var med Bengts stöd som vi redan 1991 påbörjade ett nydanande arbete inom patientsäkerhetsområdet. Det var också Bengt som skrev RiskRonden – ofta med underfundiga och slagfärdiga rubriker. Hösten 1992 arrangerade vi i Örebro den första MTO-utbildningen inom svensk hälso- och sjukvård med *Jean-Pierre Bento* som kursledare. Även *Carl Rollenhagen* var engagerad i våra utbildningsaktiviteter. Stort tack till er båda för de nya perspektiv ni tillförde. Nu är tiden mogen för den förändring vi försökte genomföra då.

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Kärnkraftsinspektion, *Krister Egnér*, chef för säkerhet och miljö vid kärnkraftsverket i Ringhals, *Hans Kjäll*, flygsäkerhetsanalytiker på Luftfartsinspektion, *Uno Andersson* vid Upplands flygflottilj, *Linda Halvorsen* och *Olaf Thuestad* båda vid Oljedirektoratet i Stavanger. Jag vill också tacka *Carin Sundström-Frisk*, *Lena Kecklund*, *Erik Hollnagel* och *Lars Harms-Ringdahl* – samtliga säkerhetsforskare.

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De som ekonomiskt har möjliggjort avhandlingsarbetet är *Socialstyrelsen*, *Landstingsförbundet* (numera Sveriges Kommuner och Landsting), dåvarande *SPRI*, *Diabetesförbundet* och *Institutet för kvalitetsutveckling (SIQ)* – ett stort tack till er alla.

Till sist – *Jenny och Sofie* med familjer – nu lovar jag att inte alltid vara upptagen med mina papper...

Eskilstuna i mars 2006

Synnöve Ödegård

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FROM PUNISHMENT TO PREVENTION? Medical Errors Reported in Sweden in 1989 and 1993

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ABSTRACT

This study describes the Swedish self-reporting system for serious injuries caused by medical treatment, how the authorities handle cases reported by health care providers, and how this influences the willingness to report medical errors. The focus shifted from punishment to prevention when the state authority was reorganised in 1991. The present study was performed in order to identify whether there was a change in reporting medical errors between 1989 and 1993. There was a great increase in the number of reported cases, and the manner of handling *lex Maria* changed during that period. Cases forwarded for disciplinary action decreased from 35 to 5% of reported cases. There was also a change in the categories of personnel reported, with an increase for medical doctors and a decrease for nurses. Employees with organisational responsibility were not reported to a greater extent than earlier. One of the major problems with the Swedish *lex Maria* system still remains, since the National Board of Health and Welfare retains the duty to report to the Medical Responsibility Board. The question can be posed as to whether the present self-reporting system, which is run by a state authority with the duty to forward reports for disciplinary action, really contributes to improved patient safety.

INTRODUCTION

This study describes how Swedish authorities handle medical errors reported by health care providers, and also describes effects on the willingness to report medical errors. The Swedish self-reporting system for medical errors focuses on serious injuries caused by treatment in the health care sector and has its origin in an incident that occurred in 1936 at the Maria Hospital in Stockholm (Ödegård and Löfroth, 1996). Four patients died following injection of mercuric oxycyanide instead of a local anesthetic. The first law in 1937 focused on disciplinary action, assigning the duty to report patient injuries to both the National Board of Health and Welfare (NBHW) and the police. The regulation (called *lex Maria*) has been changed over the past 60 years, as has the manner in which the NBHW handles *lex Maria* cases. The focus has changed from having a disciplinary aim, where the issue was to determine guilt, to the aim of prevention. In connection with a reorganization of the NBHW in 1991, a variety of measures were adopted in order to widen the scope of prevention in the area of patient injuries caused by medical treatment. Extensive information was distributed to health care personnel in order to achieve a better understanding of the importance of reporting medical errors.

In this report the phrase "medical error" is used, but it is important to be aware of the fact that a reported *lex Maria* case does not necessarily have to involve an error. It can involve an injury that was impossible to avoid. Every serious patient injury, or even the risk of serious injury, caused by medical treatment should be defined as a *lex Maria* case.

BACKGROUND

There are several reasons for examining medical errors in the health care sector. One of the most important issues is to obtain information about primary causes in order to develop activities that can prevent the recurrence of similar mistakes (Vincent, Audley and Ennis, 1993). By their very nature, medical errors are costly in both human and financial terms. However, some obstacles exist with respect to reporting medical errors. One is the medical culture, where “error-free practice” is the aim, and others are the fear of litigation and the lack of definitions concerning the scope and nature of the problem (Leape, 1994). An additional reason is that these events are not only traumatic for the patients and their relatives, but also for the health care staff who have been involved in the events. Anger, distress, and feeling personally attacked are common responses to litigation (Bark et al., 1997).

Reducing the number of medical errors is a frequently discussed subject in professional medical journals and even over the web (Leape, 1997). The growing openness regarding mishaps with patients has led to an increasing number of partnerships between human factor specialists and doctors (Bogner, 1994; Reason, 1997; Svensson, 1997). The understanding of human error and how multiple latent failures lie behind accidents can contribute to knowledge concerning the nature of an accident.

Within the health care sector, an incorrect judgment in one simple operation or a stressful situation that disturbs concentration for a split second can have serious consequences for the patient. However, risks within the health care sector are not only associated with individual events or medical equipment. There are frequently deficiencies with respect to organizational structures, procedures and processes, and with respect to resources for implementing quality management (Rasmussen, 1997). Ambiguity regarding the responsibilities of several occupational groups, or regarding different activities, or in relation to other units and areas of responsibility, can also be related to risks (Larsson and Ödegård, 1993). The role of organizational factors in the genesis of accidents has been analyzed and discussed by Reason (1991, 1997) and Rasmussen (1997) from the perspective of health care organization.

National information systems and procedures concerning medical errors in Sweden

There are three different reporting systems in Sweden at the national level that can provide information concerning medical errors (Figure 1).

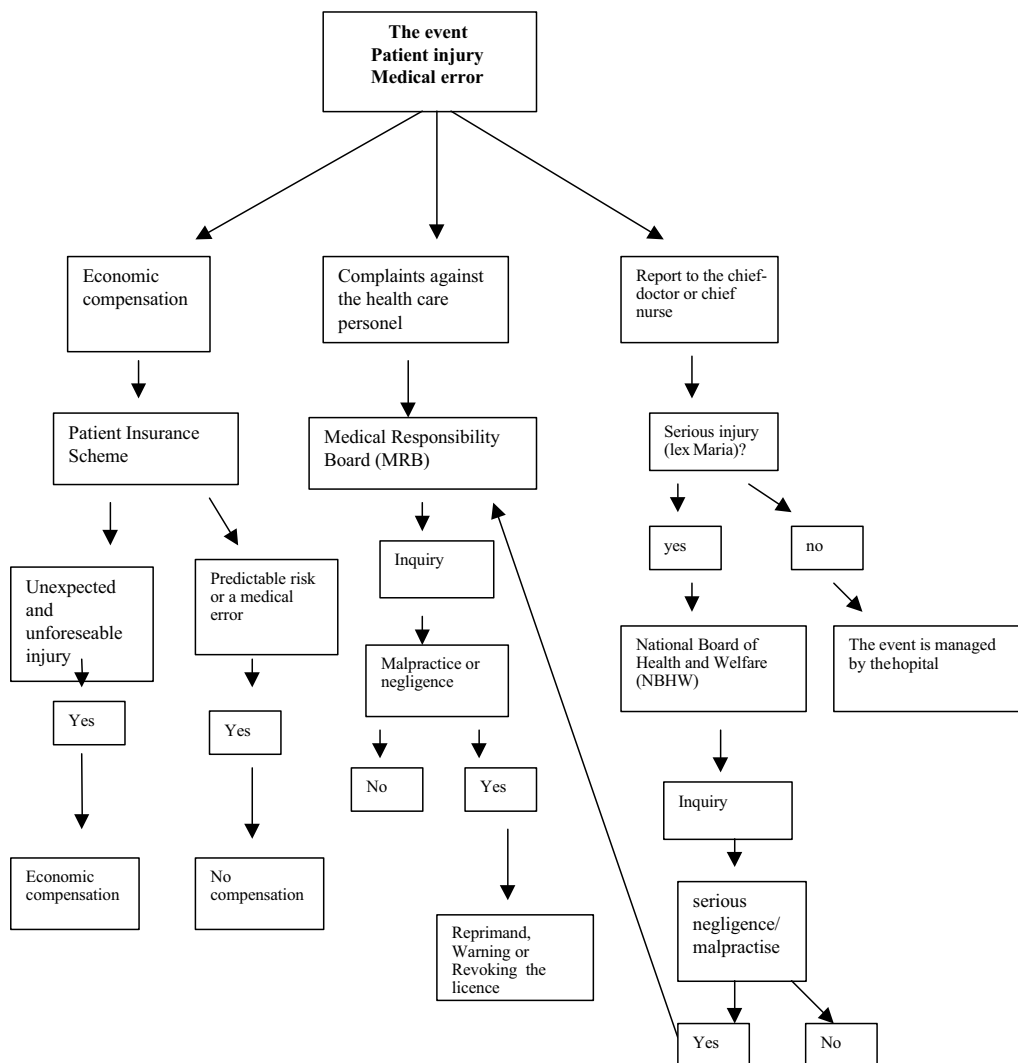


Figure 1 Flow chart of the national information systems for medical errors in Sweden.

The Patient Insurance System. Through the patient insurance system a patient can report an injury caused by treatment, and receive economic compensation whether or not malpractice has taken place. The insurance plan does not compensate all medical injuries, but is instead limited to those that are unexpected and unforeseeable or improbable in the judgment of the attending physician. If an injury is a predictable result or risk of a medical encounter, it is generally not compensable (Oldertz, 1984).

The Medical Responsibility Board (MRB). This authority receives complaints against doctors, nurses, dentists and other health-related personnel. It is a freestanding authority that can be compared to a civil court for medical issues (Rosenthal, 1988). Patients can report directly to the MRB, which investigates whether the accused individual has been negligent or has given substandard care. Many of the claims submitted to this authority are the result of poor communication and misunderstanding among the health care staff, primarily doctors, and the patients. The Board can give health care providers a reprimand, a warning, or revoke their license to practice. The NBHW can also report cases for disciplinary review to this Board.

The National Board of Health and Welfare (NBHW). If a patient becomes seriously injured or ill while receiving medical treatment or services, even if there was a serious risk of injury, it is the duty of the health care staff to report the event to the NBHW. This regulation is called *lex Maria*, and it is a self-reporting system with preventive purposes. The inquiries can lead to criticism of an individual or manager, as well as to demands for changes in routines. Secondly, if the Board finds that an individual has made a serious mistake (negligence or malpractice), it can forward the report to the MRB for disciplinary review. This means then that the state authority must deal both with prevention and with sanctions. The NBHW is the primary medical supervisory authority, and its overall purpose is to foster quality and safety in the health care sector.

Regulations - Historical background

Two events have had particular influence on the debate concerning the legal system for dealing with medical errors in Sweden. The first, which took place in 1936 at the Maria Hospital in Stockholm, resulted in the first regulation, *lex Maria*, which was enacted in 1937 (Ödegård and Löfroth, 1996). The second event occurred in 1983. Three patients died and 12 were in mortal danger following dialysis treatment at the Linköping University hospital. In spite of the fact that the *lex Maria* regulation had been changed in 1982 and now had prevention as its purpose instead of its previous disciplinary focus, where the issue was to determine guilt, the investigation nevertheless focused on the person at the end of the series of events that contributed to the adverse event. A hospital nurse was found guilty of manslaughter and endangerment of life. This accident was followed by extensive debate concerning the legal system and the need for a “scapegoat”, which had dominated the inquiries.

In connection with a reorganization of the NBHW in 1991, changes were made in the way *lex Maria* cases were handled. The ambition was to increase the willingness of health care staff to report medical errors in order to obtain a better base for activities aimed at prevention. A variety of methods were adopted in order to broaden the scope of prevention in the area of patient safety.

One of the activities initiated to help achieve this new purpose was the Risk Data Base project (Ödegård, 1995a). The purpose of the project was to collect and structure the experiences from cases of medical errors (*lex Maria*) and to improve the potential for risk identification in order to reduce or eliminate risk before injuries occurred. A computerized information-system was developed containing information about *lex Maria* cases reported since 1992 and suggesting preventive actions. The information in the Risk Data Base is anonymous with respect to both hospitals and individuals. The argument was that there was no need for identification in order to achieve preventive objectives. Another reason was that identifying a hospital or an individual could have negative effects on the willingness of health care staff to report medical errors. The purpose was to improve the potential for a systematic risk appraisal and to inform health care providers about discovered risks.

Another activity was “RiskRonden” (1992), an information pamphlet issued periodically that highlights a single injury or incident by describing and analyzing it in detail. The dual purpose of the pamphlet was to stimulate debate on safety and to encourage health care staff to report medical errors. The pamphlet was targeted at special groups e.g. chief physicians or ward managers, depending on the type of incident being reported.

An additional part of the Risk Data Base project was “Risk Analyses and Patient Safety”, a project in which critical incidents associated with medical errors that occurred on hospital wards were collected. Critical incidents were collected into risk scenarios as described by the staff and compared with the reports compiled in the RDB. This information was also reported back to the ward staff and managers with the aim of upgrading and specifying local safety routines.

The most important overall purpose of these activities was to shift the focus from the sole aim of blaming a particular person to more constructive actions aimed at reducing or eliminating risks for patient injuries. At the same time, employees managing *lex Maria* cases at the NBHW were introduced to a new approach for investigating medical errors. This was done in a three-day course organized in collaboration with the nuclear power industry and focusing on Man, Technology and Organizational analyses (Bento, 1992).

Extensive information was provided about the advantages of reporting *lex Maria* cases in order to avoid similar errors in the future (Ödegård, 1995 b). Information given to health care professionals emphasized

the fact that medical errors are often due to system failures rather than individual shortcomings. It was pointed out that the disciplinary focus in the management of medical errors and incidents should be changed to a focus on prevention. This also involved a change in the criteria for submitting cases to the MRB. Another ambition in dealing with these issues was to focus on clinical department heads and their responsibilities for their departments. It was pointed out that when analyzing medical errors, the issues of most importance should be guidelines, routines, local regulations, organizational structures and the introduction of new employees. The focus on responsibility should target clinical department heads when medical errors are being analyzed. However, an association still remained between the lex Maria reporting system and disciplinary action. If it was found in the investigation that an individual had been negligent or provided substandard care, the authority would propose disciplinary action and forward the report to the MRB.

The starting point for this study was the new regulation and the new way of handling reported medical errors (lex Maria) at the NBHW. The study examines whether the intended purpose of changing the focus from punishment to prevention has influenced the willingness to report lex Maria cases. The study period was from 1989 to 1993 in order to compare the situation before and after 1991, when most changes were introduced. The underlying questions were:

- Had the number or type of lex Maria cases reported to the NBHW by health care providers changed during the period?
- Had the number or type of lex Maria cases forwarded to the MRB by the NBHW changed since the reorganization in 1991?
- Were clinical department heads reported to a greater extent in 1993 than in 1989?

MATERIALS AND METHODS

The study sample consisted of the total number of lex Maria cases reported by health care providers to the NBHW during the years 1989 and 1993, and the number of cases forwarded from this state authority to the MRB during these same two years. The reports were classified by type of activity, type of error, type of professional involved in the event, and whether sanctions were suggested by means of forwarding the reports to the MRB. In order to establish whether there had been any change from 1989 to 1993, a systematic review of every case was conducted to determine whether an individual who was reported to the MRB was the staff member who had performed the medical error.

During the study period from 1989 to 1993, three regulatory changes took place which affected the analysis. First, responsibility for the care of the elderly and services for the disabled was transferred from the county councils to the municipalities in 1992. A second change was that from 1991 and onwards, suicides in the psychiatric sector were not to be reported as lex Maria cases unless they were judged to be preventable. In addition, reports from dentistry and pharmacy were included as lex Maria cases starting in 1991.

RESULTS

Lex Maria cases reported to the NBHW

In 1989, 242 cases were reported to the NBHW compared to 1,348 cases in 1993, excluding psychiatry, dentistry and pharmacy (Table 1). There were 724 cases reported from the municipalities in 1993, which was 54 % of the total number. Excluding this group, there were 242 reports in 1989 and 624 in 1993 from hospitals and the primary health care sector (excluding psychiatry). In the subgroup 'hospitals and primary health care', 83% (n=202) of the cases came from hospitals in 1989 and 84% (n=529) of the cases in 1993.

Table 1 Type and number of lex Maria cases reported to the NBHW in 1989 and 1993

Type of cases	1989	1993
	n (%)	%
From hospitals and primary health care		
Drug error	38 (16)	145 (23)
Diagnostics	33 (14)	98 (16)
Surgery	36 (15)	125 (20)
Anesthesiology	11 (5)	22 (4)
Obstetrics	9 (4)	14 (2)
Other treatment	79 (33)	200 (32)
No code	36 (15)	20 (3)
<i>Subtotal (hospital and primary health care)</i>	<i>242 (100)</i>	<i>624 (100)</i>
From the municipalities		
Drug errors	-	521 (72)
Accidental falls	-	100 (14)
Other	-	103 (14)
<i>Subtotal (municipalities)</i>		<i>724 (100)</i>
Total	242	1348

Including cases reported to the NBHW from psychiatry, dentistry and pharmacy, a total of 694 cases were reported in 1989 and a total of 1477 cases in 1993.

Cases due to drug errors was the category that increased most, both numerically and percentage-wise, comprising 49% (666 of 1,348) of the total number. Of cases reported by municipalities, drug errors represented 72% of the total number. Another group in which there was an increase in reported cases is surgery, where there was an increase from 15 to 20%. The study data also shows that only 4% of the total number of reported cases in 1993 came from the category anesthesiology.

Lex Maria cases forwarded by the NBHW to the MRB for disciplinary action

The numbers of cases forwarded to the MRB has varied during 1989-1993 between 52 to 81 cases (Table 2). However, since the number of cases reported to the NBHW had increased in 1993, the proportion forwarded for disciplinary review has decreased. Of the total number of lex Maria cases reported to the NBHW during 1989, 35% were forwarded to the MRB, whereas only 5% were forwarded in 1993.

Table 2 The yearly distribution of number of cases forwarded for disciplinary action to the MRB by the NBHW according to type of errors.

Type of cases	1989	1990	1991	1992	1993
	%	%	%	%	%
	(n=66)	(n=81)	(n=52)	(n=71)	(n=69)
Drug errors	55	58	25	15	17
Diagnostics	12	12	17	30	28
Surgery	20	10	23	17	26
Anesthesiology	3	5	4	8	4
Obstetrics	4	4	10	14	4
Other treatments	6	11	21	15	20

The authority has drastically changed its policy on drug errors (Table 2). In 1989, drug errors comprised 55% of all cases forwarded for disciplinary review. The corresponding proportion in 1993 was only 17%, despite the fact that drug errors still constituted the dominant category of cases reported to the NBHW (Table 1). Most of the 36 drug errors forwarded to the MRB in 1989 were due to insufficient of control resulting in the wrong drug or the wrong dose. The 12 cases in 1993 mainly had other causes and more

serious consequences, and only three cases were due to an incorrect dose. Another obvious change is the proportion of diagnostic cases, which increased from 12% in 1989 to 28% in 1993.

Staff categories reported to the MRB

There was also a change in the categories of staff reported to the MRB by the NBHW (Table 3). During 1989, 35% of the total of 85 individuals reported were medical doctors, whereas in 1993, 73% of the total of 80 individuals reported were doctors. The percentage of nurses reported decreased from 53% in 1989 to 21% in 1993.

Table 3 The yearly distribution of number of individuals in each staff category reported to the MRB by the NBHW for disciplinary action

Staff categories reported to the MRB*	1989	1990	1991	1992	1993
	% (n=85)	% (n=99)	% (n=56)	% (n=79)	% (n=80)
Doctors	35	37	57	75	73
Nurses	53	44	30	18	21
Others	12	18	13	8	6

**The number of individuals in each staff category is numerically greater than the number of reported cases. This is because several persons can be involved in a particular case.*

Analysis of each case (Table 4) showed that in 1993 it was still generally the case that an individual was reported and not department heads. In implementing the new policy, one intention was to examine an event in a broader perspective than before, which would include the increased importance of organizational factors. In 1989, 78% (62 of 79) of the individuals reported could be categorised as those who 'performed the error'. The corresponding figure in 1993 was 91% (69 of 76). Only a few individuals categorised as

Table 4 Number of persons reported to the MRB by the NBHW categorized with respect to the type of error.

Probable cause	Performed the error		Directly contributed to the error		Indirectly responsible for the activity (management)	
	1989	1993	1989	1993	1989	1993
Diverged from routines; no control performed	43	17	8	-	-	-
Inadequate routines, regulations; insufficient organization	5	12	1	2	7	3
Other factors	14	40	1	2	-	-
Total	62	69	10	4	7	3

There was insufficient information about six of the persons reported in 1989, and four in 1993.

DISCUSSION

The aim of this study was to analyze whether the policy of the NBHW for handling lex Maria cases has influenced the reporting of medical errors by the health care sector. Data presented in this study showed that the number of reported lex Maria cases increased from 242 cases in 1989 to 1,348 cases in 1993. A large proportion of the new cases in 1993 came from the municipalities, comprising 54% (n=724) of the total number of cases (1,348) (Table 1). The large number of lex Maria cases reported resulted in extensive debate focusing on the quality of care given by the municipalities. Some of the cases were associated with

the new structure and organization, but it is not very likely that this change was responsible for the entire increase in cases reported.

It is important to keep certain circumstances related to the regulatory changes in mind with respect to the results. The regulation was changed in 1992, and responsibility for the care of the elderly was transferred from the county councils to the municipalities. At that time a new category of staff was given the responsibility to report *lex Maria* cases to the NBHW. Before 1992, clinical department heads at the hospitals were generally responsible for selecting cases reported by the health care staff to be forwarded to the NBHW. When the municipalities took over responsibility for the elderly, a chief nurse was given this responsibility. These chief nurses had new functions, and they were informed about the significance of reporting *lex Maria* cases to the NBHW. Another factor was that, in 1993 from an organizational point of view, patients in the elderly care sector were physically closer to the person whose responsibility it was to report the event. It is important to note that prior to 1992, such patients belonged to the category “hospitals” or “primary health care.” The *lex Maria* responsibility of the clinical department head was much wider, comprising all areas.

Even excluding the cases from the municipalities, there has been an increase in the number of *lex Maria* cases. It seems reasonable to believe that this increase could be due to the intensive information campaign in connection with the reorganization of the NBHW in 1991. The information stressed that the reporting system was important regarding future preventive initiatives and improved feedback from reported cases, and that employees with organizational responsibilities for routines and procedures would have greater accountability than earlier.

One of the issues taken up in the present report concerned whether the number or type of cases reported to the NBHW that were forwarded to the MRB had changed during the period. Major changes took place, indicating that some policy modifications had occurred at the NBHW during the period. The proportion of cases reported to the NBHW that were forwarded for disciplinary review to the MRB decreased from 31% in 1989 to 5% in 1993. Excluding cases from the municipalities, this proportion decreased to 11% in 1993.

The type of cases the NBHW forwards to the MRB changed during the period. The authority drastically changed its policy regarding drug errors, and these cases were forwarded to a lesser extent than earlier, decreasing from 55% to 17%. For the category of diagnostics there was also a change, although in the opposite direction, from 12% to 28%. These changes influenced the structure of the staff categories that were reported. In 1989, 35% of all individuals whose cases were forwarded to the MRB for disciplinary review were doctors, and 53% nurses. In 1993, 73% of all *lex Maria* cases reported to the MRB were doctors and only 21% nurses.

It appears as if the intention of the reorganization, which was to include organizational factors to a larger extent than earlier in the review of reported medical errors, has not been fulfilled. Individuals below the management level continued to be reported for disciplinary review in 1993, although the number of medical doctors increased and the number of nurses decreased. The problem of differentiating between an individual and his or her dependence on the organizational structure can be exemplified by drug errors, a major category. A likely explanation is that these kinds of adverse events are rather easy to discover. In addition, the final error is in most cases performed by a single individual who is, in many cases, at a lower level in the medical hierarchy. It may be more difficult to review an adverse event at a higher level, including possible failures at the management level. Rosenthal (1994) describes informal mechanisms regarding doctors, and discusses ‘colleague problems’ including the protecting of one another.

The results of this study imply that the new policy has had a positive effect in increasing the number of reported medical errors. Different studies have tried to estimate the extent of medical errors, and there is a growing openness in discussing and confessing these problems as well as how the risks to patients can be reduced. The aim of this study is not to estimate the number of patient injuries caused by medical treatment. Nevertheless, the underreporting of *lex Maria* cases is of interest. When these results are compared with those of other studies, it is reasonable to believe that there is substantial underreporting. The Harvard Medical Practice Study showed that adverse events occurred in 3.7% of cases (Brennan et al., 1991). In a later study in the US, the proportion of adverse events was estimated at 11%, with 42.5% preventable (Bates et al., 1995). The Quality Australian Health Care Study revealed that 16.6% of admissions were associated with adverse events and 51% of the adverse events were judged to be

preventable (Wilson et al., 1996). Another indicator of the magnitude of patient injuries is the Patient Insurance System. In 1993 there were 6,398 cases reported, and in 1998 there were 8,823. Complaints from patients to the MRB increased from 2,000 cases in 1993 to 3,107 cases in 1998. Lex Maria reports have decreased from 1,348 in 1993 to 1,133 in 1998.

Although these results cannot be compared with the number of lex Maria cases reported due to different definitions of adverse events, they are indicators of the magnitude of the problem and suggest that underreporting exists in Sweden. It is important to keep the terminology in mind when referring to reported lex Maria cases. A reported case does not necessarily mean that someone has been negligent; it may have resulted from circumstances that could not have been avoided.

One essential requirement for reducing medical errors is a safety culture in which health care providers, independent of level or position, dare to talk about and also report medical errors (Leape, 1994; Wu et al., 1991). Bogner (1994) discusses the blame trap, and that blaming leads to ineffective counter-measures. Furthermore, reporting may also cause a colleague or a subordinate to receive a warning or a reprimand, or even to lose his/her license. The lex Maria regulation established that the overall purpose of reporting medical errors is prevention. This is difficult due to the fact that, along with its preventive duties, the authority is also obligated to report serious errors to the MRB. This dual role may result in the tendency to underreport, which in turn may make preventive measures more difficult to achieve.

There are several reasons for examining patients' injuries that are caused by medical treatment. One of the most important issues is to obtain information about primary causes in order to develop activities that can prevent recurrences of similar errors (Vincent, Audley and Ennis, 1993; Leape, 1994; Reason, 1997). An additional reason is that these events are not only traumatic for the patients and their relatives, but also for the health care staff that have been involved in the events (Hilfiker, 1984; Christensen et al., 1992; Bogner, 1994). Medical errors are also of concern in the area of occupational health (Sundström-Frisk, 1994; Baldwin, Dodd and Wrate, 1997).

The national Risk Data Base could provide an important base for regulations and recommendations as well as for future medical supervision. However, knowledge about the magnitude and type of patient injuries is an important base for the prevention strategy at the NBHW. Handling lex Maria cases takes considerable resources which may be used ineffectively if cases reported as lex Maria cases do not reflect reality.

Rasmussen (1997) discusses the need to direct attention to aggressive and competitive environments that have been related to several severe accidents in the industrial sector. Reports from several accidents such as at Bhopal, Zeebrugge and Chernobyl, demonstrate this (Perrow, 1984). It seems that Rasmussen's arguments are pertinent to the health care sector, which has also been subjected to extensive structural changes and economic restrictions.

Supervision of the health care sector in Sweden has undergone change during the last few years, and health care providers now have greater responsibility for self-monitoring. The state authority now monitors to a greater extent the way in which health care providers monitor their own activities. This increases the demand for intrinsic control of the activity. Since 1997 all medical services are obligated to have their own local reporting system for adverse events, but their duty to report lex Maria cases to the NBHW still remains.

Results presented in this study estimate that the number of reported lex Maria cases has increased dramatically during the years 1989 to 1993. It is clear that the state authority's manner of handling lex Maria cases has changed during the period. But it also seems that there is a large underreporting of lex Maria cases. One of the major problems with the Swedish lex Maria system still remains, since the NBHW is obligated to report to the MRB. In spite of the fact that lex Maria is regulated by law, and health care providers have the duty to report medical errors, this is dependent on the willingness to report medical errors to the NBHW. The question can be posed as to whether the present manner of handling lex Maria really contributes to improved patient safety. It is problematic to have a self-reporting system run by an authority that is obligated to forward reports for disciplinary action.

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II

Reporting system, disciplinary measures and patient safety – a Swedish study

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ABSTRACT

Objectives: To increase understanding of the motive of the regulatory agency's decisions for disciplinary measures against health care personnel involved in patient injuries. **Design:** Register study. Setting: Reported cases from the health care to the regulatory agency. **Sample:** All reported cases in 1998 (n= 1.116). Main outcome measures: Examination of cases that were judged to justify a disciplinary measure from the regulatory agency to the Medical Responsibility Board. These cases were chosen for analysis by Reason's explanatory model of types of errors (18). **Results:** Ninety-eight cases involving 109 individuals were reported for disciplinary measures. Of individuals, 26% were placed in the category unintended actions and the subgroup skill-based error. Incidents related to the handling of medications predominate in this category. The intended actions category comprises the subgroups mistakes and violations/nonchalance. The cases categorized as mistakes comprise 59 % of the individuals. Nearly half were judged to lack relevant competence and experience for the task. The subgroup violations/nonchalance comprises 15% of the individuals. In these cases, descriptions of the incidents in the decisions have been interpreted as showing that the individual consciously and nonchalantly overstepped his or her professional responsibility.

Conclusions: From a preventive perspective it is difficult to understand the motive for a disciplinary measure for the majority of individuals reported to the Medical Responsibility Board. The results thereby also illustrate the difficulties in combining the preventive aim with the legal requirement to make a decision concerning guilt regarding an incident that has occurred.

Key word: patient safety, disciplinary measure, reporting system, types of errors

INTRODUCTION

The fact that patients are injured in connection with care and treatment has been shown to be a widespread problem that has received increased attention in recent years, both in Sweden as well as in other countries (1-8). One way of obtaining knowledge about the problem in Sweden is through the reporting of patient injuries by the health care system to the regulatory agency, the National Board of Health and Welfare. Difficulties in getting satisfactory reporting of accidents are acknowledged in many sectors and underreporting is common (9-11). The preventive value of reporting systems is affected by the number of reported incidents, the perspective of the analysis of the incident, and the extent to which information on reported incidents is fed back to the health care system.

A number of countries require the reporting of patient injuries to the respective regulatory authority (4, 12-15). Sweden has had a national reporting system for patient injuries, the Lex Maria system, since 1937. Up until 1982 the aim was to establish evidence so that the individual who "committed the error" and was considered to have caused the injury could be made to answer for his or her actions (16). Since 1982 the overall aim of Lex Maria has been preventive. Information from reported Lex Maria cases is registered in a national risk database at the National Board of

Health and Welfare since 1992. A number of changes have been made in the regulations with the aim of attaining increased reporting but it can be assumed that underreporting is still a reality (4). This supposition is based on the fact that in 1998 there were only 1 116 serious incidents reported by the health care system to the regulatory agency. The same year 9500 patients applied for financial compensation from the patient insurance system for an injury judged to have been caused by care or treatment. An additional reason for considering the reporting to be low is that results from international studies indicate that the number of patient injuries is higher than shown by Lex Maria reporting (1-3, 5-8).

The Swedish reporting system

The Swedish Lex Maria reporting system comprises the entire health care sector, public and private, as well as dental service. Reporting occurs in different steps (figure 1). All health care staff is required to report adverse events of significance to patient safety to the local reporting system. In turn, the chief medical officer are to report especially serious incidents to the regulatory agency, the National Board of Health and Welfare, in accordance with Lex Maria (17). Risks for serious injury are also to be reported. The regulatory agency is divided into six regional units that independently make decisions concerning the cases.

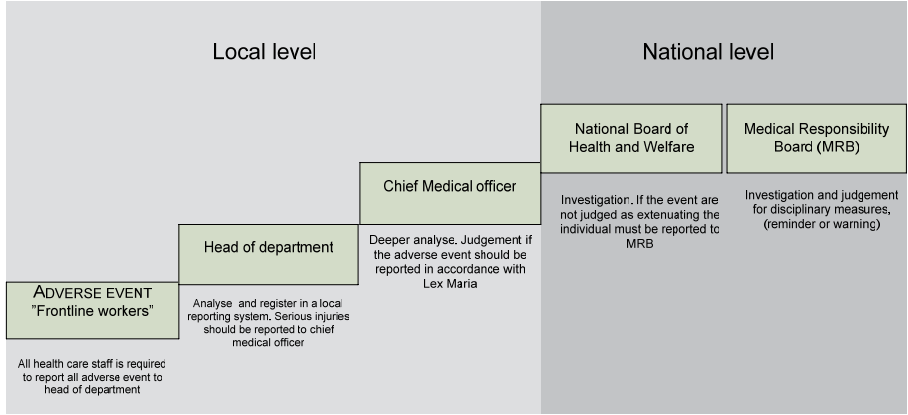


Figure 1. The Swedish Reporting system, Lex Maria

If when investigating an incident the regulatory agency judges that an individual has seriously neglected his or her professional responsibilities or if the event can't be judged as excusable, this is to be reported to the Medical Responsibility Board. The board is a freestanding national authority with a judicial function and the power to take disciplinary action against health care staff. A disciplinary measure is expected to have future individual or general preventive effects. This means that it is assumed that the person who gets a disciplinary measure will improve and that others will be guided by the case. In addition to reporting the individual who made the active failure resulting in the injury, the regulatory agency can also report the person with overall responsibility for the area where the incident occurred. It is also possible for the agency to refrain for reporting the incident to the Medical Responsibility Board if the circumstances surrounding the incident are judged as extenuating. A study of reported Lex Maria cases during the period 1989 to 1993 showed that those reported to the Medical Responsibility Board were mainly those working in "the sharp end", despite the fact that there were obvious deficiencies at the system level (the blunt end) over which these individuals had no control (4).

Two difficulties can be identified in the Swedish Lex Maria reporting system. One is the connection between the local and the national reporting system and the resulting risk to disciplinary measures. The other is that disciplinary measures are usually directed at those working in “the sharp end” that made the active failure, which can lead to a lack of trust in the reporting system as such. As a result of these difficulties, incidents in which patients are injured may not be reported. This in turn can result in the overall aim of the Lex Maria system not being fully met, or in other words that incidents that could contribute to preventive work regarding patient safety are not available to the health care system to the extent desired.

Despite probable underreporting, the Lex Maria cases that have been reported can provide valuable knowledge for preventive work with patient safety. The decisions of the National Board of Health and Welfare following reported Lex Maria cases are public documents. They contain a detailed description of the incidents, their investigation, and the judgment of the agency. The decisions can therefore be expected to have great teaching potential and it is consequently important to analyse them. From a learning perspective, two basic goals can be identified by analysing an incident in which a patient has been injured (18). The first is to examine an individual incident to find the circumstances that are specific to the incident, as well as the factors that can have influenced the course of events leading to the injury. The other is to try to identify circumstances that are common to many incidents in order to identify patterns and deficiencies at the system level (19).

It is of special interest to analyse patient injuries reported in accordance with Lex Maria, which the regulatory agency has determined should be sent to the Medical Responsibility Board for disciplinary action, from various perspectives. First of all, these are incidents where the professional has been judged to fail in the exercise of his/her work and where the agency has judged that extenuating circumstances regarding the incident are lacking. Secondly, a report frequently results in widespread publicity, which is often experienced as mentally stressful for the person reported (20). Thirdly, a report to the Medical Responsibility Board can be experienced as unjust by the person reported if the motive for the report is not understood (21). In this study Reason’s explanatory model of types of errors (22) was chosen for analysis of the Lex Maria cases that were judged to justify a disciplinary measure. Based on the preventive objective of Lex Maria, the aim of the study is to increase understanding of the motive for the regulatory agency’s decisions for a disciplinary measure as well as to identify system deficiencies.

MATERIAL AND METHOD

Sample and data collection

The study is a population study based on all patient injuries reported by the health care sector to the regulatory agency in accordance with Lex Maria during 1998 (n=1 116) and of these, the group sent to the Medical Responsibility Board to be considered for possible disciplinary measures. Data collection was carried out by examination of register data (23) concerning the cases reported during 1998 to the official register of the National Board of Health and Welfare. Information concerning cases sent to the Medical Responsibility Board for disciplinary consideration is found in the “register image” of the case and was thereby identified. The written decisions concerning these cases, which are public documents, were procured.

Analysis

All of the Lex Maria cases were sorted with respect to the type of health care institution that reported the incident and the regional regulatory unit that received the report. Analysis of the Medical Responsibility Board cases was based on the written decisions of the agency. They were classified according to type of care and type of activity that were underway when the incident occurred as well

as the category of professional that was involved. Another factor that was examined was whether it was the individual in the sharp end that committed the active failure or the person with overall responsibility for the care unit that was reported to the Medical Responsibility Board. Table 1 shows the respective categories of activities.

Table 1. *Categorization of incidents based on type of activity when the incident occurred*

<i>Activity</i>	<i>The activity involves</i>
Dental care service	Cases related to treatment in the mouth, except for medication-related incidents.
Diagnostics	Delayed, missed or wrong diagnosis or medical assessment.
Labour and delivery	Cases directly related to management of a delivery, although not incorrectly administered medication, which was placed in the medication category.
Medications	Incorrect ordering, preparation and administration of medication or incorrect dispensing of medication at the pharmacy
Surgical procedures	Different types of surgery including invasive procedures for diagnostic purposes.
Other	Other health care treatment, deficient nursing care and reports from psychiatry.

The incidents were thereafter analysed using Reason's (22) explanatory model of types of errors based on the individual's intentions regarding the action that "caused" the injury (Figure 2). Two main categories were used in the analysis, unintended actions and intended actions. The explanatory model used in the analysis is illustrated below.

In those cases where the incidents were categorized as "unintended actions" the plan of the measure was judged as adequate, but the action failed to go as planned. The intended goal of the action was therefore not attained. Characteristic of this type of action is that the individual has difficulty explaining afterwards how the incident could have occurred. These are incidents that have not been judged as being related to a lack of competence, for example. To simplify, it can be said that the individual thought right but acted wrong. These types of errors are commonly called "slips" or "lapses" (22). Slips are related to observable actions such as the nurse who takes the wrong bottle of fluid for injection. Lapses are related to memory such as when the individual writes "1" instead of "7" when writing an order. In the analysis, both of these types of errors were classified in the subgroup "skill-based error".

The main category intended actions comprises the subgroups mistakes and violations/nonchalance. Characteristic of these types of errors is that the individual consciously chose or chose not to carry out a measure. With a mistake the action may conform exactly to the plan but the plan is inadequate to achieve its intended goal and the results were not as expected. In the original model mistakes was divided into two subgroups, "rule-based" and "knowledge-based" mistakes (22, 24). Rule-based mistakes are characterized by either the individual having chosen the wrong rule or by the rule that was used being correct but used incorrectly. The subgroup knowledge-based actions are related to insufficient knowledge. As this study is based on secondary material from the agency's investigation and the description found in the decision, it was not possible in all cases to analyze whether an incident was due to insufficient knowledge or if it was a rule-based action. The two subgroups are therefore reported on together.

The main category intended actions also includes the subgroup violations/nonchalance. This group comprises cases where the individual was judged to have exceeded his or her professional responsibility by carrying out a measure or allowing a measure to be carried out due to nonchalance or by consciously violating existing regulations. First author did the classification and the analysis.

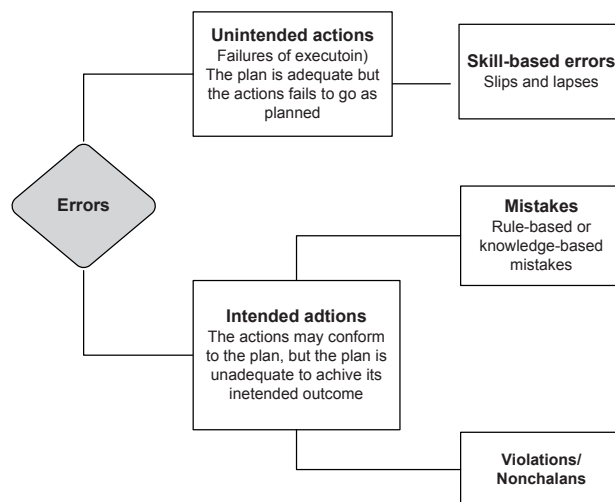


Figure 2. Types of errors (Reason (1997) (22).

RESULTS

Of the total of 1 116 Lex Maria cases that were received by the regulatory agency in 1998, 98 cases involving 109 individuals (9%) were sent to the Medical Responsibility Board for judgement regarding disciplinary measures. The number of individuals is greater than the number of cases because more than one individual can be reported in the same case. The percentage of reports sent to the Medical Responsibility Board varied from 5 to 17% among the regional agency's units. The figures are based on the Lex Maria cases that were reported to the respective regional units during 1998 and which were then sent to the Medical Responsibility Board.

Of the 109 individuals reported to the Medical Responsibility Board, 106 were directly involved in the incident that resulted in a patient being injured (active failure), and three were indirectly involved in the incident. None of the 109 individuals was reported as being responsible for inadequacies at the overall system level. Of the cases reported for disciplinary measures, medication-related incidents constitute the most common category (n=37) (table 2). Thereafter come incidents related to diagnostic measures (n=32) and surgical procedures (n=18). Of those reported, 59% were doctors and 22% were nurses. In addition, child-minders, alarm operators, naprapaths, physiotherapists and dentists were among those reported.

A total of 512 Lex Maria cases (46%) were reported by hospital care, which predominated in reporting to the regulatory agency. Of these, 12% were sent to the Medical Responsibility Board. Of the 83 (7%) cases reported from primary care, 17% were sent to the Medical Responsibility Board. There were 289 (26%) Lex Maria cases reported from elderly care, of which 3% were sent on to the Medical Responsibility Board (table 3).

Types of errors

Unintended actions

In the analysis, 28 (26 %) of the individuals reported to the Medical Responsibility Board were placed in the category unintended actions and skill-based errors (table 2). Incidents related to the

handling of medications predominate in this category and involve 19 of the 28 individuals. The most common cause is mix-ups, either of patients or medications (n=17). Examples of incidents related to diagnostic measures are interpretations of X-rays and referral results later found to be erroneous. A total of four individuals were placed in this group. One of the four incidents related

Table 3. Number and percentages of Lex Maria cases reported to the National Board of Health and Welfare in 1998 and the number of cases the National Board of Health and Welfare sent to the MRB for disciplinary sanctions according to health care area from which the report had come.

Health care area	All Lex Maria cases reported to the National Board of Health and Welfare		Proportion of Lex Maria cases sent to the MRB
	n	%	%
Dental service	87	(8)	7
Elderly care	289	(26)	3
Hospital care	512	(46)	12
Other	67	(6)	9
Pharmacy	78	(7)	5
Primary care	83	(7)	17
Total	1 116	(100)	-

to surgical procedures concerns a surgical nurse who forgot a surgical towel in a patient's abdomen when counting towels after completion of an operation. Another example concerns a nurse who disconnected an alarm and thereafter forgot to reactivate it. Other examples illustrating an unintended actions resulting in an incident are cases 1 and 2 in table 4a.

Intended actions

The intended actions category comprises the subgroups mistakes and violations/nonchalance. The cases categorized in the subgroup mistakes are based on the judgment that the individual consciously chose to carry out a measure in the belief that it was adequate. This category comprises a total of 64 individuals (59%), (table 2). Nearly half were judged to lack relevant competence and experience for the task. The category is dominated by incidents concerning diagnostic measures (n=23). Examples of such incidents are incorrect interpretation of an EKG, incorrect assessment of a cut on the thumb, a missed diagnosis of testicular torsion, and incorrect interpretation of X-rays. Surgical procedures where the doctor performed procedures without sufficient experience are other

Table 4a. Examples of incidents that motivated a disciplinary measure according to error types in Reason's explanatory model (22).

Unintended actions / Skill-based errors

Case 1. The pharmacist dispensed the wrong medication

At the time in question there was a line to use the computer and many customers were waiting. To make room as fast as possible for the next pharmacist, the pharmacist took a shortcut and registered the product number instead of the name of the medication. The wrong product number was registered which resulted in the child getting the wrong medication.

Case 2. A 4-year-old girl got paracetamol solution intravenously

Intravenous antibiotics and a pain medication, paracetamol by mouth, were ordered for the child. A student nurse prepared the injections under the supervision of a nurse. The work situation was stressful and the child was crying and did not want to cooperate. The student nurse therefore got to work "a little on her own" and the nurse stayed in the background. When the injections were going to be given the medications were mixed up and paracetamol solution was administered intravenously.

examples of incidents that can be related to a lack of competence. Examples are illustrated in table 4 b, cases 3 and 4. The subgroup mistake also includes incidents judged to be related to routines. Seven of these incidents were associated with surgical procedures. One example concerns a surgeon who deviated from the routine by not examining the patient himself before the operation, which resulted in serious complications. Another surgeon did not read the patient's medical record carefully enough before the operation. As a result the patient was operated on for the wrong indication and underwent an unnecessary operation. Other examples are a dentist who extracted the wrong tooth and a biomedical scientist who trusted in the information on the computer and dispensed the wrong blood, although without consequences for the patient. Examples are illustrated in table 4b, cases 3 to 6.

Table 4b. Examples of incidents that motivated a disciplinary measure according to error types in Reason's explanatory model (22).

Intended actions / Mistakes
<i>Case 3. The first on-call doctor missed diagnosing an aortic aneurysm</i> A 50-year-old man presented with chest pain, a generally affected condition, and rising blood pressure. A computed tomography investigation of the thorax was done with the question "aortic aneurysm?" In the preliminary response from radiology the doctor wrote "no basis for aortic dissection." Later during the day a routine double check of the CT results was done by the doctor on second call, who ascertained a dissecting aortic aneurysm. The patient had already died.
<i>Case 4. The intern misjudged a cut on the thumb</i> A 9-year-old boy who had fallen and injured his thumb on a pane of glass was examined by a preregistration house officer at an emergency room. This doctor assessed the injury himself and did not call on a more experienced colleague. Routines for managing this type of injury were lacking at this emergency room. When after a number of weeks the boy could not bend his thumb he was referred to orthopaedics where it was ascertained that the diagnosis of tendon injury had been missed.
<i>Case 5. Did not check information on the surgery schedule against information in the medical record</i> The orthopaedic surgeon suspected nerve incarceration in a patient who presented with decreased sensation in the foot. There was an incorrect DRG code in the handwritten operation application, which resulted in an incorrect operation being written on the surgical schedule. On the day of surgery the surgeon read only the surgical schedule and did not check this against the diagnosis in the medical record, and therefore performed the wrong operation.
<i>Case 6. Ongoing warfarin treatment was not restarted when the planned operation was postponed</i> A 77-year-old woman on warfarin treatment was to undergo surgery. According to notes in the medical record, warfarin was to be discontinued before surgery and thereafter restarted. The surgery was postponed, however, but restarting warfarin treatment was forgotten. This resulted in the Patient's PK value rising from 28% to 108% in three days, which led to the patient sustaining an arterial embolus in her right leg and the leg had to be amputated.

The subgroup violations/nonchalance is also included in the category intended actions. In these cases, descriptions of the incidents in the decisions have been interpreted as showing that the individual consciously and nonchalantly overstepped his or her professional responsibility. A total of 17 (15%) individuals were assigned this category. In 10 of the 17 cases the person reported carried out relevant measures or neglected to carry out relevant measures despite repeated viewpoints or remarks from other staff. An example is the nurse who did not call an anaesthetist despite obvious problems with the anaesthesia and who gave a three times too high dose of an anaesthetic agent to a two-year-old child without an order. Further examples are illustrated in table 4, cases 7 and 8.

DISCUSSION

The results show that those working in “the sharp end” were the ones reported to the Medical Responsibility Board, despite the fact that the decisions showed deficiencies at the system level and that conditions for carrying out safe care were not always optimal. One reason that disciplinary measures were directed in all cases at the individual who committed the active failure can be that the association between individual and system errors is complex in nature (22, 25, 26). Another reason can be that in the investigation, the mandate of the regulatory agency is to take the issue of guilt into consideration as well as to establish a preventive perspective. Examples are illustrated in table 4c.

Table 4c. Examples of incidents that motivated a disciplinary measure according to error types in Reason’s explanatory model (22).

Intended actions / Violation/nonchalance
<i>Case 7. A patient with depressed respiration got morphine, without an order, from a nurse.</i> The patient, who was cared for in a group dwelling, had breathing difficulties and was moribund. The staff contacted the nurse. There was a standing order for Stesolid rectal tube 5 mg, but to be on the safe side the district nurse gave 10 mg and 2 paracetamol suppositories. When this did not give the expected effect, she gave Morphine 5 mg, without an order, which was repeated after 45 minutes
<i>Case 8. Adequate measures were not taken during the delivery despite clear warning signs</i> The midwife noted a pathological CTG curve in a 29-year-old primipara and tests showed that the baby was acidotic. The doctor was called repeatedly but did not take adequate measures. When the doctor on second call was contacted, the baby was delivered with ventouse vacuum extraction.

The expected effect of disciplinary measures is to increase patient safety by means of individual or general prevention. For incidents where the professional consciously acted carelessly or nonchalantly, the motive for a disciplinary measure can be understood based on the preventive aim of the legislation at the individual level, i.e. that the individual is made aware that the action is unacceptable. Only 15% of all cases reported from the regulatory agency’s to the Medical Responsibility Board (n=17) were placed in this category (table 4, cases 7 and 8). The remaining 85% of those reported to the Medical Responsibility Board were judged to have acted “in good faith”, and skill-based errors or mistakes were the types of errors attributed to them, which means that they carried out a measure in the belief that their action was correct (table 4, cases 1-6). For these types of errors it seems difficult to explain a disciplinary measure based on prevention from an individual perspective, since the professional is aware that the measure did not lead to the expected result. The decision could, however, be explained from a general prevention perspective, i.e. that the disciplinary measure would result in others becoming aware of the incident. This presumes that knowledge about the incident and underlying causes is dispersed to health care professionals throughout the country.

Latent failure

Identifying and clarifying system deficiencies is essential, since they are super ordinate in the sense that they can generate accidents that can at first seem different in character but that in an analysis of aggregated data can be seen to have the same origin (19, 22). It is known from other areas that latent failure, deficiencies at the system level, can indirectly affect the course of events (27, 28). In many of the cases in this study there are indications of underlying system deficiencies that probably influenced the course of events. However, they were not judged by the regulatory agency as having constituted extenuating circumstances that would preclude a report to the Medical Responsibility Board. For example, a stressful environment was found in many of the cases placed in the skill-

based errors category, and that may have contributed to the individual being disrupted in his or her work or choosing a shortcut in order to save time, (cases 1 and 2, table 4). Another example was a nurse who forgot to check the content of an infusion bag. Factors that probably influenced the incident and that emerged in the investigation were that the workload that particular day was extremely heavy; infusions for many patients were mixed at the same time, which was common in that care unit despite the fact that this was not in accord with current regulations. Activities had greatly increased in scope; for example the proportion of cytostatic infusions had increased by 33% during the past one-year period.

Incidents falling into the category of mistakes can indicate that the professionals lacked relevant competence or guidance (table 4, cases 4-5). In the mistakes group where the individual chose a measure in the belief that it was correct, incidents related to insufficient competence constitute close to half the cases. According to existing regulations, the Chief Medical Officer of the organization has overall responsibility for assuring that the person carrying out a measure has relevant competence (29). Many incidents in the mistakes category can be attributed to inadequate routines or to the fact that existing routines were not followed (table 4, cases 5-6).

In complex systems such as health care there is always a risk for accidents. There must therefore be control systems and barriers that eliminate, forewarn or decrease the consequences of unsafe acts (22, 25, 26). An example of barriers can be technical warning systems that alert the individual to an inappropriate measure. Other types of barriers are administrative, such as continuing education on a regular basis, requirements for supervision of professionals without relevant experience in performing particular tasks, and control systems when new methods of treatment are introduced. The results of this study indicate that such barriers were either lacking or were not sufficiently effective to prevent the occurrence of an injury.

Although only 9% of the reported Lex Maria cases in 1998 were sent to the Medical Responsibility Board so that disciplinary action could be considered, it can be assumed that just the risk of disciplinary measures has a negative effect on the willingness to report (10, 11). One reason for this is that these cases receive widespread publicity in the media and are often reported in the professional literature. If the individual also feels that the report is unjust, this can be assumed to have an effect on future reporting (20, 30). An area that has accepted the consequences of difficulties combining a preventive perspective with the legal requirement to investigate the issue of guilt is the aviation industry (10). When an accident or serious incident has occurred, it is compulsory to report this to the regulatory agency, which then investigates the incident, but in addition, there is also a requirement for a special accident investigation. It is clear from these requirements that the issue of guilt is to be separate from the investigation, the explicit aim of which is a preventive perspective (31). Such requirements are lacking in Swedish health care. In the U.S., those reporting to the voluntary Aviation Safety Reporting System (ASRS) have immunity that is stipulated by law, under the condition that the action is not criminal (32). The regulatory agency for civil aviation, The Federal Aviation Administration, has judged that getting access to risk information is more important than the need for punishment. There is a significant difference between the Swedish Lex Maria reporting system and the ASRS (33). Reporting to the ASRS only concerns incidents, while Lex Maria concerns incidents in which patients have been injured. However, there are basic factors that should be highly relevant for most reporting systems. These are experienced benefits of the system, its freedom from sanctions, and trust in the system (10-11). Studies have shown that staff experience frustration over the fact that blame is usually placed on the person who commits the active failure, despite the fact that there have been obvious system inadequacies (11, 21).

Weaknesses of the study

A weakness of the study is that the analysis is based only on the regulatory agency's description of

the course of events and the judgment that constituted the basis for the decision. This means that the results may be coloured by the agency's investigation and description of the event, and by the first author who analysed the material and who in turn interpreted the description in the decision. In order for the information to reflect the course of events as optimally as possible, it is necessary for those involved to be interviewed as close in time as possible to the incident. It has nevertheless been judged relevant to use the decisions as the starting point, since this is the information that is accessible at the national level. Some incidents included in the analysis were difficult to categorize. Therefore the "mistakes" category, for example, was not reported for different subgroups. Despite these weaknesses, the study shows that Reason's model (22) can improve the information about the individual incident and provide a better overview of the aggregated data.

CONCLUSION

Understanding why people make mistakes is essential in order to take preventive measures. The judgment, as to whether an action was right or wrong, is by definition always a judgment after the fact (20, 22). Since the person analysing an incident has the "results" of the outcome of the incident, there is a risk hindsight bias (26). The explanation for the occurrence of the injury will be oversimplified in that the investigator does not take into account the context in which the individual found himself/herself when the error was committed. Adaptability and flexibility in human work are the reasons for its efficiency but that they are also the reasons mistakes occur. According to this view it is natural, and necessary, to take shortcuts to get a work unit to function, and there is always a balance between efficiency and accuracy - the ETTO principle (Efficiency Thoroughness Trade Off) (26).

Accidents are complex in character and cannot be described in simple cause and effect terms. The study is only one window on the system. This model has focused only on the individual's unsafe acts, but despite that we believe that the results indicate deficiencies at the system level. The results also show that from a preventive perspective it is difficult to understand the motive for a disciplinary measure for the majority of individuals reported from the regulatory agency to the Medical Responsibility Board. The results thereby also illustrate the difficulties in combining the preventive aim with the legal requirement to make a decision concerning guilt regarding an incident that has occurred. The question is therefore whether the National Board of Health and Welfare's duty to decide about the issue of guilt in the investigation of a Lex Maria case may counteract the preventive aim of Lex Maria.

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III

SAFETY MANAGEMENT IN CIVIL AVIATION - A USEFUL METHOD FOR IMPROVED SAFETY IN MEDICAL CARE?

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Abstract - Medical errors can result in the devastating consequences of life-long suffering for the individual patient. Studies have also shown that the fear of making mistakes, as well as the fear and threat of being reported, contribute to the psychological pressure experienced by personnel in the health care sector. Therefore, improving safety is vital from the work environment perspective. There are many indicators showing that risks in the health care sector are increasing, despite the fact that fewer reports are being sent to the monitoring authorities. This study attempts to analyze whether the methods of risk management used by civil aviation have any relevance to the health care sector. A comparison shows that the health care sector lacks an organization on both the local and national levels that specifically deals with safety-related matters. The system of risk reporting and management used in civil aviation can provide valuable insight in designing a similar system within the health care sector. Requirements for periodic proficiency testing and regulation of the length of work shifts are other areas in which aviation can serve as a model for improving safety in health care. The study shows that the safety-related efforts made in civil aviation are in many cases highly relevant to the health care sector, even in relation to the formulation of legislation.

INTRODUCTION

Medical errors are also a work environment problem

Within health care, incorrect assessment or a stressful situation with a fraction of a second's inattention can lead to devastating consequences for the individual patient. Medical errors also contribute to higher costs for society in the form of extended treatment, sick-leave and the loss of income (Bogner, 1994). In addition to the suffering incurred by the individual patient and his/her loved ones, the medical error also involves mental strain, and sometimes social trauma, on the part of the personnel involved in the event (Wu et al, 1991; Christensen et al, 1992; Bark et al, 1997). According to a study from the Swedish National Institute for Working Life, these concerns constitute a greater stress factor than to traditional work environment problems (Sundström-Frisk, 1994). Consequently, these issues related to improving safety within the health care sector are also significant from the work environment perspective.

The Swedish reporting system, lex Maria

The Swedish system for reporting medical errors (lex Maria) is the result of an event in 1936 when four people died after receiving mercuric oxycyanide instead of an anesthetic (Ödegård & Löfroth, 1996). Lex Maria requires by law that health care personnel report serious near-accidents and errors to the National Swedish Board of Health and Welfare (NBHW). The original purpose for reporting such events, which was to attain evidence to facilitate a police investigation, had a clearly disciplinary aim the result of which was that investigations came to be focused on the individual caregiver. Over the years the intention of the legislation has changed, and it now has a preventive aim where the purpose of reporting is to obtain

knowledge about the risks. Nevertheless, the state authority still has the responsibility of determining the need for possible disciplinary action. This means that health care personnel are required to report errors for which they may receive sanctions (SFS 1998:531). During 1998, 117 lex Maria incidents were forwarded to the Medical Responsibility Board (MRB) by the NBHW for possible disciplinary action.

The perception of mistakes

The culture in the health care sector is characterized by a striving for faultlessness and by the nonacceptance of mistakes (Rosenthal, 1994). This view contributes to feelings of guilt and shame. In addition to the fear of making mistakes, there is also the threat and fear of being reported (Wu et al, 1991; Vincent, 1997; Cristensen et al, 1992), and the one-sided focus of the mass media on the individual can contribute to this (Crane, 1997). Furthermore, the health care unit runs the risk of negative "publicity," since a report to the NBHW constitutes a public document that is accessible to the mass media. Another factor that further influences the perception of errors is the connection between the reporting system and sanctions, something that can also lead to a decreased tendency to report incidents on the part of health care personnel. It is probably the case that these factors affect the openness about discussing risks in health care and that they also contribute to the reduced reporting of risks (Lucas, 1991; Leape, 1994; Reason, 1997).

Medical errors

Various studies have tried to determine the scope of injuries resulting from health care and treatment. In 1960, a prospective study in the USA showed that the proportion of iatrogenic injuries amounted to 20%. Of these, 20% were comprised of serious injuries or death (Shimmel, 1964). In one of the studies receiving most attention, which was conducted in 1984 in 51 hospitals in New York State, 31,121 randomly selected medical records were examined. The percentage of "adverse events" was determined in the study to be 3.7% (Brennan et al, 1991). An "adverse event" was defined in the study *"as an injury that was caused by medical management (rather than the underlying disease) and that prolonged the hospitalization, produced a disability at the time of discharge or both"* (Brennan et al, 1991). If these figures are extrapolated to include the entire population of New York State, i.e. approximately 2.6 million patients, 98,600 adverse events would have taken place. For the entire USA, corresponding figures would mean that 1.3 million people are injured annually in the health care sector, which is more than double the number of traffic injuries occurring annually in the USA.

A similar study in Australia showed that the percentage of adverse events was 16% (Wilson et al, 1995). A later study from the US confirms the Australian results (Andrews et al, 1997). In the Australian study "adverse events" were defined as being unintentional injuries or complications caused by the health care sector resulting in disability, death or prolonged hospitalization. Of these adverse events, 13.7% resulted in permanent disability and 4.9% in death. However, the study also showed that 51% of the adverse events were deemed preventable. The corresponding figure in the USA was 69% (Leape et al, 1991). No similar studies have been conducted in Sweden.

The risks are increasing

Modern health care places high demands on personnel through the use of more technically complicated apparatus and advanced monitoring equipment. Furthermore, major structural changes are underway, often involving large financial incentives (NBHW, 1998). A larger number of more seriously ill patients are cared for at home, while at the same time fewer opportunities exist for further education for health care personnel, especially those lowest down in the health care hierarchy, i.e. nursing assistants and practical nurses. The substance of health care education is changing, which may result in erroneous expectations concerning, for example, the clinical skills of newly graduated nurses. And in combination with an inadequate introduction to a new job, this may constitute a risk factor. Furthermore, there are growing numbers of alarming reports on stress, the fast tempo and the poor staffing, as well as the unreasonably long length of work shifts, especially for doctors in emergency care. Baldwin et al (1997), have demonstrated the association between the number of estimated serious errors and a heavy workload and a feeling of incompetence.

Reports in Sweden

Information concerning the scope of the problem in Sweden can be obtained by compiling the reported events submitted to the MRB, the Patient Insurance System, and the NBHW, which are the monitoring authorities for the health care sector. Patients who are dissatisfied with the care they have received can report personnel to the MRB, which can be likened to a court for medical issues. Financial compensation for medical errors can be obtained by applying to the Patient Insurance System, which is a "no-fault" insurance program. Therefore, the question of guilt is irrelevant with respect to compensation. The criterion for compensation is a complication that was not anticipated. Another source of information concerning medical errors is comprised of the events reported to the NBHW in accordance with *lex Maria*. The general public may also report complaints regarding health care to the NBHW. The compilation in Table 1 shows that reports from patients to both the Patient Insurance System as well as to the MRB are increasing, while reports from the health care sector to the NBHW have decreased in recent years.

According to the quality assurance regulations introduced in 1996 (SOSFS 1996:23) the health care providers are required to monitor unwanted events and to draw systematic conclusions from such information. The authorities believe that the decrease in the reporting of risk events partly is due to this increased responsibility. Therefore, the number of risk events can be assumed to be much greater than that reflected by the *lex Maria* reports.

Table 1 The number of injuries reported to the Patient Insurance System, the MRB, and the NBHW

Reports to	Years				
	1994	1995	1996	1997	1998
Patient Insurance System	7 311	7 371	7 321	7 775	8 283
MRB	2 414	2 521	2 659	2 860	3 107
The NBHW					
Lex Maria	1 567	1 418	1 371	1 202	1 133
Complaints from individuals				1 060	1 337

International Safety Research

The fact that patients are accidentally injured in connection with health care and treatment can naturally be related to the medical treatment and constitute a normal risk. An error may also be the result of human error, such as lack of concentration, forgetfulness, or a misinterpretation of a situation.

In international safety research, which has its origin in cognitive psychology and "human-error" research, terms such as *active* and *latent* errors (or latent conditions) are used (Reason, 1990; 1997). Active errors are usually committed by individuals who, last in a long chain of events, trigger the accident, such as pilots, nurses and doctors. The action leads to an immediate consequence. In contrast, latent errors originate from faulty decisions often made by people who are indirectly involved in production. These decisions can later result in negative consequences through chain reactions that lead to active errors. Examples of latent errors can be the restructuring of work units, insufficient resources that lead to staff reductions, faulty design of technical equipment, inadequate coordination of resources, poor access to competent professionals during on call hours, unrealistic scheduling, etc. These are factors that can affect the individual's actions and constitute the indirect cause of an "active error".

Another theoretical point of departure is Rasmussen's (1987) so-called "SRK model" which defines human error using three dimensions: Skill-based, Rule-based, and Knowledge-based levels. Skill-based behavior refers to routine tasks that require little or no attention to be completed, which also means that other tasks can be done simultaneously. Rule-based behavior refers to normal activities that require a certain degree of decision-making. The knowledge-based level refers to problem-solving activities such as when one is confronted with situations for which a solution is not yet known.

Research in behavioral science that explains the causes of human error in complex systems has for many years influenced work conducted in the area of safety in high technology areas such as aviation, offshore operations and nuclear energy (Perrow, 1984; Rasmussen, 1987; Reason, 1990). How these industries manage risks is becoming increasingly interesting to the health care sector, especially in technology-intensive areas such as surgery, anesthesiology, and intensive care (Eagle, 1992; Gaba, 1994; Helmreich, 1997).

PURPOSE AND METHODS

The overall purpose of this study is to examine whether the methods of risk management used by civil aviation are relevant to work with prevention concerning patient safety, and thereby the work environment of health care personnel, and whether it is also possible to apply these methods throughout the health care sector, even in non-technical areas. The foundation for this study includes not only civil aviation, but also military aviation and nuclear power. Only experiences from civil aviation will be reported in this article.

The material is based on interviews with those responsible for safety and quality in civil aviation in Sweden and the USA. Interviews were also conducted with representatives of the Board of Accident Investigation, as well as with the monitoring authorities for civil aviation in Sweden (the Aviation Safety Department) and the USA (the FAA - the Federal Aviation Administration). In addition, interviews were conducted at NASA regarding the incident reporting system used by the US civil aviation industry. The material is also based on regulations and other written documentation. A total of 12 interviews were conducted on location in aviation organisations, all of which were recorded and transcribed in their entirety. Following the interviews, supplementary questions were posed where appropriate via telephone. The questions were focused on safety, with emphasis on risk management. A compilation of the basic material was communicated to those interviewed. Those parts of the risk management system used in the civil aviation, and which are considered applicable to the health care sector, are presented in this study.

RESULTS

Safety in civil aviation is based on international guidelines in accordance with the Chicago Convention, and the guidelines have been operational since 1944. In order to administer the agreements from the convention, the International Civil Aviation Organization (ICAO) was formed. There are 183 member nations, and each nation determines its own regulations. The European unification efforts are having an increasing influence on Sweden's regulations. Work is underway to develop common inspection routines and a mutual inspection database for member countries in Europe. Since the regulations in Sweden and the USA are relatively similar, this account is mainly based on Swedish civil aviation and Scandinavian Airlines (SAS).

Monitoring

The National Aviation Authority monitors operations as well as individual pilots and flight technicians. The same is true regarding the FAA in the USA. SAS, which is the largest civil aviation company in Scandinavia, has its own monitoring authority, as a result of its ownership situation. This is because the company is under the jurisdiction of legislation in three nations, and is subject, in principle, to the most rigid requirements in each country. SAS is monitored by the Scandinavian Supervisory Office (STK). Aviation monitoring has previously focused to a large degree on checking the physical details of the equipment. The advanced technology characterizing the aviation industry today no longer permits this type of inspection and monitoring. This is one of the reasons why operational monitoring was instituted. Operational monitoring means that each company itself has the main responsibility for directing and monitoring safety. The existence of established routines and standards is monitored by the authority (SOU 1996:74).

Representatives of the aviation monitoring authorities in both Sweden and the USA have said that one of the difficulties at their level is the dual role involving both prevention as well as supervision and inspection. When regulations are violated in the aviation industry, sanctions are possible both in Sweden and the USA, but authorities are very restrictive with regard to sanctions.

Organization of work concerning safety

The larger airline companies in Sweden and the USA have a specific organization for work related to safety. In addition to the groups that work on general safety issues, there are groups concentrating on the development of methods and on analyzing reported incidents. And the Swedish Aviation Safety Department and its American counterpart, the FAA, have specific groups that work exclusively with safety analysis.

Investigations of serious aviation incidents in Sweden are carried out by the Board of Accident Investigation (SHK) which is an independent authority. The SHK investigates aviation accidents that result in death, serious injury or major damage to the aircraft or environment (SFS 1990:712). In addition, the SHK investigates marine and railway accidents and near-accidents. Other serious accidents may also be the subjects of SHK investigations. The SHK was established to avoid partiality, or in other words so that the authority responsible for monitoring safety would not also be responsible for investigations in this area, which could result in a situation where the authority would refrain from criticizing the area under investigation too harshly. The American counterpart to the SHK is the National Transportation Safety Board (NTSB).

SAS also has a special inquiry group within the company called "the Saint Group," which in principle works according to the same standards as the SHK. The composition of the group is determined by the type of incident that has occurred. The Chair of the investigation group is required to report all significant findings that are judged to require immediate measures to those responsible in the line of command. Those persons who are directly involved in the incident are given the opportunity to read and comment on the rough draft of the report.

Examples of safety-related work in the aviation industry

Risk reporting

In addition to reporting to authorities, each airline is responsible for an internal reporting system. These requirements are based on ICAO recommendations. In Sweden, reporting is to be done to the National Aviation Authority, and for SAS, reporting is to be done to their own authority. Reports are made using special forms or forms created by each individual company. A comprehensive reporting system exists within SAS for various types of risks, with detailed instructions for definitions, reporting criteria and the handling of information.

According to ICAO recommendations, an investigation should include information gathering, examination of the data and analysis of all available, relevant information, and if possible, it should identify causes of the event. The only purpose of an investigation is to prevent accidents and/or incidents. The final report should also suggest recommendations for measures to improve safety. All legal or administrative measures that may involve guilt or punishment must be kept separate from the investigation. A specific restriction states that information discovered during an investigation may not be disclosed if the information will be used for disciplinary purposes. *"If such information is distributed, it may, in the future, no longer be openly disclosed to investigators. Lack of access to such information would impede the investigative process and seriously affect flight safety."* (ICAO, 1994 Annex 13).

Risk Analysis - Monitoring

In order to increase information used for work with prevention and safety, SAS has established a special monitoring system for its cabin staff, in addition to the traditional reports for deviations related to safety. Through this certain predetermined items are investigated. The purpose of the system is to study how well established procedures are followed and whether these procedures have weaknesses. This insight provides the flight operative unit with a basis for improvements with respect to quality and safety-related issues. In order to make examination of possible trends possible, most items are repeated from month to month. And to maintain continuous interest in the system on the part of the flight operatives unit, there is space for temporary items for shorter periods of time (one or two months). This makes it possible, for example, to check the implementation of new procedures or to carry out special studies. The flight manager selects specific areas for examination. Approximately 3% of all SAS flights are monitored each month, which generates between 800-1,000 reports.

A new type of flight safety monitoring is planned for pilots, which means that their actions and a number of predetermined items will be evaluated. Prior to a flight the pilot will obtain a form with questions selected by the company concerning information of interest. An additional type of monitoring used in the aviation industry is the flight recorder, the so-called black box, which can measure up to approximately 1000 variables and which provides valuable information about how the flight is carried out. At SAS the flight recorder is analyzed after each flight. There is also a voice recorder, which is analyzed only after accidents.

The reporting system used by the civil aviation in the USA

The reporting system used by the civil aviation in the USA was established with the aim of increasing the reporting of incidents. The Aviation Safety Reporting System (ASRS) represents "transactional immunity". This means that the FAA refrains from issuing fines or other disciplinary measures in exchange for an open account of the causes of the incident. The ASRS may not be used for disciplinary purposes, which is regulated by legislation, with the exception of criminal acts (US FAR 91.25, 1985). Events that are reported concern risk situations as well as situations that could have involved risk situations. The significance of the human factor is an important focus in the ASRS. By means of analysis of reported incidents, the aim is to obtain a base for preventive measures and improvements in the system, as well as to obtain an increased understanding of safety-related problems within aviation. Three specific factors in the system are that it is voluntary, confidential and free from sanctions.

The reporting system has its origin in two events that occurred in the beginning of the 1970s that indicated, following analysis, that there had been inadequate management of reported information by the authorities. On December 1, 1974, TWA flight 514 collided with a mountaintop while flying into Dulles International Airport in Virginia, and all on board perished. The aircraft flew at too low an altitude because the pilot misunderstood information received from the air traffic controller. Six weeks prior to the accident, a United Airlines (UA) aircraft barely escaped a similar accident thanks to the attentiveness of the pilot. The pilot had informed United Airlines and the FAA about the incident. Unfortunately, all airlines were not made sufficiently aware of information about the episode, which the accident in Virginia made very plain.

One of the investigations initiated after these events called for a better reporting system, and in May 1975 the FAA established a "non-disciplinary" and anonymous reporting system. Few incidents were reported, however, because of a distrust of the authority's promise of no disciplinary action. Following intensive debate about the design of the system, where the pilots' union demanded not only immunity and anonymity, but also that the authorities would not be allowed to monitor the system, it was decided that the National Aeronautics and Space Administration (NASA) would be given the task of developing a confidential reporting system. Furthermore, immunity would be regulated through legislation.

Proficiency Tests

Within civil aviation, regular testing of theoretical and practical knowledge is required for pilots, flight controllers, and flight technicians. In Swedish civil aviation this is regulated by the BCL; Regulations for Civil Aviation (LFS 1993:7). From 1999 the regulatory framework (JAR-FCL; Flight Crew Licensing) has been coordinated throughout Europe. For pilots, the testing comprises both theory and practice, with, among other things, flight simulator training which is done each six months. In accordance with the ICAO, 80% of the questions in each test must be answered correctly. In addition to checking the pilot's knowledge of flight regulations, the theory part of the tests also comprises knowledge of the aircraft's technical system. It is the responsibility of each airline to make sure that these tests are carried out. Furthermore, the authority also requires that each pilot complete a "line check" each year. This means that the pilot flies with an observer who evaluates and observes how the flight is carried out and how communication functions in the cockpit, with air traffic controllers and with ground personnel. An evaluation is made based on a specific schedule and is communicated to the pilot after the flight. There are also proficiency tests for cabin personnel, but these are not related to individual performance.

Experiences from serious accidents within the civil aviation industry have shown that inadequate communication and collaboration are obvious risk factors (Helmreich, 1997). This resulted in the development of a special educational program where communication between the crew in the cockpit and

other crew members, as well as with air traffic controllers is the focus. The program is called Crew Resource Management (CRM), and has now been implemented in the civil aviation industry. The CRM approach seeks to utilize the human resources in the cockpit through well-planned cooperative routines, interactive support and the breaking down of negative authoritarianism. This promotes cooperation and teamwork in the cockpit; formally the Captain is still in charge, but in practice all decisions are made by the team.

Restrictions on work hours

In both Swedish and American civil aviation there is legislation concerning work hours as well as restrictions limiting the length of work shifts from a safety perspective. The regulations apply to all crew members. The Swedish system is based on points, and is regulated by the BCL (LFS 1980:6). When schedules are made up, the amount of time on duty is not allowed to exceed 90 points during active duty, and the total number of points during the period, which is to comprise 7 calendar days, may not exceed 270 points, not counting points for landing. However, the commanding officer can agree to a maximum of 18 additional points for events which could not have been foreseen when the schedules were made up (Table 2). The airlines are required to check the work shifts and rest periods for each individual ordered to work as a crew member, and those who work for more than one airline are required to supply the necessary information to the airline in question so that scheduling can be done according to regulations.

Table 2 Calculation of on-duty points in civil aviation in Sweden

Type of activity	Time of day	On-duty points/hour
Active flight duty	06.00-22.00	6 points/hour
	22.00-06.00	8 points/hour
Landings		5 points/landing
Flight training in an aircraft or simulator		14 points/hour
Passive flight duty on the ground		>4 hours = 0 points <4 hours = 3 points/hour
<i>Decrease in on-duty points</i>		
Rest periods	06.00-22.00	6 points/hour
	22.00-06.00	8 points/hour

Even the length of rest periods is regulated, and they are to be at least 8 hours in length, and at least every other rest period should be long enough to allow the total number of points to fall to 0. In addition, within a 14-day period a crew member should be allotted 2 long-term rest periods of at least 26 hours each. These should be calculated from the timepoint at which the crew member's total number of points falls to zero. The airline is required to maintain a running record of each crew member's total number of points, and this journal must remain accessible for at least a 12-month period.

COMPARISON WITH THE HEALTH CARE SECTOR

Organizations for safety and monitoring

An obvious difference when comparing the aviation industry with the health care sector is that the larger airlines in Sweden and the USA have separate units that work with safety-related issues. Examination of the three largest hospitals in Sweden shows that there are no corresponding units working with patient safety-related issues. Patient safety is most often combined with other quality issues.

Corresponding differences also apply to the respective monitoring authorities in that civil aviation in Sweden and the USA both have separate units that work with safety issues, with special sections for investigation and analysis of reported risks (Table 3), which are not found in the NBHW. Nor are special "accident investigations" required when serious incidents or accidents occur, despite the fact that arguments

about partiality are probably the same for the monitoring authorities of the health care sector and the aviation industry, respectively.

Table 3 A comparison between civil aviation and the health care sector with respect to risk management

Type of activity	Organization for work concerning safety	Regular proficiency tests	Restrictions concerning length of work shifts*	Regular risk analyses
Civil aviation	Yes	Yes	Yes	Yes
Health care sector	No	No	No	No

*over and above the law concerning work time

Both the Civil Aviation Commission and the NBHW have decentralized organizations, and they carry out both monitoring both of activities and of individuals. Of the approximately 140 employees at the Civil Aviation Commission 2 are lawyers (1%), which can be compared to 24 of the 110 (22%) employees working with monitoring activities at the NBHW.

Reporting System

The reporting of incidents comprises an important basis for work with prevention in civil aviation. Within the health care sector, the national reporting system, lex Maria, comprises only the reports of serious events or risks for serious events. Experience has shown, however, that in principle, the latter are not reported. This means that national reporting of both serious risks as well as near-accidents is lacking in the health care sector. Furthermore, the formulation of the regulations means that lex Maria reporting and health care providers' local systems for handling deviations have an indirect connection to sanctions, which can contribute to a decreased tendency to report incidents (Lucas, 1991; Reason, 1997). In this respect the American civil aviation industry's system for incident reporting, the ASRS, is of particular interest since the person making the report has legal immunity, provided that he or she can prove that the event has been reported. Furthermore, this system is voluntary, confidential and is outside the control of the authority. In addition, feedback of experience has a very high priority.

Proficiency testing

A pilot in Sweden or the USA must undergo proficiency testing every 6 months to retain his/her flight certificate. This requirement is regulated by law and is based on common international regulations. In the health care sector, a license is a guarantee that the individual has obtained a certain level of proficiency. This license therefore can be said to constitute society's label for safe health care and is valid for the individual's lifetime. Compared with the aviation industry, health care legislation has relatively vague requirements regarding proficiency testing of licensed personnel and other caregivers. It is true that regulations concerning quality issued by the NBHW (SOSFS 1996:23) state that health care providers should make sure that staff have the necessary competency for the duties they perform. Continuous proficiency testing, however, has thus far not been a tradition in health care. That this type of "risk analysis" can provide important information concerning patient safety was demonstrated in a study conducted in the municipal health care sector, where the knowledge of 3000 nursing assistants and practical nurses concerning diabetes was tested. Among other things, the study showed clear deficiencies in how the administration of insulin was delegated to these groups, as well as serious deficiencies in knowledge (Ödegård, 1997).

Human factor research has shown that inadequate communication and an unclear distribution of responsibility can contribute to obvious risk factors (Reason, 1997). In civil aviation, this knowledge has led the authorities to require Crew Resource Management training. An example of risks in health care where a counterpart could be relevant would be during surgery, where there can be some uncertainty in the communication between the surgeon and the anaesthesiologist, and between the operating room nurse and the nurse anaesthetist. Other examples of risk factors in this area can be found in connection with reorganization in a hospital or with organizational mergers of hospitals where established routines are

changed and the composition of personnel groups is split up. Therefore, the requirement for CRM by civil aviation should probably also be relevant to the health care sector, even in areas other than anesthesiology and intensive care, where similar programs are being tested (Holtzman et al, 1995).

Restrictions on work hours

Within the aviation industry, the total number of points is not allowed to exceed 270 points during a 7-day period, or 90 points for one work shift, which corresponds to approximately 12 hours including landings (Table 3). In the Swedish health care sector a corresponding limitation in number of work hours from the perspective of patient safety is lacking. When a work schedule at an emergency department at a middle-sized hospital in Sweden was examined, it was found that a substitute doctor's schedule for a 7-day period amounted to 850 points according to the system of calculating used by the airlines - without anything extra for landings. One of the continuous shifts involved working from 7:45am on Friday until 5pm on Monday, or slightly more than 80 hours. In civil aviation this corresponds to 470 points, which is more than is allowed for a 7-day period. These calculations include planned "on-call" duty.

DISCUSSION AND CONCLUSIONS

In this study, methods for risk management used by civil aviation have been examined. The focus has been on systems for reporting risks, investigation and analysis, the organizational prerequisites for working with safety issues, the existence of proficiency testing, and restrictions in work hours as related to safety.

When compared with the health care sector, it appears that the thinking in civil aviation regarding safety is focused to a great extent on what the health care sector calls "primary prevention", i.e. measures directed at preventing the occurrence of errors. The foundation for the safety-oriented work in civil aviation is based on international research on safety, which has shown that human errors cannot be completely prevented (Rasmussen, 1987; Reason, 1995). It is also probable that the causes of human error, which may result in hundreds of people on a plane losing their lives, may be the same as when a newborn in a neonatal clinic receives the incorrect dosage of medicine, or when a patient has the wrong kidney removed. Within the aviation industry, the knowledge generated from human-factor research, for example, has resulted in a change in the thinking about safety that has influenced both legislation as well as attitudes regarding errors (Rasmussen, 1996).

Risk Reporting

A functional system for reporting risks in health care is particularly important since there are many indications that risks in the health care sector are increasing. With the present formulation of legislation regarding the reporting of risks (lex Maria), there is an obvious risk that work with prevention will be made more difficult because the risks are not reported. This means, therefore, that legislation that is intended to increase patients' safety instead constitutes an indirect obstacle to prevention. This issue is especially interesting against the background of the fact that the number of lex Maria reports continues to decrease while reports to both the MRB and the Patient Insurance System are increasing in number.

Everyone interviewed in this study felt that the most important aspect of a reporting system, irrespective of whether the reporting is to a central or a local reporting system, is that the person doing the reporting trusts the system and does not risk sanctions. The fact that sanctions can be assumed to have an inhibiting effect on the tendency to report, with the risk that serious deficiencies are not reported by the individual who committed the error, is discussed in a number of studies (Leape, 1994; Bark et al, 1997; Vincent, 1997).

Based on the association between sanctions and the reporting of errors in the Swedish reporting system, lex Maria, there is reason to consider a change in the design of the system. Sanctions against an individual who is usually very familiar with the task but who made a serious error on one occasion, probably does not result in improved safety. Work should instead be directed towards other solutions (Leape, 1994; Vincent et al, 1998; Reason, 1997). An example is mistakes with medication which, despite disciplinary measures for the individual, are one of the most frequent medical errors in health care. So-called "active errors" in handling medications constitute an area where today's technical possibilities regarding prevention

are probably greatly underutilized, which may be explained by the insistent assertion that the personnel "must learn to read".

In an information system with the purpose of gathering information for preventive measures, "near-errors" are important because they help achieve the necessary volume and because they provide important information about weaknesses in the system (Van der Schaaf, 1992). Near-errors are events that could have had negative consequences, but did not. Reason (1997) states that near-errors provide free lessons and can, if analyzed in the right way, function as a vaccine in order to mobilize resistance. In contrast to the aviation industry's incident reporting system in the USA, where the reporting of incidents is encouraged, the Swedish health care sector has restricted the criteria for what should be reported. Two examples are injuries due to falls and medication errors.

Restrictions in work hours

There have been recurrent discussions in the health care sector concerning the work hours of doctors, in particular, although usually not in terms of patient safety. Despite the fact that extremely long work shifts are not as common today as in the past, long shifts regularly occur at some departments. Scheduling a doctor in an emergency department to work an 80-hour shift is an example of what is considered a latent error in safety research. Using this example in which a doctor has an unrealistic work schedule, the reason for an error should be sought in the organization and the administrative manager. It is true that in this example on-call duty is included, but a doctor on first call or second call in the area of emergency care has a high probability of being called. That an individual's judgment and ability to react are reduced as a result of sleep deficiency and fatigue has been demonstrated in simulator studies (Howard et al, 1997). In addition to these risk factors, an extremely long period of on-call duty can mean that other staff members take this into consideration and incorrectly hesitate to "disturb" the doctor. Arguments focused on increased costs and technical scheduling difficulties should be considered in relation to the individual patient's safety, but they are also relevant from a work environment perspective

Risk analyses

Within the aviation industry, it appears that work concerning prevention, including legislation, is more offensive and focuses on identifying risks before they result in errors, which can be explained in terms of the nature of the industry. In a comparison between a cockpit and an operating room, however, it is probable that the activity in the operating room would be judged to be more risk-filled. This indicates that the thinking about safety should be as well-developed in the health care sector as it is in the aviation industry. Similar clear requirements, with restrictions concerning the length of work shifts, and risk analyses when organizational changes are planned and prior to planned vacations, when making work schedules and on-call systems, as well as proficiency testing, would all contribute to increased safety. Introduction of new equipment and methods is another area where risk analyses are motivated. This would also increase awareness about risks in health care and thereby result in an improved basis for measures to increase safety.

Organizational prerequisites

A number of factors may have contributed to the fact that the health care sector does not have the well-developed awareness concerning safety as does, for example, the aviation industry. It may be that the effects of an error are of some significance, since an error in civil aviation can mean that hundreds of people lose their lives, while an error in the health care sector is not as obvious, which has therefore meant that the problem has not received more attention. Today the health care sector does not have an authority with prevention as its sole purpose, which investigates adverse events in health care. The same is true on the local level. Insufficient insight about the causes of human error and what is called "organizational accidents" in safety research (Reason, 1997) can result in an incorrect focus on those at the lowest end of the health care hierarchy, who make a mistake. This means that the latent errors remain, with the risk that the errors will be repeated.

The possibility of examining the issue of guilt when an error has occurred is naturally important to the general public. The Swedish model with the MRB is therefore valuable and should be maintained. The "court-like" function of the MRB is probably advantageous for "accused" health care personnel. On the other hand, it is doubtful whether safety in health care benefits from the fact that both the MRB and the

NBHW investigate possible issues of guilt, particularly when there is no authority/organization that explicitly works with safety in health care from a national perspective.

CONCLUSION

The conclusion of this report is that organizational prerequisites for working with safety should be improved at both local and national levels, with units working explicitly with patient-related safety issues with no focus on issues of guilt. A national, voluntary reporting system which also includes so-called near-errors, without any connection to sanctions or the monitoring authority, should be considered. Work with prevention should be based to a greater extent on identifying weaknesses and deficiencies in both existing and planned activities. For example, there should be clearer requirements for carrying out risk analyses. Restrictions concerning length of work shifts should be considered for all health care personnel, as should regular proficiency testing. Patient safety in the health care sector should receive increased attention as a problem area, and research and development should be promoted. Furthermore, the prerequisites for work with prevention and patient safety should be optimal, and the legislation intended to increase patient security and safety should be clear, unambiguous and readily applicable.

One year after the airline accident in the USA, the resultant reporting system, the ASRS, became legislation. In the Swedish health care sector, a serious dialysis accident occurred in 1982, costing three people's lives. The debate still continues regarding the need for an increased focus on the system instead of on the individual when medical errors are investigated. Questions pertaining to organizational prerequisites for secure and safe health care, such as work conditions and the length of work shifts, were discussed in an editorial in one of Sweden's daily newspapers as early as 1936 in connection with a serious medication error at Maria Hospital in Stockholm.

Cognitive psychology and safety research have shown that certain incorrect behaviors cannot be eradicated by education or punishment. For such cases, other types of barriers must be developed that make it more difficult or impossible to make errors. Not until this is understood will safety consciousness in the health care sector develop - which is something that would benefit both patient safety as well as the work environment of the staff, who, in addition to experiencing the fear of committing an error and the threat and fear of being reported, often work in a hard-pressed situation.

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IV



Perceived potential risk factors in child care

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Keywords *Patient care, Children, Health and safety, Risk assessment*

Abstract *This study is based on semi-structured interviews focusing on staff members' opinions about potential risk factors that could threaten patient safety. The aim was to acquire more in-depth knowledge about the causes of patient injuries. The study, which was conducted at a children's hospital, has a qualitative approach that is influenced by the critical incident technique. A total of 28 persons were interviewed. Analysis of the data resulted in five qualitatively differentiated categories of potential risk factors: a large influx of patients, a lack of professional experience, a lack of inter-professional communication and cooperation, and deficiencies related to work hours and to the physical environment. The results reflect a complex picture where the risks, as described by the informants, can either alone or in concert directly or indirectly affect the individual in the practice of his or her profession or contribute to a mistake.*

Background

An increasing number of studies show that patients injured in health care constitute a substantial problem (Brennan *et al.*, 1991; Wilson *et al.*, 1995; Thomas *et al.*, 2000; Vincent *et al.*, 2001; Schiöler *et al.*, 2001). In a much discussed article entitled "To err is human" (Kohn *et al.*, 1999), data were extrapolated from two large-scale studies in the USA. The results showed that between 44,000 and 98,000 patients die every year due to injuries caused by health care. It is estimated that more people die in the USA as a result of such injuries than from traffic injuries, breast cancer and/or AIDS. In addition to human suffering, these patient injuries involve high costs for health care, society and the individual (WHO, 2002; Classen *et al.*, 1997). Bates *et al.* (1995) estimated the annual costs for medication-related injuries judged as preventable at a 700-bed hospital at 2.8 million US dollars.

Preventive work aimed at decreasing the number of patients injured in health care requires access to information that sheds light on the risks involved and the factors influencing the origin of these risks (Cook *et al.*, 1998). Information based on reported risk situations and incidents constitutes a common basis for work with patient safety (Gosbee, 2001). However, due to underreporting, which is a well-known problem associated with reporting, it is likely that such information does not reflect the actual risks (Billings, 1998; Leape, 1994). One reason for this is the fear of negative consequences for the reporter, which can lead to attempts to conceal the incident (Wu *et al.*, 1991; Ennis and Grudzinskas, 1993; Bark *et al.*, 1997). Other possible reasons can be a lack of time, or that reporting is not perceived as beneficial, which can result in a lack of motivation to report incidents (Billings, 1998). The problem can also be of a qualitative character due to lack of information. Another reason can be inadequate analysis of the incident, with the consequence that underlying factors related to the incident are not identified (Hale *et al.*, 1991). This can result in an incorrect focus regarding preventive measures. Additional problems are related to qualitative shortcomings in reporting patient injuries, and that feedback regarding experiences



comes far too late, with the result that the information does not shed light on the risks in question.

All in all, there are many weaknesses associated with information based on reporting, irrespective of whether the reporting system is local or national. Information based solely on such systems can therefore be expected to provide inadequate support for decisions in preventive work with safety. An important argument as to why reporting of patient injuries is inadequate from a preventive point of view is that "the injury has already occurred".

Experiences from safety research, which have long influenced work with safety in other high risk activities, are beginning to have an increasingly greater effect on health care (Helmreich, 2000; Reason, 1997; Hollnagel, 1998). Analyses of accidents in areas other than health care have shown that underlying deficiencies are often of crucial significance regarding the occurrence of an accident (Perrow, 1984; Rasmussen, 1997). Knowledge of underlying factors that can influence the occurrence of patient injuries is of decisive importance regarding the focus of preventive work (Reason, 1997). In the ongoing debate concerning health care in Sweden, health care professionals often express their frustration and feeling of powerlessness regarding the conditions under which they are forced to work. Examples of newspaper headlines include "Health care staff under increasing pressure", "Tired doctors a danger in health care", "We're thrown in the water before we can swim", where the articles deal with the insufficient introduction doctors receive. On the whole, the articles signal deficiencies, indicating that it should be possible to identify potential risk factors before they result in negative consequences for patients. In addition, international studies have shown that a large proportion of patient injuries (57 percent to 76 percent) are judged as being preventable (Leape *et al.*, 1991; Wilson *et al.*, 1995).

The question is whether semi-structured interviews based on staff members' opinions about risks can contribute to improved access to information for use in preventive work to decrease patient injuries in health care. Based on the ideas and perceptions of this group concerning potential risk factors in health care, the aim of the study is therefore to acquire more in-depth knowledge about the causes of patient injuries, in order to improve the basis for preventive measures.

Method

The study has a qualitative approach and is influenced by the critical incident technique (CI), a method for identifying critical incidents that was developed during the Second World War in the American Airforce Aviation Psychology Program (Flanagan, 1954). The method was originally used by trained observers, with good knowledge of the activities in question, who studied critical incidents that had been defined beforehand in accordance with specific criteria. In concrete terms, this method means that based on his/her professional experience, the respondent reflects on specific situations experienced as critical. Incident was defined as "any observable human activity that is sufficiently complete in itself to permit inferences and predictions to be made about the person performing the act" (Flanagan, 1954, p. 327). For an event to be "critical" it should occur in a situation where the aim or intention of the activity "seems fairly clear to the observer and its consequences are sufficiently definitive to leave little doubt concerning its effects" (Flanagan, 1954, p. 327). The technique has come to be used in many areas, including health care.

By systematically interviewing staff members about their recollections of critical incidents, which can have occurred recently or farther back in time, a number of conceivable risk scenarios are surveyed. In this study the critical incident method was modified, and it is based upon open interviews with health care staff concerning their perceptions of conditions, situations and behavior that could directly or indirectly result in the injury of a patient.

Survey group, selection and implementation

The study was conducted at a children's hospital. Selection of the respondents was done by group leaders, with the understanding that these individuals were to represent a normal staff profile. This meant that staff with both short and long experience, those who worked in the daytime as well as those who worked at night, and those with different professional backgrounds were to be included in the study. Prior to the interviews, the presumptive respondents received an information letter about the aim of the study, a written inquiry concerning participation in the study, and information about the fact that participation was voluntary. Appointments for the interview were then made for those who were willing to participate. The interview took between 40 and 60 minutes and a total of 28 persons were interviewed (15 nurses, eight doctors, three assistant nurses, one children's nurse and one secretary). Owing to the acute nature of this health care area, some of the planned interviews could not be carried out. Instead, individuals were interviewed who had not been asked in advance about participation but who had time, at that particular occasion, and who were interested in taking part in an interview.

Open interviews

Prior to the interviews, a number of general questions were formulated focusing on areas such as technology and organization, communication, and teamwork related to patient safety. All the respondents agreed to having the interview recorded under the condition that the material would be handled confidentially. Each interview was therefore given an ID number. The interviews were conducted in the form of individual conversations with the respondents and began with information about the preventive aim of the study and its particular focus on identifying problems or deficiencies that could threaten patient safety. The respondents were then asked to think of situations, behavior or conditions they felt could result in a patient being injured. Follow-up questions were posed depending on the answers the respondents gave. The questions concentrated on personal professional experiences and the respondents' recollections of situations that involved risk. In conclusion, the respondents were asked what they felt was the greatest threat to patient safety.

Analysis of the data

Analysis of the transcribed data was performed in two steps. The initial coding was done using a qualitative computerized analysis program (Atlas ti), by means of which every paragraph got a number that was related to the ID number of the respective interview. A general coding was done based on quotations containing concepts, situations and conditions the first author (SÖ) related to potential risk situations, and that could be related to a direct or indirect risk that a child could be injured. The codes were continually compared so that similar phenomena or situations received the same

designation. The ID numbers of the interviews made it possible to go back to the original interviews to ensure the “content” of a certain code (the part) by once again analyzing it in its correct context (the whole).

In step two, the codes were grouped into general categories that described as clearly as possible what they dealt with, with the aim of reducing and summarizing the data. This part of the analysis was done manually. In each phase of the analysis, great emphasis was placed on verifying that the categorization was in accord with the original meaning in the interview material. A main category was determined when it was obvious that the pattern in the interviews could be related to the same category.

Results

Analysis of the data resulted in five qualitatively differentiated categories describing staff members’ perceptions of potential risk factors in health care (Table I). Each of these potential risk factors, or several of them working together, can result in patients in pediatric care being injured in connection with their care and treatment. A detailed description of the content of each category (risk factors) is presented below and illustrative quotations from the interviews are included. In reporting the results, the risk factors were not ranked.

Large influx of patients

Many respondents described factors experienced as indirectly threatening safety in health care. The prevailing work situation with a very large influx of patients, resulting in a heavy workload for the staff, was experienced as an important risk factor by the informants. The large influx of patients was considered an example of the consequences of political decisions. Difficulties in reaching different clinics and primary care centers by telephone, i.e. the inaccessibility of care, results in parents going to hospital emergency departments, even for less serious complaints and symptoms. As health care staff cannot turn away parents with sick children, the result is that children are examined who, from a medical standpoint, have only minor complaints:

When this place was opened the idea was that it should be for the sickest patients. Without any real statistics, I’d guess that 25 percent don’t need to be seen by a health care professional at all, perhaps 25 percent should see a nurse or doctor in an outpatient care setting in the next 14 days, and 50 percent should come to an emergency department, so of course there are many who come here who shouldn’t be here at all; I feel there’s a risk in this large influx we have – in the brief moment you have with the child, seeing that this is a child who’s just a little bit sicker is difficult.

According to the interviews, the staff have great understanding for the fact that parents want to see a pediatric specialist, but they say that many doctors working at the emergency department are actually inexperienced in pediatric medicine and lack experience in caring for sick children.

A heavy workload means that one must rely on co-workers’ assessments to a greater extent than one would really like. The difficulty in attaining an adequate, professional overview of the children’s conditions results in a feeling of insufficient control over one’s work situation.

Perceived potential risk factors	Perceived risk-increasing factors
Large influx of patients	Heavy workload for the staff Difficulty in attaining adequate professional overview of the children's conditions Large number of patients leads to insufficient time for reflection and the necessity of relying on others' assessments Long waiting times lead to irritation on the part of parents, which has a negative effect on the staff Insufficient backup from the doctor on second call leads to an increased press for time and an increased workload for the doctor on duty Increased number of tests and examinations ordered as self-protective measure on the part of the doctor Intense tempo can lead to deficiencies in handling referrals
Lack of professional experience	Difficulty in correctly interpreting signals from the children can lead to risks for incorrect assessments and prioritizing of care measures Insecurity in one's professional role affects one's own actions as well as those of others. Inexperienced staff do not dare to question anything and others do not dare to trust those who are inexperienced Because of insecurity doctors admit too many children, which affects other staff both in the clinic and on the ward.
Lack of interpersonal communication and cooperation	Unclear delineation of responsibilities Incomplete documentation and incomplete medical record notes with increased press for time New technology can hinder the daily increase in nurses' competence Too little time for reporting between doctors when going on and off duty
Deficiencies related to the physical environment	Inadequate space for emergency procedures in the daytime can lead a non-optimal times for operations Lack of beds on the wards can lead to the child being admitted to the "wrong" ward, which can mean that the staff do not have the right competence for the specific area or that the child is forgotten on rounds Crowded premises and inadequate access to examination rooms affects the possibility of good documentation Injection pumps with loud alarms
Deficiencies related to work hours	Long tours of duty when on call can result in deficient acuity, observation and judgment Management is "forced" to break the law in order to get the system to function Other staff avoid calling the doctor so as not to disturb him/her Long work hours also affect other categories of staff negatively Fatigue, stress and far too fast a work tempo

Table I.
Overview of categories describing the health care staff's perceptions of potential risk factors and related risk-increasing factors in child care

When sick kids and their parents pour in so it's like a buzzing swarm of bees when you're sitting here at the admission desk ... when you don't have any control over what comes in and how they feel; it gets like a line for a sale out there. Being able to analyze each patient and adequately treat each one as if you only had one patient – that's almost impossible in the current environment.

The large influx of patients that results in long waiting times for parents and children is experienced as a significant risk factor. Regarding the heavy workload, a doctor expressed the following:

The whole time you have to plug up the holes where it's leaking the most, and this constitutes an element of risk and above all a work environment problem.

The staff also worry that a child sitting in the waiting room will get worse without the parents making them aware of this. Another source of worry is that a child in acute need of professional care will “disappear in the crowd”. According to the interviews, it is often the considerate, quiet parents who get into trouble. A heavy workload, in combination with the fact that there are sometimes deficiencies in the doctors' backup-system, is also considered a risk. If the doctor on second call does not come in to work despite the need, the doctor on duty has trouble managing all the other patients. The workload at the clinic thereby increases, according to the interviews. The increased burden on the doctor on duty can result in patients being admitted to the ward without medical orders or current notations in the medical record being available. Increased demands for test taking and other examinations in order to make a definitive diagnosis also contribute to an increased workload:

There's a much greater demand today not only to make a probable diagnosis but also to rule out the 20 other diagnoses, and that in turn results in an enormously increased number of tests and examinations. And this is also a burden on the patient. You know yourself that you do a large number of tests to protect yourself and to rule out things that are serious.

The interviews showed that the staff are aware that a lack of time leads to risks in health care:

As far as right and left are concerned it's very easy for mistakes to be made. Stress constantly creates risks for the patient – a lot has to be done very fast in relation to the staff and time and even checking things. Double checks are also supposed to go fast – everything should go faster today and that means that the risk for the patient increases. You miss a certain percent – that must be the case when the tempo increases. If you're the only one on duty and the waiting room is full, then you can't examine everyone thoroughly – but it's the production speed we're supposed to maintain ... from the perspective of patient safety this is naturally totally unacceptable – but this is something we have no control over.

A lack of time, especially because of a heavy workload, recurs in the interviews as a perceived risk factor that can endanger children's safety in health care. In addition to experiencing stress, the staff perceive not being able to do a good job as mentally stressful:

You don't have time to think and maybe ventilate to the extent you might want, it's not possible to double check, and then of course we have quite a few (children) who are pretty healthy, you're scared to death of missing something.

According to the informants, the lack of time and the stress caused by this can also result in inadequate handling of referrals at the clinic or ward:

... when you're under so much stress and you just rush by one another because you have so much to do, it could be that you forget to look at a referral reply, for example. You have three different boxes you have to check and you also have to have time to go there. Then maybe test results are lying there that you don't have time to follow up. I had a child that came back after treatment for a urinary tract infection and when she finished taking the medication she got sick again, and then I called the lab and it was resistant to ... the results must have come to someone but weren't followed up.

Lack of professional experience

Many informants mentioned lack of professional experience as a significant threat to patient safety. Since children present different symptoms than adults, experience in pediatrics was judged necessary in order to identify symptoms in sick children. The risks pointed out in the interviews were mainly incorrect assessment and prioritizing of the child upon arrival at the hospital. According to the informants, incorrect prioritizing can have devastating consequences, especially against the background of the large influx of patients and the feeling experienced by these informants of insufficient monitoring of the children in the waiting room:

With triage (a function at the clinic), they sort out those who are the sickest and they do that all the time, but it's hard to prioritize sick children, and if you have inexperienced nurses doing this there's naturally a risk that a child who should probably be given priority ends up in the waiting room.

The risk with lack of experience in relation to prioritizing care measures can be illustrated by an inexperienced nurse who only read what was written on the referral without understanding what it meant. The event concerned a one-year-old child with abdominal pain who was given the wrong priority by an inexperienced nurse:

An experienced nurse wouldn't have bothered with what was written on the referral, but would instead have said, "OK, a one-year-old with intermittent abdominal pain – we have to examine him right away".

Lack of experience was also considered a risk associated not only with one's own duties but that could also result in insecurity concerning one's own professional role. One nurse said that if you are new at a job perhaps you do not dare to question an incomplete or ambiguous order:

You can hardly see what they write in their orders; you get a verbal order right over the counter like, "should get fluid", and then they go and write the order. Some have very bad handwriting and for anesthetics sometimes they just write "anesthetize", and then there can be misunderstandings.

Doctors with a lack of experience, such as those whose backgrounds are in areas where the tempo is not as fast as in acute care, are also considered a risk in pediatric care. According to the interviews, acute care clinics must have a high tempo so that waiting times for parents and sick children can be reduced. Too slow a tempo is thought to have negative effects on safety, in that longer waiting times lead to irritation on the part of parents and stress on the part of the staff. Another reported risk related to a lack of experience on the part of doctors is that the doctor is far too cautious and admits

more patients than necessary. According to the interviews, criteria for the concept of experience have changed because of the high staff turnover. "Staff members who were new six months ago are considered old today."

Lack of interprofessional communication and cooperation

A risk factor described in the interviews that was related to a heavy workload and a lack of control over the situation in the waiting room was an unclear delineation of responsibilities between different categories of staff. An example was uncertainty regarding when responsibility passes from the nurse to the doctor. For instance, one of the respondents wondered if you can take responsibility for someone you have not seen.

Incomplete documentation, such as incomplete orders and medical record notes for patients who are being admitted to the ward, was experienced as a recurring risk in pediatric care. According to the informants, these risks, which primarily concern medication orders, are associated with the increasing pressure for time in health care. Some thought that computerization was a problem because it was felt to take more time than before and that the system had not yet been completely introduced in the hospital. The medication module in the computer system was also felt to be far too unreliable. Many informants felt that introduction of new computer technology increases the risk of mistakes during the introductory phase:

It was a good idea to be able to write orders on the computer, but the picture doctors saw was totally different from the one nurses saw when they were preparing the medication. It's crazy. The pediatric ICU forbade this system because it was so dangerous.

In the radiology department, it was thought that introduction of new technology could hinder the daily increase in competence of the nurses in the long run. Nurses previously got a direct response when they showed the films to the doctor. Introduction of the new technology was felt to constitute an element of risk, since nurses and doctors thereby communicated less with one another. Too little time for reporting between doctors when going on and off call was also thought to be a potential risk factor in health care:

I think that sometimes there's too much reliance on secondhand information so there really isn't enough time for giving verbal reports ... some tours of duty have a half hour overlap and some don't.

Deficiencies related to the physical environment

Factors related to the layout and design of premises were reported in the interviews as risks that indirectly contributed to the children's safety. An example was inadequate space for emergency procedures in the operating room during the daytime. This leads to delayed treatment of the patient, which can mean that the patient's condition deteriorates and the need for care measures becomes acute. The lack of space for acute procedures during the daytime can result in patients being operated on at night, even when an emergency operation is unnecessary:

But if I don't go in and operate at night I ruin the next day's schedule. So no matter how tired you are you go in and operate ... with some things the quality would be better if they were left to the next day. The clinic was built for 30,00 patients and we get 50,000 per year instead. I think that says it all.

Another risk reported in the interviews concerned the effects of a lack of beds on the wards. This can result in children being admitted to a ward not specialized in what the child's illness requires. The informants perceived the risk to be that the staff then lack competence in this specific area:

It's wrong if a child with abdominal pain or a child who's had an appendectomy or something like that has to be on an orthopedic ward, I think that's wrong ... because they aren't as used to seeing children with abdominal pain, they (the children) don't react the same way; then maybe it isn't as easy to think in surgical terms if you're used to handling diabetes or something else. Abdomens are something you really want to check. I've been involved in some things ... they haven't been operated on in time, but there hasn't been any serious incident, but you can feel it in the air that it could happen any time.

Another example of risks when children are admitted to the "wrong" ward is that they are not seen on rounds, which was not considered uncommon:

You forget that you admitted someone up there if they don't call from the ward and let you know ... in the afternoon they can realize that there's a patient that should be somewhere else, but I think admitting patients where they don't belong is a built-in error in the system.

Crowded premises and inadequate access to examination rooms in the clinic, in combination with a large influx of patients, is another risk pointed out in the interviews. Inadequate access to examination rooms also means that writing referrals and other documentation is also affected negatively:

You're happy if you have time to look at someone in passing and send them up to X-ray, the rooms are occupied by children who need to lie down and if you're going to wait for a room then they have to wait an intolerable length of time. I'd like to have screening where the doctor is in a somewhat permanent place ... If they stood here like in a waiting room and passed through one at a time and I palpated the right body part and wrote down adequate information, then you could keep track of them, but in this mess it's a very difficult problem.

Injection pumps with loud alarms that can go off for no apparent reason were stressful both for staff and patients. A high level of stress on the part of the staff can result in the alarm being turned off:

Sometimes they (the children) have had to wait a long time in the emergency room, it's not the best environment in the world, and then they come here and can't sleep because the alarms keep going off.

Deficiencies related to work hours

A lack of clarity and attentiveness when on call was reported to be a risk factor. One of the informants describes the doctor's on-call duty as follows:

We begin the day of the upcoming on-call duty ... at 7am, work at full speed during the day, and then are on-call at 4pm and continue being on call. If we're specialists ... and only have one person on call, then we can sometimes, in the worst of cases, continue the whole night, usually up until 1-2am, and sometimes maybe the whole night – 24 hours – it's happened a number of times – then the next day you start working as usual ... we make an attempt to go home at 2pm but time after time this doesn't work because there aren't enough of us.

The system is also considered frustrating by management, which can be illustrated by the following quotations from the interviews:

You have to make sure that the acute units function and there you're in a fix. The result is that we get an overtime ceiling – the Working Hours Restriction Act goes into force – and we're not allowed to do that. Now and then we're forced to make people take time off in order to fulfill the demands of the Act, and then the workload of others is even greater. This is an unbelievable problem and a terrible frustration – I can't respect either law, I think the system is horrible (the Working Hours Restriction Act and the Swedish Health and Medical Care Act).

According to the interviews, judgment was negatively affected by the mental fatigue caused by long and demanding on-call duty:

I don't think you're as alert, I notice that when I try to read something and I have to read it several times to understand what it says. And it gets harder to make decisions ... you ask yourself what you've forgotten now since you're so tired.

One of the doctors said the following in relation to the on-call system:

It's been questioned and of course you're tired, but we haven't seen any direct mistakes. But you're not in top shape the way you could be.

According to the interviews, it happens that the staff avoid calling the on-call doctor during the night if they know the doctor has had a long tour of duty and that he/she went to bed late. This can result in the nurse making excessively independent decisions, which can result in a potential risk situation. An experienced doctor related the following:

... in the on-call system it may be the case that doctors don't want to ask too many questions, and want to manage things themselves. I'm on second call a lot, but it's very seldom that someone calls me – very seldom.

According to the interviews, work hours also seem to be longer for nurses both regarding number of hours and number of days without time off. In addition to the fact that on-call duty can involve risks for making incorrect decisions, the informants thought it also affected other categories of staff. One of the nurses related the following:

... you can feel that they're tired ... they have trouble making decisions ... you don't want to bother them if you know they've been up for a long time – then you hesitate doing so – You make a few more decisions yourself.

A few of the respondents reported that they themselves had been involved in incidents that resulted in a child being injured or coming close to being injured in connection with care and treatment at the hospital. The examples given were related either to the handling of medication or to diagnostics. The reasons for these situations were felt to be fatigue, stress, and far too fast a work tempo:

... the patient had been getting a dose for a long period of time and then was to get a smaller dose, and I interpreted the order to mean that he was to get this amount but for a shorter period of time ... It was really hard because this was my first evening tour of duty by myself ... I couldn't handle so many patients myself.

I had an incident last winter where I was so wiped out and so exhausted that I made an error. I gave the wrong dose ... an overdose to a child.; It happens that you're about to miss things and that you miss diagnoses is obvious, for example with fractures you look at an X-ray and then it's more or less by accident that your eye fastens on the fracture ... and it happens that

you miss them the first time you look . . . or that you misinterpret an X-ray – you simply read it wrong.

Discussion

The picture that emerges from the interviews indicates quite a number of potential risk factors judged by the informants as being able to result in patient injuries. In the interviews, both direct as well as indirect risks were pointed out. The majority of risks mentioned during the interviews were not the kind directly resulting in injury. Many informants provided a similar picture of a work situation characterized by a heavy workload where time for reflection is sometimes lacking. Respondents said they were aware that an abnormally fast tempo can lead to increased risks, something experienced as frustrating since they feel they have little chance to influence the situation. The results generally illustrate a complex picture where the risks, each one alone or in concert, can directly or indirectly affect the individual in the practice of his/her profession and contribute to the occurrence of a mistake. The analysis indicates complex chains of causes that cannot be described in simple cause-effect terms.

One way to make it easier to understand how accidents arise is to analyze the incident by means of an accident model (Kjellén, 2000; Hollnagel, 2002). In a review article, Hollnagel (2002) reported on the development of different types of accident models, one of which is the epidemiological accident model. The results of the present study will be discussed based on this model. In the epidemiological accident model an accident is likened to an illness where a multitude of different factors happen to coincide in terms of time and place. Some deficiencies are apparent and others are concealed. One of the most frequently cited models in the category of epidemiological accident models is Reason's (1997) "Swiss cheese model". Reason uses the concepts of active failure and latent conditions. Active failures are caused by those who find themselves at "the sharp end" and they usually lead to a direct consequence. What characterizes an active failure is usually that it is obvious who committed the "error". Latent conditions originate from decisions that are made at a higher organizational level (the blunt end) but that indirectly affect the professional at "the sharp end".

In contrast to active failures, latent conditions are detected long after a decision has been made. Latent conditions can derive from decision making at different organizational levels. They can be exemplified by the indirect risks judged by the informants as threatening patient safety. An example is the large patient influx to the hospital clinic that the informants thought could derive from general political decisions concerning the design of pediatric health care. Due to the lack of access to health care within primary care, patients are forced to go to the hospital clinic, even for less serious complaints. Examples of negative consequences of all too great an influx of patients were a heavy workload, lack of surveillance in the waiting room, unclear delineation of responsibilities among different categories of staff, and work under pressure, which led to perceived stress.

Another example illustrating latent conditions in the organization is the lack of hospital beds, which according to the informants can mean that children are sometimes admitted to the "wrong" ward, which was perceived as a risk of inadequate supervision and suboptimal staff competence. The lack of operating room space during the day means that the best timepoint for surgery with respect to patient safety is not always

available. Premises considered to be unsuitable were judged to affect the daily work of doctors, in particular, in a negative way and to increase the risk of incomplete documentation. These indirect risks can be traced to decisions regarding the design and planning of health care. The negative consequences of such decisions that lead to latent conditions in the organisation can be concealed for long periods of time.

Latent conditions are superordinate to active failures in the sense that they can lead to accidents that can appear to be totally different but that upon later analysis are shown to have the same origin (Reason, 1997). This means that they are initially not understood to be associated with the incident that directly led to the injury. They are described as pathogens that can trigger an active failure when they are spread throughout the organization and work together with local risk-increasing factors. If barriers preventing the active failure from resulting in a negative consequence are lacking, this can lead to a patient being injured.

The interviews indicate that the staff are sometimes forced to take chances so that the system functions. They do not have time to assess each patient as they would like to do and they are often aware that this involves forgoing patient safety. The situation is perceived as frustrating, since blame for a mistake is usually placed on the person who made the mistake. Examples that emerged during the interviews of direct risks, i.e. those that can directly lead to a patient injury, were incomplete and incorrect orders, inadequate control, incorrect priority setting, incorrect decisions, mix-ups, answers to referrals that were not examined in time, and misreading X-ray films. If direct risks result in a patient being injured, they can be considered as active failures (Reason, 1997).

There is a tendency in health care to consider the individual who commits the "error" as the cause of the accident (Leape, 1994). With this view of accidents, measures are directed either toward the individual considered to have committed the error, or corrective measures are taken with the aim of correcting whatever is thought to have caused the error. Incidents in which a patient is injured constitute a high-level stress factor for involved staff members (Wu *et al.*, 1991; Christensen *et al.*, 1992). This is due to the injury incurred by the patient, the reporting process, and the media attention that can be a consequence of what has happened (Crane, 1997). Above all, it is the unjust treatment that was perceived as frustrating. The staff felt they were forced to work in a system that "did not measure up", and that the individual was then forced to bear the consequences if an error was committed. A feeling of powerlessness concerning deficiencies in the system was also found in a Norwegian interview study of health care staff who had been reported (Eldevik, 2001). A Swedish study showed that disciplinary measures are usually directed toward the individual who committed the "error" (Ödegård 1999).

The results of the study are in accord with investigations of accidents in areas outside health care showing that underlying deficiencies in the organization are often of decisive significance regarding the occurrence of accidents (Perrow, 1984; Rasmussen, 1997; Turner and Pidgeon, 1997). The fact that most of the identified risks can be considered as latent conditions in the organization provides an important base for preventive work with patient safety. The study indicates that preventive work aimed at decreasing injuries must focus on searching for underlying causes. Too narrow a view of safety, where the focus is only on the individual who committed the error, means that underlying deficiencies remain. The need for a greater focus on the

system instead of the individual is receiving increasing attention in the debate on how to decrease patient injuries (Bogner, 2000; Nolan, 2000).

Our study has shown that the staff constitutes an important resource for obtaining a basis for preventive work with patient safety. An advantage of the method in our study, as compared to reporting that is usually based on events that have already occurred, is that the interviews were not conducted because a patient had been injured. This is probably the reason for the great frankness observed in the interviews. The informants were positive toward having the opportunity to relate their perceptions of potential risk factors in an area all of them felt was essential. Preventive risk analyses can therefore constitute a valuable complement to traditional reporting. Perhaps the most important advantage of this approach is the possibility of identifying potential risk factors before they give rise to injuries. A more explicit proactive focus on work with safety is beneficial for all parties in the health care system. Against the background of rapid developments taking place in health care with respect both to technology and treatment, as well as organizational changes, this type of knowledge also provides information about current risks.

In order for this type of risk identification to have a positive effect on the work of decreasing patient injuries in health care, it is necessary for management to be committed and to take the initiative in carrying out risk inventories on a regular basis. The results can become an important basis for discussions concerning which preventive measures should be given priority at different levels of health care.

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V

Knowledge of diabetes among personnel in home-based care: how does it relate to medical mishaps?

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ÖDEGÅRD S. & ANDERSSON D. K. G. (2001) *Journal of Nursing Management* 9, 107–114
Knowledge of diabetes among personnel in home-based care: how does it relate to medical mishaps?

Objective To assess the influence of knowledge about diabetes on the performance of diabetes care for the elderly involving insulin treatment, with special attention to aspects of patient safety in home care.

Design A questionnaire was administered to nurse's aides and assistant nurses ($n=3144$). Answers to questions about knowledge of diabetes were related to 'relevant' or 'risky measures' as judged from a hypothetical diabetes case. A 94% response rate was obtained. The study took place in January 1997 in 15 of Sweden's 289 municipalities.

Results Insufficient theoretical knowledge about how the blood sugar is related to an insulin reaction led to an almost threefold increased risk of taking a 'risky measure'. Insufficient knowledge about reasons for an insulin reaction also resulted in a higher risk, as was the case for personnel working in home based care in contrast to those working solely in Institutional care. In addition, the risk that a nurse's aide would take a 'risky measure' was higher than that for an assistant nurse. This may indicate that the basic theoretical knowledge of nurse's aides is inadequate.

Conclusion Deficiencies in basic knowledge of diabetes among nurse's aides and assistant nurses constitute a major cause of potentially serious mishaps in home care of elderly diabetic patients treated with insulin.

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Introduction

The number of elderly individuals with diabetes is increasing in society (Andersson *et al.* 1991). The same is true for elderly persons with diabetes who require treatment with insulin. In Sweden there has been a 25% increase in this latter group during the last 5-year period (Apoteksbolaget). As a consequence the need for help, such as with administration of insulin, will probably increase, as elderly persons with diabetes are not always able to manage the self-care required by the disease. In Sweden, the administration of insulin to persons who

are unable to manage the procedure themselves is a task that can be transferred from a registered nurse to personnel without formal competence by means of so-called delegation. However, the nurse who delegates such a task is always responsible for seeing that the person receiving the delegation has sufficient knowledge and skills to be able to carry out the task. This procedure is regulated by directives, which are binding regulations from the National Board of Health and Welfare.

Comprehensive structural changes have taken place in Swedish health care during the past decade (Johansson

& Thorslund 1991), particularly in out-patient care and the care of the elderly. For example, the number of beds in geriatric care was reduced by 30% between 1992 and 1994 (Socialstyrelsen 1998). Studies of nursing home care show that although the care load has increased, the number of qualified nurses and physicians involved in nursing home care has been reduced (Socialstyrelsen 1998). As a consequence of this development, a shift in the tasks of personnel working with the elderly has taken place, from primarily service-orientated tasks to those that in some cases are skilled health care tasks (Socialstyrelsen 1996), such as giving insulin. Furthermore, personnel who work in non-institutional settings, such as home-based care, often work without easy access to competent medical support and thereby have limited opportunities to discuss an acute situation with an experienced colleague.

Increasing attention is being focused on the fact that mishaps in care constitute a widespread problem (Brennan *et al.* 1991; Wilson *et al.* 1995; Andrews *et al.* 1997; Ödegård 1999). For incidents in which patients have been seriously injured or were at risk of being seriously injured due to care and treatment, health care personnel in Sweden are required to report to the supervisory and monitoring authority for the health care sector, the National Board of Health and Welfare. Following investigation of a reported incident, the information is systematized and registered in a national database of risks, the so-called RiskDataBase (Ödegård 1999). Incidents involving medication comprise the most frequently reported category, and insulin is the medication most often found in reports from the area of elderly care (RiskRonden Special 1998). During the years 1996–97, 123 cases involving insulin were reported.

Presumably, changes that have occurred within elderly care should result in increased requirements for competence on the part of nurse's aides and assistant nurses working closest to patients. However, significant deficits in knowledge on the part of personnel working closest to those receiving care were shown in two Swedish studies (Carlson & Stattin 1997; Bylund *et al.* 1995). The aim of our study was to assess the influence of deficiencies in knowledge about diabetes on performance in diabetes care, with special attention to aspects of patient safety. As it is feared that delegations will lead to increased risks of mishaps in care, the study focused on personnel who had a delegation to give insulin.

Methods

The study is based on a written questionnaire originating from an inventory of problems that was carried out during

supplementary education for personnel with long experience in home care (Ödegård 1998). The term home care refers in this study to medical assistance given both in an individual's own home (home-based care) and in special forms of housing (institutional care such as nursing homes) in which assistance is available round the clock.

The questionnaire concerned the theoretical knowledge about diabetes of all nurse's aides and assistant nurses. One important question involved deciding what should be done based on a case description in which an elderly woman with diabetes shows signs of incipient insulin coma (see case description in Box 1). Only one of the eight possible alternatives could be chosen. Three answers involved giving the patient insulin, which based on the described symptoms could have been life-threatening. The answers were categorized into 'relevant' and 'risky measures.' As the aim of the study was to identify risks, particularly among those with a delegation to give insulin, both those who chose incorrect answers as well as those who did not answer the question were categorized as belonging to the 'risky measure' group. For those who had a delegation to give insulin there were also questions concerning the extent to which their knowledge about

Box 1

Case description of an elderly woman with diabetes who shows signs of incipient insulin coma

Case description

Greta is 81 years of age. She lives alone and has no relatives, but she has several close friends. Greta's diabetes began 15 years ago. At first her treatment included tablets and a diabetic diet. She did not require any help until 6 months ago when her disease became worse and she had to start getting insulin. Since her eyesight is very poor, personnel from home based services now give Greta's insulin injections. Greta has had a cold for several days, and the last 2 days she has been unable to eat and has only been able to drink tea. She also has difficulty getting out of bed, as she feels dizzy when she stands up. The worst thing is her upset stomach, because she has to go to the toilet so often. When you get to Greta's home she is a bit worried and irritated because you are late. At the same time she complains that she is so shaky that she cannot hold the glass and drink herself. Her blood sugar was checked a week ago and it was stable like before, around 6.1 mmol/L.

What should you do in this situation?

When I arrive at Greta's the very first thing I would do would be to:
(You can choose only one answer—the one you think is the very most important!)

- Give her a sweet fruit drink
- Measure her blood sugar
- Give the usual dose of insulin
- Give the insulin and contact a doctor or nurse
- Not give the insulin but instead contact a nurse or doctor
- Give extra insulin
- Measure ketones in the urine
- Another measure. What?

diabetes and insulin administration had been tested at the time they were given the delegation.

The questionnaires were administered to all nurse's aides and assistant nurses who worked in home care in 15 of Sweden's 289 municipalities on the morning of 15 January 1997. The selection of the municipalities was made in an earlier study where the aim was to evaluate consequences of an organizational change in the primary health care system (Ödegård 1998). In short, all municipalities with a community-based primary care organization ($n=5$) participated, together with a random sample of municipalities with county-based primary care ($n=10$). With the help of supervisors, 3144 questionnaires were distributed to the different places of work within home care throughout the participating municipalities. The questionnaires were answered and handed in during the work shift. Answers were obtained from 2966 persons (a response rate of 94%).

The data were computerized and analysed using the SAS software release 6.12 (SAS Institute, Cary, NC, USA). The χ^2 test was used for the bivariate analyses. The possible relationships between diabetes knowledge and taking a risky measure were tested using the logistic regression technique in its multivariate form. Odds ratios (OR) with 95% confidence intervals (CI) were computed with logistic regression taking into account variables that

showed statistical significance in the bivariate analyses. All tests were two-tailed. P -values $<5\%$ were accepted as indicating statistical significance.

Results

Presentation of the study results is based on whether or not the respondents had a delegation to give insulin. This information was missing for 66 persons, so the results are consequently based on 2900 persons, 1442 of whom had a delegation. More assistant nurses than nurse's aides had a delegation to give insulin. Personnel who worked in home-based care were less likely to have a delegation than those who worked solely in institutional care (Table 1).

Assessment of the case description

The distribution of answers to the question about the case description in which a patient shows symptoms of incipient insulin coma is reported in Table 2. Ten per cent (286) of the answers were categorized as 'risky measures', meaning either that the person chose to give insulin or not to answer the question. Six per cent (91) of the personnel with a delegation chose a 'risky measure.' Of those, 44 chose to give insulin and 47 did not answer the question.

Table 1
Individual and job-related factors for nurse's aides and assistant nurses with or without a delegation to give insulin

Studied factors	All <i>n</i> = 2900		With delegation <i>n</i> = 1442		Without delegation <i>n</i> = 1458		<i>P</i> -value
	<i>n</i>	(%)	<i>n</i>	(%)	<i>n</i>	(%)	
<i>Gender</i>							
Male	100	(3)	50	(3)	50	(3)	NS
Female	2767	(95)	1368	(95)	1399	(96)	
Information lacking	33	(1)	24	(2)	9	(1)	
<i>Position</i>							
Nurse's aide	1533	(53)	431	(30)	1102	(76)	0.001
Assistant nurse	1367	(47)	1011	(70)	356	(24)	
<i>Employment</i>							
Permanent employee	1990	(69)	998	(69)	992	(68)	NS
Temporary employee or employed by the hour	476	(16)	231	(16)	245	(17)	
Information lacking	464	(16)	213	(15)	221	(15)	
<i>Place of work</i>							
Home-based care	1279	(44)	557	(39)	722	(50)	0.001
Institutional care only	1621	(56)	885	(61)	736	(50)	
<i>Knowledge about the patient, judged to be</i>							
Most often sufficient	1988	(69)	989	(69)	999	(69)	NS
Not always sufficient	878	(30)	440	(31)	438	(30)	
Information lacking	34	(1)	13	(1)	21	(1)	
<i>Contact with a doctor or nurse, judged to be</i>							
Most often sufficient	2290	(79)	1124	(79)	1166	(80)	NS
Not always sufficient	575	(20)	305	(21)	270	(19)	
Information lacking	35	(1)	13	(1)	22	(1)	

Table 2

Answers about the case description given by nurse's aides and assistant nurses with or without a delegation to give insulin

<i>Answer alternatives for relevant or risky measures</i>	<i>All n = 2900</i>		<i>With delegation n = 1442</i>		<i>Without delegation n = 1458</i>	
	<i>n</i>	<i>(%)</i>	<i>n</i>	<i>(%)</i>	<i>n</i>	<i>(%)</i>
<i>Relevant measures</i>						
Give her a sweet fruit drink	462	(16)	190	(14)	272	21
Measure her blood sugar	1124	(39)	837	(60)	287	(22)
Not give the insulin, but instead contact a nurse or doctor	863	(30)	294	(21)	569	(44)
Measure ketones in the urine	1	(0)	0	(0)	1	(0)
Another measure	164	(6)	30	(2)	134	(10)
Total for relevant measures	2614	(90)	1351	(94)	1263	(87)
<i>Risky measures</i>						
Give the usual dose of insulin	15	(1)	8	(1)	7	(1)
Give insulin and contact a nurse or doctor	61	(2)	36	(3)	25	(2)
Give extra insulin	0	(0)	0	(0)	0	(0)
Did not answer the question	210	(7)	47	(3)	163	(11)
Total for risky measures	286	(10)	91	(6)	195	(13)

Theoretical knowledge and in-service education

Personnel who had a delegation had better knowledge of diabetes than nurse's aides and assistant nurses without a delegation (Table 3). Despite the fact that those personnel with a delegation judged their knowledge about diabetes to be adequate to a greater extent than did personnel without a delegation, 78% (1125) did not think they had sufficient knowledge about diabetes (Table 3).

Procedures at the time of delegation

Nine percent (113) of the personnel with a delegation ($n=1442$) reported having undergone a written test of theoretical knowledge (Table 4). Practical skills, especially those related to injecting insulin, were tested for three-quarters of those who received a delegation, while checking that they could do blood sugar tests was done for only half of them. Questions were also asked about their feeling of security when giving insulin. Fifteen percent (210) reported having felt insecure when giving insulin and nearly one-quarter had felt forced to take on work tasks with which they felt insecure.

Risky measures among personnel with a delegation

As the task of giving insulin is restricted to those personnel with a delegation, we limited our analyses of 'risky measures' to this group. The independent effect on 'risky measures' of the variables that were significant in the bivariate analyses (not shown) was tested in a set of logistic regression analyses. The variable showing the strongest relationship to 'risky measures' was lack of

knowledge about the blood sugar level when there is a hypoglycaemic insulin reaction. Of those who gave the wrong answer, 15% were categorized as being in the 'risky measure' group compared with 5% of those who answered the question correctly (OR 2.7) (Table 5). A greater proportion of nurse's aides (9%) than assistant nurses (5%) chose answers belonging to the 'risky measure' category (OR 1.8). The same was true for personnel who worked in home-based care (OR 1.8). Insufficient knowledge about the reasons for a hypoglycaemic insulin reaction was also significantly related to the 'risky measures' category (OR 1.7).

Discussion

Insufficient theoretical knowledge on the part of nurse's aides and assistant nurses about how the blood sugar is related to an insulin reaction led to an almost three-fold increase in taking a 'risky measure' in an acute situation. Insufficient knowledge about reasons for an insulin reaction also resulted in a higher risk. In addition, our study showed that the risk that a nurse's aide will take a 'risky measure' is higher than that for an assistant nurse. This may indicate that the basic theoretical knowledge of nurse's aides is inadequate. There is also an increased risk for personnel working in home-based care, in contrast to those who only work in institutional care, where personnel are available round the clock.

If adequate medical actions are to be taken for the chronically ill elderly persons in home care, all personnel must have sufficient knowledge to enable them to observe and interpret important changes in the well-being of the

Table 3

Questions about theoretical knowledge and in-service education in the area of diabetes answered by nurse's aides and assistant nurses with or without a delegation to give insulin

Questions and answers	All n = 2900		With delegation n = 1442		Without delegation n = 1458		P-value
	n	(%)	n	(%)	n	(%)	
<i>What should be the composition of a diabetic diet?</i>							
Right (rich in carbohydrates and fibre, low in fat)	1509	(52)	829	(57)	680	(47)	0.001
Wrong/don't know	1391	(48)	613	(43)	778	(53)	
<i>How is the blood sugar affected by infections?</i>							
Right (blood sugar increases)	1818	(63)	1067	(74)	751	(52)	0.001
Wrong/don't know	1082	(37)	375	(26)	707	(48)	
<i>What is the blood sugar level in an insulin reaction?</i>							
Right (low)	2169	(75)	1238	(86)	931	(64)	0.001
Wrong/don't know	731	(25)	204	(14)	527	(36)	
<i>How does an insulin reaction develop?</i>							
Right (fast)	2245	(77)	1246	(86)	999	(69)	0.001
Wrong/don't know	655	(23)	196	(14)	459	(31)	
<i>What could be the reasons for an insulin reaction?</i>							
Right*	1475	(51)	746	(52)	729	(50)	NS
Wrong/don't know	1425	(49)	696	(48)	729	(50)	
<i>Do you think your knowledge about diabetes is adequate?</i>							
Yes	350	(12)	278	(19)	72	(5)	0.001
No/don't know	2388	(82)	1125	(78)	1263	(87)	
Information lacking	162	(6)	39	(3)	123	(8)	
<i>How worthwhile do you think it would be to get in-service education concerning diabetes?</i>							
Of greatest possible value or of great value	2622	(90)	1397	(97)	1225	(84)	0.001
Of little value, of no value or not applicable	144	(5)	35	(2)	109	(7)	
Information lacking	134	(5)	10	(1)	124	(9)	
<i>Do you get recurrent education/information about diabetes?</i>							
Yes	315	(11)	233	(16)	82	(6)	0.001
No/don't know	2397	(83)	1172	(81)	1225	(84)	
Information lacking	188	(6)	37	(3)	151	(10)	

*All of the following alternatives are required: vigorous exercise, the insulin was given intramuscularly instead of subcutaneously, the patient ate too little, too high a dose of insulin.

Table 4

Control measures at the time of delegation for the nurse's aides and assistant nurses and their feeling of security when giving insulin

Questions	Yes	(%)	No	(%)
<i>Questions about testing of theoretical knowledge</i>				
Was your knowledge tested verbally?	1094	(76)	388	(24)
Was your knowledge tested in writing?	131	(9)	1311	(91)
Was your knowledge checked concerning a checklist of what should be observed before the injection?	742	(51)	700	(49)
<i>Questions about practical skills</i>				
Were your practical skills checked?	1166	(81)	276	(19)
Was your injection technique checked?	1052	(73)	390	(27)
Was a check made concerning how to do a blood sugar test?	740	(51)	702	(49)
Was a check made that you could give insulin 'for real'?	1072	(74)	370	(26)
Was a special check made that you carried out all the safety checks before the injection?	931	(70)	405	(30)
<i>Feeling of security when giving insulin</i>				
Do you feel unsure of yourself when giving insulin?	210	(15)	1189	(85)
Have you felt forced to take on tasks you have felt uncertain about?	319	(23)	1082	(77)
Is it easy for you to contact a doctor or nurse when you feel uncertain about giving insulin?	1225	(92)	103	(8)

Table 5

Logistic regression analysis of the relationships between 'risky measures' and job-related factors, questions about theoretical knowledge and questions concerning testing at the time of the delegation for nurse's aides and assistant nurses with a delegation to give insulin

Studied factors	All n = 1442	Risky measure (%)	Odds ratio	Confidence interval
<i>Position</i>				
Nurse's aide	431	9	1.75	1.11; 2.75
Assistant nurse	1011	5		
<i>Place of work</i>				
Home-based care	557	8	1.77	1.13; 2.77
Institutional care only	885	5		
<i>Knowledge about the patient, judged to be</i>				
not always sufficient	440	9	1.20	0.95; 1.51
most often sufficient	989	5		
<i>Contact with a doctor or nurse, judged to be</i>				
not always sufficient	305	9	1.18	0.91; 1.52
most often sufficient	1124	5		
<i>What is the blood sugar level in an insulin reaction?</i>				
Wrong answer/don't know	204	15	2.66	1.62; 4.38
Right answer (low)	1238	5		
<i>How does an insulin reaction develop?</i>				
Wrong answer/don't know	196	10	1.36	0.76; 2.41
Right answer (rapidly)	1246	6		
<i>What could be the reasons for an insulin reaction?</i>				
Wrong answer/don't know	696	8	1.72	1.08; 2.72
Right answer*	746	5		
<i>Was your theoretical knowledge tested at all?</i>				
No	717	8	1.20	0.71; 2.02
Yes	725	5		
<i>Was your theoretical knowledge tested verbally?</i>				
No	348	9	1.41	0.83; 2.39
Yes	1094	5		
<i>Was a special check made that you carried out all the safety checks before the insulin injection?</i>				
No	700	8	1.19	0.70; 2.02
Yes	742	5		
<i>Was your insulin injection technique checked?</i>				
No	390	8	1.31	0.77; 2.20
Yes	1052	6		

* All of the following alternatives are required: vigorous exercise, the insulin was given intramuscularly instead of subcutaneously, the patient ate too little, too high a dose of insulin.

elderly to whom they give care. Not only did we find a lack of such knowledge among the personnel with a delegation to give insulin, or in other words those who should be best educated, but our study also revealed deficits in diabetes knowledge that were even more serious among those without a delegation.

Our findings are in accordance with an earlier study from one urban community in southern Sweden (Bylund *et al.* 1995), in which nurse's aides showed insufficient knowledge about diabetes symptoms and where only 45% of nurse's aides recognized common symptoms of hypoglycaemia. Our study included both assistant nurses and nurse's aides and was undertaken in 15 of

Box 2

This is an incident that was reported to the National Board of Health and Welfare in accordance with lex Maria

'The patient got insulin despite the fact that he was in a state that should have been assessed as incipient insulin coma'

Due to a very heavy workload on the evening in question, available personnel were redistributed, which resulted in the patient being visited by someone who was not part of the ordinary personnel. The assistance given the patient consisted of giving him his eye drops and serving his evening meal.

Normally, the patient gave his insulin himself when the caregiver came each evening. However, the assistant nurse visiting the patient determined that the insulin had not been given, that the patient did not seem to feel well, and that he was sluggish but conscious.

As the assistant nurse had not met the patient before she called her colleague to get advice. This person came right away and contacted a third colleague, who normally cared for the patient and therefore knew him well. According to the two assistant nurses who were with the patient, the third assistant nurse advised them by telephone to give insulin, food and something to drink.

The patient got his insulin, but did not want any food. His level of consciousness then deteriorated. The on-call car was summoned and the patient was transferred to a Hospital for care.

Sweden's 289 municipalities. Although selection of the municipalities was not altogether random, we have no reason to believe that our findings are not valid for Sweden as a whole. The municipalities represented both rural and urban areas, and the response rate was very high. Whether primary care in a particular area was community based or county based did not affect the outcome of the study (Socialstyrelsen 1998). It might be argued that the use of a hypothetical situation to determine the measures personnel would select differs from a real life situation. However, the seriousness of the lack of knowledge that emerged from the hypothetical case is emphasized by the number of similar incidents registered in the RiskData-Base of the National Board of Health and Welfare. In these incidents insulin was given despite low blood sugar values and clinical signs of hypoglycaemia. Examples of such cases are, 'Received ordinary insulin dose despite low blood sugar value', 'Thought that the "low" value on the blood sugar instrument meant that the patient should have insulin', and 'Got regular dose of insulin despite low blood sugar' (Box 2).

Several factors contribute to underlining the significance of our findings. Nurse's aides and assistant nurses constitute a large occupational group in an organization with a weak medical tradition. This problem is intensified by the fact that the proportion of elderly individuals with diabetes who require treatment with insulin has increased (Apoteksbolaget). Furthermore, the only individuals who get assistance in their homes are generally elderly and have extensive needs for help (Socialstyrelsen 1998), which places heavy demands on the personnel. An additional

Latent Errors

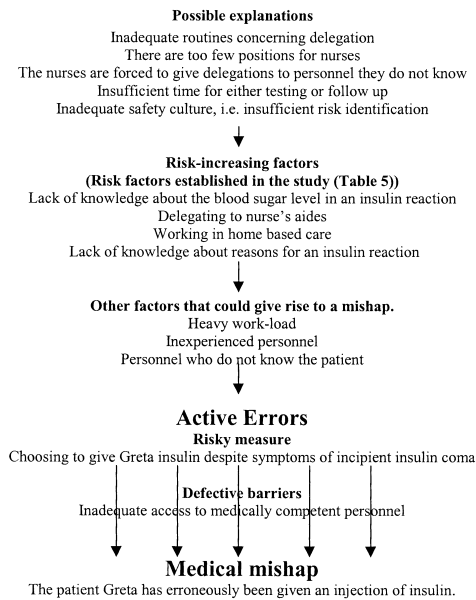


Figure 1

Theoretical model modified according to Reason's explanatory model for active and latent errors. The analysis is based on the choice of a risky measure in the patient description included in the study by nurse's aides and assistant nurses with a delegation to give insulin

cause for concern is the predicted lack of educated and trained personnel in the health care sector in Sweden in the next few years.

An analysis of the results based on Reason's (1997) 'active and latent errors' indicates deficiencies which can be related to the organizational level (Figure 1). Plausible explanations for insufficient testing in connection with giving delegations could be an inadequate number of nurses, resulting in many delegations and insufficient time for either testing knowledge or for adequate follow up. Another reason could be inadequate routines for the delegation procedure. If the risk-increasing factors that were found in the study coincide with real life situations characterized by heavy workloads or inexperienced personnel who do not know the patient, a risky measure could be provoked. Combined with inadequate access to medical support an incorrect judgement can result in a medical mishap, which can sometimes be life-threatening (Table 6).

The home care sector employs personnel with a relatively low educational level and a high turnover rate (Fahlström 1999). It is frequently the case that they must make difficult decisions about the frail condition of the

persons receiving care. To assure high levels of safety for patients it is necessary to develop a management culture that makes quality control of care the top priority among all staff. Continuous in-service education, alertness in identifying latent risks in the organization, and learning from mishaps are important components in a quality system. The work to improve patient safety also demands a change in how mishaps are viewed. In the health care sector people who commit mistakes are all too frequently blamed and looked upon as scapegoats (Mulcahy & Rosenthal 1999). This makes the work of improving patient safety more difficult and can result in failure to find the real causes of an error. Safety-related work focused on identifying risks before they result in an error should therefore be given increased emphasis throughout the entire health care sector.

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VI

Insulin treatment as a tracer for identifying latent patient safety risks in home-based diabetes care

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Objective To explore whether attitudes and opinions in areas of importance to patient safety expressed by nurses with medical responsibility were related to the knowledge of diabetes among home care personnel.

Design A questionnaire survey was used to evaluate the knowledge of diabetes among 3144 nurses' aides' and assistant nurses working in 15 municipalities in Sweden. In each municipality a nurse with medical responsibility answered another questionnaire dealing with patient safety matters in general and diabetes in particular.

Results There were large differences in the knowledge of diabetes among home care personnel on the municipality level. Attitudes and opinions of the nurses with medical responsibility in the areas of leadership, guidance and continuing education were significantly related to the knowledge of diabetes among nurses' aides' and assistant nurses.

Conclusions Our study shows that factors that are related to attitudes and opinions about patient safety among nurses with medical responsibility can increase the risk of home care personnel to make mistakes in the direct care of patients with diabetes.

Keywords: home-based care, insufficient knowledge, latent conditions, medical error, patient safety

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Introduction

The fact that patients are injured in connection with care and treatment is a widespread problem that is receiving much attention worldwide (IOM 1999, 2004, DH 2000). The need for strategic and systematic work with patient safety, with greater focus on the system and less on the individual, is the subject of increasing debate (Berwick & Leape 1999, Nolan 2000, Kuhn & Youngberg 2002). This is also the case regarding the need for increased focus on a proactive approach where risks are identified before an accident has occurred

(Carthey *et al.* 2001). Knowledge and experience obtained from safety-related work in aviation, nuclear energy and offshore industries is now accepted to an increasing extent in health care (Weick 1987, Bogner 1994, Helmreich & Merritt 1998). Studies in these areas as well as in health care have shown that there have often been latent conditions in the organization that, along with 'triggering factors', have caused the accident (Reason 1997, Turner & Pidgeon 1997, Perrow 1999). Reorganizations and changes in areas of activity have been shown to be particularly critical from a risk perspective, which was made clear in the

investigation of events that occurred at the Bristol Royal Infirmary in Great Britain (Walshe & Offen 2001, Weick & Sutcliffe 2003).

Background

Latent conditions and active failures

In work aimed at decreasing the number of injuries in care, it is important that the individual staff member's prerequisites for carrying out safe care receive increased attention (Reason 1997, Berwick & Leape 1999, Nolan 2000, Aiken *et al.* 2002). Reason (1997) introduced the concepts of latent conditions and active failure. Latent conditions concern the area of activities where super-ordinate decisions are made. They may for instance represent budget or staff reductions, reorganizations or a worsened policy concerning continuing education. Latent conditions are thought to affect 'front line workers', such as nurses, nurses' aides' and assistant nurses, to make mistakes in their direct work with the patients. Such mistakes are called active failures, as it is often very easy to recognize the action that threatened the safety of the patient. In municipal health care there are many indications of the importance of studying latent conditions (Ödegård & Andersson 2001, Socialstyrelsen 2004).

Organizational changes in the health care of the elderly

Comprehensive changes in the Swedish health care system were made in 1992. As a result of this reform, municipalities that previously had only been responsible for providing social services to the population now assumed the county councils' responsibility for health care for persons with extensive needs for care in special housing, primarily the elderly and the disabled. These forms of housing provide access to staff around the clock.

Nurses with medical responsibility – the blunt end

In connection with the municipalities' assumption of responsibility for the health care of the elderly in special housing a new category of professionals was created – nurses with medical responsibility. Such a person has overall medical responsibility for municipal health care. The duties of this nurse are stipulated in official directives (SOSFS 1997, p. 10). These include responsibility for developing and maintaining work with patient safety in the municipality or a part of a municipality.

Another duty involves elucidating the need for health care so that sufficient importance is attributed to health care issues in relation to other competing municipal activities. This means that the nurse with medical responsibility also has an important role in the local government board, which has ultimate responsibility for municipal activities. There are no doctors employed in municipal health care. General practitioners are summoned when needed from the county council's primary health care system. This makes it necessary to have a clear division of responsibility and documented routines for how contacts should be initiated between different occupational groups. As the nurse with medical responsibility has overall responsibility for patient safety, these issues constitute an essential part of the duties of this professional. An important tool in this regard is the directive on quality systems (SOSFS 1996, p. 23), which includes a requirement for a quality system in every municipality. Local quality systems should guarantee the existence of routines that assure a high level of patient safety. It is the duty of the nurse with medical responsibility that such a system is formulated for municipal health care. Thus, the nurse with medical responsibility has many assignments related to patient safety. However, not included among their tasks is primary responsibility for the specific care of individual patients.

The nurses with medical responsibility are said to be working in the 'blunt end' of the home care system, i.e. their actions do not directly lead to medical mishaps, but medical mistakes made by home care personnel can often be derived from decisions by the nurses with medical responsibility or their superiors.

Registered nurses, assistant nurses and nurses' aides' – the sharp end

Registered nurses, assistant nurses and nurses' aides' perform direct health care measures in municipal health care. They are said to work in the 'sharp end' of the home care system as they perform direct health care measures and consequently any mistakes they do have an acute effect on the patient. Nurses' aides' and assistant nurses comprise a particularly important occupational group in municipal health care. They are the ones who encounter the individual care recipient in daily care and who are forced to decide about the need to call for medically qualified professionals. A number of Swedish studies have, however, shown that the level of medical knowledge of nurses' aides' and assistant nurses is far too low in relation to the tasks they are expected to carry out (Bylund *et al.* 1995, Carlsson &

Stattin 1997). In a study in municipal health care, the theoretical knowledge of nurses' aides' and assistant nurses concerning diabetes was related to their skill in handling a serious situation when caring for a patient with diabetes (Ödegård & Andersson 2001). The results showed a threefold increased risk of performing a risky measure when staff members had insufficient theoretical knowledge about diabetes. The study also indicated inadequacies with respect to the checking of knowledge and follow up of delegations.

The delegation procedure

In 2002, a total of 158 000 nurses' aides' and assistant nurses and 10 200 registered nurses worked in municipal health care in Sweden (Socialstyrelsen 2004). It has been difficult to satisfy staffing needs and there has been a high turnover rate for staff. A relatively high proportion of the locums lack adequate education and training (Socialstyrelsen 2004). There are not enough registered nurses in municipal health care to enable them to carry out all the medical tasks that require formal competence. This means that unlicensed personnel are permitted to perform advanced medical tasks when these are delegated by registered nurses (Box 1). A commonly delegated task is giving insulin to care recipients unable to do this themselves. The delegation process entails registered nurses in municipal health care to act as clinical supervisors of nurses' aides' and assistant nurses. As the number of elderly persons in Sweden with insulin-treated diabetes has increased and a continuous scarcity of registered nurses is expected, the need for delegation in elderly care will probably increase.

Controlling risks in municipal health care

In recent years, far-reaching structural changes have taken place in health care, both in Sweden as well as in

other countries (DH 2000, IOM 2001, Socialstyrelsen 2004). The possibilities for treating different conditions have increased, and growing numbers of elderly individuals are offered advanced treatments. At the same time, the number of hospital beds has decreased and the care periods are shorter, resulting in increased pressure on the care offered outside of hospitals (IOM 2004). Since the Swedish reform in 1992, this has contributed to increasingly sicker patients being cared for in home environments and in special housing. Relatively little is known about the risks associated with such care forms, as most studies are based on medical records from hospital care (Brennan *et al.* 1991, Wilson *et al.* 1995, Thomas *et al.* 2000, Schiöler *et al.* 2001, Vincent *et al.* 2001).

Serious incidents reported to Socialstyrelsen, the National Board of Health and Welfare (NBHW), which is the Swedish regulatory agency for health care, show that the predominant type of reported incident involves the handling of medication. Of a total of 12 418 reported incidents during the 10-year period (1994–2003), 4409 concerned medication incidents of which 675 were related to giving insulin. Of these, 498 came from municipal care.

Diabetes is a common disease among care recipients in the municipal health care. For patient safety, the teamwork between different professionals in the health care is important for patients treated with insulin (Ödegård 2003). Nurses' aides' and assistant nurses need basic knowledge concerning the symptoms of diabetes and how a patient can be expected to react in different situations. This is particularly important when a task to give insulin have been delegated. The nurse with medical responsibility is responsible for making sure that there are written, detailed guidelines for the handling of medication. In this study, diabetes has been chosen as a 'tracer' in order to identify latent conditions at the blunt end that could threaten patient safety in connection with insulin administration.

Box 1

Facts – delegation

In Sweden, giving insulin to care recipients who cannot manage this themselves is a task that can be transferred from licensed personnel to personnel without formal competence through so-called delegation (SOSFS 1997, p. 14). However, the person who delegates a task is always responsible for assuring that the person who is given the delegation has sufficient knowledge and skills in order to carry out the task. It is the responsibility of the nurse with medical responsibility to establish routines regarding the criteria that should be met in order for a person to be allowed to perform tasks for which he or she does not have formal competence.

Aim

The aim of the study was to identify latent conditions in areas over which the nurse with medical responsibility in municipal health care has or ought to have influence on and that can, from the standpoint of safety, indirectly result in the risk that nurses' aides' and assistant nurses make active failures that can result in injury to the individual patient.

Methods

Study populations

The study is based on material from two categories of health care personnel working in Swedish home care. The first category consisted of personnel in the home care organization with limited theoretical knowledge and responsibility. In all, 3144 nurses' aides' and assistant nurses were asked to answer a questionnaire. They constituted all nurses' aides' and assistant nurses who worked in home care in 15 of Sweden's 289 municipalities on the morning of 15 January 1997. The selection of municipalities was made in an earlier study where the aim was to evaluate consequences of an organizational change in the primary health care system (Ödegård 1998). In short, all municipalities with a community-based primary care organization ($n = 5$) participated, together with a random sample of municipalities with county-based primary care ($n = 10$).

The nurses with overall medical responsibility for health care in the 15 municipalities formed the second category. In smaller municipalities only one nurse had this responsibility, while in larger municipalities it was shared by several nurses. In these municipalities the nurses themselves decided upon which of them would answer for them all. The 15 nurses were asked to answer a questionnaire that was distributed in the spring of 1998.

Study materials

In the questionnaire for the nurses' aides' and assistant nurses there were seven questions that shed light on their knowledge about diabetes. These questions were chosen as the basis for calculating a level of knowledge about diabetes. The questions and the response alternatives (correct answers in *italics*) were:

- How is the blood sugar affected by infections (*increased/lowered*)?
- What is the blood sugar level in an insulin reaction (*high/low*)?
- How does an insulin reaction develop (*fast/slowly*)?
- Can vigorous exercise result in an insulin reaction (*yes/no*)?
- Can incorrectly administered insulin (given intramuscularly instead of subcutaneously) result in an insulin reaction (*yes/no*)?
- Can eating too little result in an insulin reaction (*yes/no*)?
- Can too high a dose of insulin result in an insulin reaction (*yes/no*)?

The questionnaires for the nurses with medical responsibility comprised a number of assertions and questions in three general areas and in two areas specific to diabetes care. The areas were:

- The importance of health care in the commitments of the municipality.
- Personnel competence.
- The safety culture in the area of care.
- Routines for delegation in diabetes care.
- Competence/continuing education in diabetes care.

Combining the two data sets

To study if knowledge about diabetes among nurses' aides' and assistant nurses working in the municipality could be traced back to attitudes and opinions about patient safety as reflected in the answers of the nurses with medical responsibility, data from the two questionnaires were combined. Three of the 15 nurses had not been working in the same municipalities as the nurses' aides' and assistant nurses at the time when the questionnaires were issued to them or during the 1-year period prior to that. Consequently, these three nurses could not have had any influence on the nurses' aides' and assistant nurses' knowledge about diabetes, and all data from these three municipalities were therefore excluded from the analyses. In the remaining 12 municipalities the nurses with medical responsibility had occupied these positions for several years before the start of the first study focusing on nurses' aides' and assistant nurses.

Statistical analysis

For the seven questions in the questionnaire answered by the nurses' aides' and assistant nurses, each correct answer was scored with one point. A mean value, which thus could vary between 0 and 7, was thereafter determined for each of the nurses' aides' and assistant nurses and for the respective municipalities where they worked. The responses from the nurses with medical responsibility were given values of 1 or 0, where 1 corresponded to different variations of yes-answers, and 0 to different variations of no-answers.

The material was analysed using the *sas* program, version 6.12 (SAS Institute, Cary, NC, USA). Correlation coefficients and bivariate associations were calculated in accordance with Spearman. The responses of the nurses with medical responsibility to different questions of importance to the medical safety of diabetes patients constituted explanatory variables, and the

mean of the diabetes knowledge levels of nurses' aides' and assistant nurses for each municipality were the outcome variables. Possible associations were tested using multiple linear regression analyses. All the explanatory variables in the bivariate analyses were included in the multivariate analyses. The variables that contributed least to explaining the knowledge level of the nurses' aides' and assistant nurses were successively eliminated until only variables with *P*-values of <0.05 remained. All tests were two-sided. *P*-values of <0.05 were generally accepted as expressing statistical significance. Very small *P*-values were expressed as $P < 0.0001$.

Results

Data were analysed from the 12 municipalities where the nurse with medical responsibility had served at least 1 year before administration of the questionnaire to the nurses' aides' and assistant nurses. Answers to the seven questions were obtained from 2463 persons (a response rate of 95%).

Table 1 shows a mean value for knowledge points for the seven questions and the staff members' own assessments of their competence in the area of diabetes. The Table also includes a description of the numbers of participating nurses' aides' and assistant nurses divided according to municipality. In addition, the number who had a delegation to give insulin and who reported having received instruction concerning diabetes is also reported.

Importance of health care

The bivariate analysis as well as the regression analysis showed that when the nurses with medical responsibility judged that they had explicit leadership responsibility for health care, the nurses' aides' and assistant nurses had a higher mean number of knowledge points (Table 2). The same was the case when they responded that registered nurses had an explicit educational function in elderly care and the care of the functionally impaired. On the contrary, there was a negative association, i.e. nurses' aides' and assistant nurses had a lower mean number of knowledge points, when registered nurses were reported to participate to a great extent in daily patient care.

A number of factors were statistically significant in the bivariate analysis but not in the regression analysis. This was the case when the nurses with medical responsibility indicated that their role in municipal health care was considered important. The situation was the same when they responded that registered nurses worked mainly as consultants in health care. When the nurses with medical responsibility answered that health care issues and social issues were of equal importance in the municipality, this was also associated with a higher number of knowledge points (Table 2). However, this association did not remain in the regression analysis either.

Table 1

Knowledge about diabetes on the part of 2463 assistant nurses and nurses' aides' in 12 municipalities presented together with characteristics of the participating nurses' aides and assistant nurses

<i>Municipality/ medical responsible nurse</i>	<i>Number of nurses' aides' and assistant nurses who answered (n)</i>	<i>Proportion of assistant nurses (%)</i>	<i>Proportion of nurses' aides' and assistant nurses with a delegation to give insulin (%)</i>	<i>Proportion who get recurrent education regarding diabetes (%)</i>	<i>Proportion who judge their own competence regarding diabetes as adequate (%)</i>	<i>Knowledge points* on the seven question test (mean value)</i>
A	121	50	54	26	6	4.37
B	47	55	45	15	15	4.17
C	46	43	26	9	15	3.80
D	116	18	71	26	12	5.01
E	618	53	63	27	18	4.27
F	507	53	47	17	11	3.83
G	163	35	15	11	10	3.85
H	243	45	59	11	11	4.40
I	64	39	25	23	13	3.73
J	259	43	60	15	12	4.10
K	189	55	56	16	15	5.05
O	90	33	19	8	2	3.12
Total	2463	47	52	19	13	4.18

Each right answer gives one point. Total points can assume a value between 0 and 7.

*Knowledge points are based on the answers on the seven questions that are described in the text.

Table 2
Importance of health care

Assertions/questions (response alternatives for nurses with medical responsibility)	Results as related to				Bivariate analysis (Spearman's correlation coefficient/P-value)	Multiple linear regression analysis		
	Medical responsible nurses (n)	Nurses' aides'/assistant nurses (n)	Knowledge points (mean)	SD		Parameter estimate	SE	P-value
Health care issues in the municipality are as important as social issues								
Yes, absolutely/yes, usually	6	726	4.35	1.85	0.058			NS
Doubtful/no	6	1737	4.11	1.92	0.0041			
My role in municipal health care is considered important by the local government board								
Yes, absolutely/yes, usually	9	1623	4.31	1.82	0.083			NS
Doubtful/no	3	840	3.92	2.04	0.0001			
I have explicit leadership responsibility for health care								
Yes, absolutely/yes, usually	8	1005	4.34	1.79	0.058	0.5608	0.0979	0.0001
Doubtful/no	4	1458	4.07	1.97	0.0040			
The registered nurses participate in direct daily patient care								
Yes, to a great extent	5	697	3.93	1.86	-0.102	-0.7753	0.1035	0.0001
To some extent/no	7	1766	4.28	1.91	0.001			
The registered nurses work mainly as consultants regarding health care issues								
Yes, to a great extent	3	406	4.55	1.86	0.098			NS
To some extent/no	9	2057	4.11	1.90	0.001			
The registered nurses have an explicit educational function in the area of elderly care and care of the functionally impaired								
Yes, to a great extent/yes to some extent	7	1709	4.37	1.83	0.142	0.5343	0.0847	0.0001
No, to a small extent/no, not at all	5	754	3.76	2.02	0.0001			

Assertions/questions, and the responses of the nurses with medical responsibility as related to the nurses' aides' and assistant nurses' knowledge about diabetes, in corresponding municipalities.

Personnel competence

There was a positive association in both the bivariate analysis and the regression analysis between a higher number of knowledge points and municipalities where there was a documented plan for continuing staff education. The situation was the same when the nurses with medical responsibility were consulted prior to the hiring of new personnel. There was also a statistically significant association between a higher number of knowledge points and the opinion of the nurses with medical responsibility that the competence of registered nurses needed improvement (Table 3).

When the nurse with medical responsibility thought there were a sufficient number of registered nurses in the municipality, or when this individual had studied administration, these factors were significantly related to a lower number of knowledge points on the part of nurses' aides' and assistant nurses. These associations also remained in the multivariate regression analysis. The opinion of the nurse with medical responsibility that the personnel generally had satisfactory competence in the area of health care was associated with a higher number of knowledge points, but only in the bivariate analysis.

The safety culture in the area of care

When the nurse with medical responsibility reported that she needed better understanding from the organization in order to improve work with patient safety there was a positive association with a higher number of knowledge points (Table 4). There was a negative association when the nurse with medical responsibility reported that there were detailed guidelines for documentation in her area of responsibility. These associations also remained in the regression analysis.

There was a negative association in the bivariate analysis when the nurses with medical responsibility confirmed the assertion that 'the directive from the National Board of Health and Welfare concerning quality systems in health care clearly elucidates how work with patient safety can be carried out'. A negative association was also the case when this nurse indicated that there was a completed system for quality in her area of responsibility. This was also the case when the nurse with medical responsibility indicated that better support was needed from politicians in order to be able to improve work with patient safety and when it stated that doctors' participation in municipal health care was adequate. However, these associations did not remain in the regression analysis.

Table 3

Personnel competence

Assertions/questions (response alternatives for nurses with medical responsibility)	Results as related to				Bivariate analysis (Spearman's correlation coefficient/P-value)	Multiple linear regression analysis		
	Medical responsible nurse (n)	Nurses' aides/assistant nurses (n)	Knowledge points (mean)	SD		Parameter estimate	SE	P-value
Generally speaking the personnel have satisfactory competence in the area of health care								
Yes, absolutely/yes, generally speaking	5	1345	4.36	1.78	0.085			NS
Doubtful/no	7	1118	3.96	2.03	0.0001			
The competence of the registered nurses/district nurses needs improvement								
Yes, absolutely/yes, generally speaking	7	1288	4.26	1.92	0.057	0.3885	0.1412	0.0060
Doubtful/no	5	1175	4.09	1.89	0.0050			
I am consulted prior to the hiring of new personnel in municipal health care								
Yes, always/yes, usually	4	421	4.56	1.78	0.096	0.3024	0.1054	0.0041
Doubtful/no, seldom/never	8	2422	4.10	1.92	0.0001			
There is a documented plan for increasing the competence of all health care personnel								
Yes	3	468	4.62	1.56	0.096	0.7336	0.1474	0.0001
No	9	1995	4.07	1.96	0.0001			
We have a sufficient number of registered nurses in the municipality								
Yes	4	589	4.06	1.86	-0.049	-0.2588	0.1062	0.0148
Doubtful/no, not at all	8	1874	4.22	1.92	0.0158			
In addition to your basic nursing education, do you have education in administration?								
Yes	6	974	3.85	1.97	-0.142	-0.2478	0.1233	0.0446
No	6	1489	4.39	1.83	0.0001			

Assertions/questions, and the responses of the nurses with medical responsibility as related to the nurses' aides' and assistant nurses' knowledge about diabetes, in corresponding municipalities.

Table 4

The safety culture in the area of care

Assertions/questions (response alternatives for nurses with medical responsibility)	Results as related to				Bivariate analysis (Spearman's correlation coefficient/P-value)	Multiple linear regression analysis		
	Medical responsible nurse (n)	Nurses' aides/assistant nurses (n)	Knowledge points (mean)	SD		Parameter estimate	SE	P-value
In my area of responsibility there are detailed guidelines for documentation								
Yes	10	2158	4.06	1.94	-0.169	-1.0426	0.1153	0.0001
No	2	305	5.04	1.37	0.0001			
The directive from the National Board of Health and Welfare on quality systems in health care clearly elucidates how work with patient safety can be carried out								
Yes, absolutely/yes, generally speaking	7	1302	4.06	1.93	-0.065			NS
Doubtful/no	5	1161	4.31	1.87	0.0013			
In order to further improve work with patient safety in health care I need: better support from politicians								
Yes	5	1505	4.07	1.97	-0.057			NS
No	7	958	4.35	1.78	0.0046			
In order to further improve work with patient safety in health care I need: better understanding from the organization								
Yes	6	1 347	4.29	1.87	0.069	0.3388	0.0763	0.0001
No	6	1 116	4.04	1.93	0.0006			
It is my judgement that the participation of doctors in municipal health care is sufficient								
Yes, absolutely/yes	2	448	4.50	1.75	0.077			NS
Doubtful/no, not at all	10	2 015	4.11	1.93	0.0001			
How far have you come in your municipality in the work of developing a quality system for health care in the municipality?								
We have a completed system for quality	1	189	5.05	1.36	0.134			NS
We are working with it/we have not started yet	11	2 274	4.11	1.93	0.0001			

Assertions/questions, and the responses of the nurses with medical responsibility as related to the nurses' aides' and assistant nurses' knowledge about diabetes, in corresponding municipalities.

Routines for delegation in diabetes care

Factors that shed light on routines for delegation and their association with the nurses' aides' and assistant

nurses' knowledge concerning diabetes are shown in Table 5. When the task of giving insulin gave a wage increment, nurses' aides' and assistant nurses had a higher number of knowledge points. A lower number of

Table 5
Routines for delegation in diabetes care

Assertions/questions (response alternatives for nurses with medical responsibility)	Results as related to				Bivariate analysis (Spearman's correlation coefficient/P-value)	Multiple linear regression analysis		
	Medical responsible nurse (n)	Nurses' aides/assistant nurses (n)	Knowledge points (mean)	SD		Parameter estimate	SE	P-value
The task of giving insulin is delegated because								
(a) There is an insufficient number of registered nurses								
Yes	4	638	4.53	1.80	0.113			NS
No	8	1825	4.06	1.92	0.0001			
(b) We have access to assistant nurses with sufficient competence								
Yes	9	1951	4.12	1.93	-0.056	-0.6556	0.1265	0.0001
No	3	512	4.40	1.77	0.0058			
(c) Having delegation to give insulin gives a wage increment*								
Yes	1	116	5.01	1.39	0.098	0.9449	0.1806	0.0001
No	10	2088	4.14	1.92	0.0001			

*Response missing from one nurse with medical responsibility.

Assertions/questions, and responses of the nurses with medical responsibility as related to nurses' aides' and assistant nurses' knowledge about diabetes, in corresponding municipalities.

knowledge points was demonstrated when the nurses with medical responsibility were of the opinion that delegation of the task of giving insulin occurred because assistant nurses with sufficient competence were available. This association was found both in the bivariate analysis and the regression analysis.

When the nurses with medical responsibility stated that the reason for delegating insulin administration was an insufficient number of registered nurses, there was an association with a higher number of knowledge points in the bivariate analysis. This did not remain in the regression analysis.

Competence/continuing education in diabetes care

In the municipality where there was a diabetes nurse whose job it was to disseminate knowledge and coordinate diabetes care, the assistant nurses and nurses' aides' had a higher number of knowledge points (Table 6). The analysis also showed that when the nurses with medical responsibility answered that all registered nurses were offered recurrent education to an adequate extent, the assistant nurses and nurses' aides' had a lower number of knowledge points. This was also the case when persons in the municipality participated in formulating a countywide programme in diabetes care. All of these associations were found in both the bivariate analysis and the regression analysis.

Discussion

In an earlier study focusing on assistant nurses and nurses' aides' we found that insufficient knowledge about diabetes was associated with a high risk for

poorer patient safety (Ödegård & Andersson 2001). In the present study, we sought explanations for why knowledge about diabetes varied so markedly among the municipalities in which the assistant nurses and nurses' aides' worked. We assumed that the nurses with medical responsibility had a key role in this connection. We therefore chose to study their opinions within the areas we judged to be of importance to patient safety in general, and knowledge about diabetes in particular. The nurses with medical responsibility were asked to consider various assertions and either agree or disagree with each one. At the municipal level we found a number of clear associations between assistant nurses' and nurses' aides' knowledge about diabetes and the answers of the nurses with medical responsibility. The responses that were given were such that, in accordance with Reason (1997), they could indicate latent conditions at 'the blunt end'. In the present context this is synonymous with the area of responsibility of the nurse with medical responsibility.

Responses that were related to a higher number of knowledge points

There was a statistically significant relationship between a number of the assertions with which the nurses with medical responsibility agreed and a higher number of knowledge points for nurses' aides' and assistant nurses. These assertions are related either to the area of 'direction and leadership' or to the area of 'competence'.

The assertions with which the nurses with medical responsibility agreed and that mainly concern the area of direction and leadership were the following.

Table 6

Competence/continuing education in diabetes care

Assertions/questions (response alternatives for nurses with medical responsibility)	Results as related to				Bivariate analysis (Spearman's correlation coefficient/P-value)	Multiple linear regression analysis		
	Medical responsible nurse (n)	Nurses' aides/assistant nurses (n)	Knowledge points (mean)	SD		Parameter estimate	SE	P-value
There is a 'diabetes nurse' in the municipality, i.e. a nurse with the special responsibility of disseminating information and coordinating diabetes care								
Yes	1	116	5.01	1.39	0.094	0.6854	0.1803	0.0001
No	11	2347	4.14	1.92	0.0001			
All registered nurses are offered recurrent education concerning diabetes								
Yes, to a sufficient extent	2	670	3.84	1.95	-0.115	-0.4874	0.0863	0.0001
Yes, but not enough/no	10	1793	4.31	1.87	0.0001			
Are you or anyone else in the municipality involved in developing a countywide care programme for diabetes?								
Yes	1	90	3.12	1.79	-0.116	-1.2010	0.2031	0.0001
No, not that I know of	11	2373	4.22	1.90	0.001			

Assertions/questions, and responses of the nurses with medical responsibility as related to nurses' aides' and assistant nurses' knowledge about diabetes, in corresponding municipalities.

- I have explicit leadership responsibility for health care.
- I am consulted prior to hiring of personnel in municipal health care.
- In order to improve work with patient safety in health care I need better understanding from the organization.
- Having delegation to give insulin results in a wage increment.

Agreeing that one has explicit leadership responsibility for care can mean that one has an overview of and control over personnel competence. Being able to influence hiring of personnel then becomes particularly important in areas characterized by high turnover and where many of the personnel lack adequate education and training in health care. Insight that understanding from the organization is necessary in order to improve work with patient safety was also significantly related to a high level of knowledge. This is in good agreement with the view of work with patient safety in the basic premise of stipulations regarding quality, i.e. that 'all personnel should participate in the systematic and continuous development of quality in their area of work' (SOSFS 1996, p. 23). Agreement with the assertion that 'having a delegation to give insulin results in a wage increment' can be seen as indicating that responsibility is highly valued and should be remunerated with an increase in wages. Such a view reflects a leadership philosophy that clearly illustrates the connection between responsibility, competence and wages.

The importance of management's responsibility and commitment regarding patient safety is supported in a number of studies both in health care, as well as in other

areas (Weick 1987, Carthey *et al.* 2001, Firth-Cozens 2001, Kuhn & Youngberg 2002, IOM 2004).

The assertions related to 'competence' comprised mainly the following.

- Registered nurses have an explicit teaching function in the area of elderly care and care of the functionally impaired.
- There are documented plans for improving the competence of all health care personnel.
- There is a 'diabetes nurse' in the municipality who is responsible for dissemination of knowledge and coordination of diabetes care.
- The competence of registered nurses/district nurses needs improvement.

In municipal health care the competence and supervisory functions of registered nurses are of particular importance from a patient safety perspective. This is due to the fact that the registered nurse has the greatest medical competence in the organization, and also because there is a scarcity of nurses. The ambition of most of the nurses with medical responsibility to have increased competence on the part of registered nurses can be seen as expressing the insight that a high degree of patient safety requires good competence. Health care tasks requiring formal competence, such as giving insulin to care recipients with diabetes, are often delegated to assistant nurses and nurses' aides' due to a scarcity of registered nurses. A prerequisite for a delegation procedure that ensures patient safety is that supervision of these categories of personnel is given priority. A registered nurse with special education and training in diabetes was employed in only one

municipality (D; Table 1). Over 70% of the assistant nurses and nurses' aides' in this municipality had a delegation to give insulin. This was also the municipality in which the nurse with medical responsibility confirmed that the task of giving insulin gave a wage increment. Assistant nurses and nurses' aides' in this municipality had among the highest average number of knowledge points.

In areas characterized by high levels of safety, i.e. high reliability organizations (HRO), focus on personnel experience and competence at all levels of the organization is of central importance, and continuous training and competence development are of high priority (Roberts & Bea 2001, IAEA 2002, IOM 2004).

Responses related to a lower number of knowledge points

Many assertions with which the nurses with medical responsibility agreed were related with statistical significance to a lower level of knowledge points for assistant nurses and nurses' aides'. These assertions can be related to areas where 'an administrative approach' characterizes the work of the nurse with medical responsibility and where 'the focus is on registered nurses' rather than on assistant nurses and nurses' aides'.

Assertions where 'an administrative approach' characterizes the work of the nurse with medical responsibility that were related to a low level of knowledge points were:

- In addition to basic nursing education I have also studied administration.
- In my area of responsibility there are detailed guidelines for documentation.
- I myself, or someone else in the municipality, am involved in work to develop a county council-wide medical care programme for diabetes.

Together, these three assertions illustrate conditions describing an administrative approach in the work of the nurse with medical responsibility. The fact that this is related to a low level of knowledge in assistant nurses and nurses' aides' can probably be explained by less time and interest being focused on issues of competence as a result of concentration on administrative work. A strong administrative focus probably also results in less opportunity for being in close contact with the area one is managing. This can result in leadership responsibility being less explicit. Too much detailed direction regarding documentation constitutes an example of this. Another example may be participation in formulating a county council-wide

medical care programme. This could have decreased the amount of time that should have been used for direct supervision of care.

Assertions where 'the focus is on registered nurses' rather than on assistant nurses and nurses' aides' that were related to a low level of knowledge points were:

- The task of giving insulin has been delegated because we have access to assistant nurses and nurses' aides' with sufficient competence.
- All registered nurses are offered recurrent education concerning diabetes.
- We have a sufficient number of registered nurses in the municipality.
- Registered nurses take part in daily direct nursing care.

These assertions and their association with a low number of knowledge points are probably the result of assistant nurses and nurses' aides' been overlooked with respect to education in diabetes. This may be because diabetes education for registered nurses took precedence or that the nurse with medical responsibility made the incorrect judgement that assistant nurses and nurses' aides' did not need increased competence. The fact that the participation of registered nurses in direct daily care was related to low knowledge levels in assistant nurses and nurses' aides' may be because the registered nurses did not give sufficient priority to their teaching function. Another explanation can be that less attention was directed towards the educational needs of nurses' aides' and assistant nurses when registered nurses took part to a greater extent in daily care.

Are the results credible?

This study points to factors that contribute to increased safety as well as to factors indicating latent conditions in municipal health care. The latter can increase the risk that personnel will commit serious mistakes in the area of diabetes care that was the focus of this study. Within the area of safety research there is unanimous agreement that latent work conditions are of decisive importance for patient safety (Reason *et al.* 2001, IAEA 2002, IOM 2004), and the need for increased focus on the system is therefore debated increasingly often (Berwick & Leape 1999, Nolan 2000, Pape 2001).

From an overall perspective, all the issues in the study can be related to the safety culture of the organization. A good safety culture is characterized by management's commitment to safety issues, focus on staff competence with regular continuing education and recurrent possibilities for training (Firth-Cozens 2001, Pape 2001). In

areas with high levels of safety despite high risks, so-called HRO, the safety culture of the company is of central importance (Weick 1987, Roberts & Bea 2001). In HROs, employees are constantly on the alert for situations and conditions that can lead to accidents. The concept of safety culture has long attracted attention in other high risk areas and is now also in focus in health care. Diagnosing the safety culture of an area is an important task and an increasing number of validated instruments are becoming accessible (Nieva & Sorra 2003, Pronovost *et al.* 2003).

The questionnaires we have used have a clearly proactive perspective. It focuses on both the sharp end and the blunt end. Analyses of medical errors tend to focus on the individual in the sharp end, with the result that latent conditions that contributed to the incident may not be elucidated. This thereby increases the risk that the measures that are taken will not be optimal from a safety perspective (Reason 1997). For continued research in the area, the instruments we chose should be applicable for both retrospective and prospective studies.

Although the first questionnaire was administered in 1997, it is our judgement that the study is highly relevant as the basic structure of municipal health care is still the same. Municipal health care continues to submit a large number of reports to the National Board of Health and Welfare concerning mishaps in health care. This indicates that from the perspective of patient safety, it remains important to focus on this area (Socialstyrelsen 2004).

What should be studied in greater detail?

A weakness in the study is that it is based on the opinions of the nurses with medical responsibility and not on observations of actions. Another weakness is that registered nurses' opinions on work with patient safety in municipal health care are lacking. Despite these shortcomings, however, the study provides important information concerning issues that should be studied in greater detail. In order to obtain increased knowledge about latent conditions that can worsen patient safety in municipal health care, the actual conditions should be studied. Registered nurses in municipal health care should be included in such studies. In addition, studies of the interaction between the nurse with medical responsibility and other municipal health care personnel should be the focus of further studies. For nurses with medical responsibility to be able to fulfil the requirements of their job they need a strong organizational position. In municipal health care the local government board has ultimate responsibility for assuring that this is the case.

Consequently, relations between the nurse with medical responsibility, the doctors' group, the director of the organization and the municipal council should be studied from a safety perspective.

Conclusion

The results of the study support the premise that latent conditions in the organization can jeopardize medical safety. This is also supported by a number of researchers (Reason 1997, Hollnagel 1998, Perrow 1999, West 2000). In our study, diabetes was used as a tracer to identify latent conditions in areas for which the nurse with medical responsibility is accountable. By identifying such conditions, preventive work should be more goal-directed and medical safety for patients in elderly care should increase. The study shows the importance of identifying factors, both at the sharp end and the blunt end that increase the risk that wrong measures will be taken by personnel. The study therefore constitutes both an important basis for discussion in continued work with patient safety in municipal health care and a basis for continued studies, irrespective of the organization.

Acknowledgement

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